Primary Health Care

ESSENTIAL DRUGS FOR PRIMARY-HEALTH-CARE STANDARD PACKAGES

STEPHANIE P. SIMMONDS GODFREY J. A. WALKER

Ross Institute of Tropical Hygiene, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT

MUCH has been written about the usefulness of a standard limited number of drugs for primary health care in developing countries,[1-4] and recommendations have been made for standard treatment and management of common conditions.[5-8] The World Health Organisation lists 200 essential drugs.[9] There are, however, several steps between deciding which preparations should be available for a primary-health-care worker and estimating how much of each drug will be needed to cover the majority of disease episodes that such a worker will be likely to encounter in a given period in a given population. We have assessed these requirements from the predicted "incidence" of various diseases and standardised treatment schedules. The impetus for this work was provided by the involvement of one of us (S.P.S.) in the health care of refugees and the provision of emergency drug supplies. However, the methods used for that particular situation have more general applicability.

METHODS

We considered a standard population of 10 000 having age structure similar to that found in many developing countries—i.e., half were aged less than 15 years. It was estimated, on the basis of reports of outpatient clinics from several countries, that the likely average number of "curative" contacts between individuals and the primary-health-care worker would be of the order of 4 per year.[10-12] This would give a figure of around 10 000 patient-contacts in a 3-month period.

It was further assumed that the type of conditions with which children and adults would present can be generalised and predicted. For these broad disease categories, decisions about treatment regimens (tables I and II) were made after wide consultations. By consideration of the likely contacts, prevalence of symptoms, and standard treatment regimens, estimates of the probable basic drug requirements for a specific population were prepared (table III). The number of preparations listed has been deliberately restricted, but a more extensive list was prepared for a more senior health person (a doctor or nurse) who could be supporting and supervising the primary-health-care worker.

TABLE I—CATEGORIES OF SYMPTOMS, PREDICTED CONTACTS, AND DRUG TREATMENT FOR A POPULATION OF 10 000 OVER A 3-MONTH PERIOD

Symptoms	Predicted "incidence" of symptoms		Predicted no. of contacts and suggested drug treatment
	%	No. of cases	
Age 0–14 yr (5000 people):			
Respiratory	30	1500	Upper respiratory tract: Paracetamol tabs (400) Acetylsalicylic tabs (350) Lower respiratory tract: Phenoxymethylpenicillin syrup (300) Phenoxymethylpenicillin tabs (350) Benzylpenicillin injections (100)
Diarrhoea	20	1000	Oral rehydration sachets
Malaria	13	650	Chloroquine syrup
Helminths	10	500	Piperazine syrup (500) Thiabendazole tabs (200)
Skin, trauma	10	500	Benzyl benzoate lotion (200) Benzoic acid and salicylic acid ointment (100) Iodine or chlorhexidine solution (200)
Anaemia/malnutrition	8	400	Ferrous salt and folic acid tabs (400) Vitamin A caps (400)
Eyes	5	250	Sulphacetamide ointment
Ears	4	200	Ampicillin syrup
Age 15 yr and above (5000 people):			
Respiratory	20	1000	Upper respiratory tract: acetylsalicylic acid tabs (700) Lower respiratory tract: tetracycline tabs (300)
Musculoskeletal	15	750	Acetylsalicylic acid tabs (500) Paracetamol tabs (250)
Digestive	15	750	Piperazine (300) Thiabendazole tabs (200) Aluminium hydroxide tabs (250) Senna tabs (200)
Diarrhoea	15	750	Oral rehydration sachets
Genitourinary	12	600	Sulphadimidine tabs (300) Procaine benzylpenicillin injections (300)
Malaria	10	500	Chloroquine tabs
Skin, trauma	5	300	Benzyl benzoate lotion (150) Gentian violet (50) Chlorhexidine (25) Iodine solution (25) Neomycin and bacitracin ointment (50)
Anaemia/malnutrition	5	250	Ferrous salt and folic acid tabs (250) Vitamin A caps (250)
Eyes	3	150	Sulphacetamide ointment

TABLE II—SUGGESTED STANDARDISED TREATMENT SCHEDULE

Drug	Form	Course	Quantity per course
Acetylsalicylic acid	Tab 300 mg	Adults 2 t.d.s. × 2 days Children 1/2–1 t.d.s. × 2 days	12 tabs 6 tabs
Aluminium hydroxide	Tab 500 mg	Adults 1 q.d.s. × 5 days	20 tabs
Ampicillin	Syrup 125 mg/5 ml	Children 125 mg q.d.s. × 5 days	1 bottle
Benzoic acid and salicylic acid	Ointment 25 g		
Benzyl benzoate	Solution 25%	All 100 ml	100 ml
Benzylpenicillin	Injection 0·6 g (1 million IU)	Children 1 daily × 5 days	5 vials
Chloroquine	Tab 150 mg/base Syrup 50 mg/5 ml/base	Adults 4 stat Children 10 mg/kg	4 tabs Average 15 ml
Ferrous salt and folic acid	Tab 60 mg/base	Adults 1 b.d. × 10 days Children 1 o.d. × 10 days	20 tabs 10 tabs
Gentian violet	25 g bottles		
Iodine: chlorhexidine	Solution 2·5%/5%		
Neomycin and bacitracin	Ointment 25 g	All b.d. × 7 days	1 tube
Oral rehydration	Sachets 27·5 g/litre	All 3 packets	3 sachets
Paracetamol	Tab 500 mg	Adults 2 t.d.s. × 2 days Children ¼–½ t.d.s. × 2 days	12 tabs 4 tabs
Piperazine	Tab 500 mg Syrup 500 mg/ml	Adults 8 stat Children 20 ml stat	8 tabs 20 ml
Phenoxymethyl-penicillin	Syrup 250 mg/5 ml Tab 250 mg	Children 125 q.d.s. × 5 days Children 125 mg q.d.s. × 7 days	1 bottle 14 tabs
Procaine benzyl-penicillin	Injection 3 g (3 million IU)	Adults 1 stat	1 vial
Retinol	Caps 200 000 IU	All 1 stat	1 caps
Senna	Tab 7·5 mg	Adults 2 stat	2 tabs
Sulphacetamide	Ointment 10% 5g tube	All q.d.s. × 7 days	1 tube
Sulphadimidine	Tab 500 mg	Adults 2 b.d. × 5days	20 tabs
Tetracycline	Tab 250 mg	Adults 1 q.d.s. × 7 days	28 tabs
Thiabendazole	Tab 500 mg	Adults 3 b.d. × 2 days Children 1 b.d. × 2 days	12 tabs 4 tabs

o.d. = once daily, b.d. = twice daily, t.d.s. = 3 times a day, q.d.s. = 4 times a day, stat = at once.

DISCUSSION

The success of primary-health-care workers depends to a substantial extent on the amount of support and supervision they receive. To be successful in their important promotive and preventive roles they need to be seen to be providing credible first-line curative services. A part of this is the continuing provision of essential drug supplies.

A method is suggested here of how the range and quantities of a limited number of essential drugs for a specific population and time period might be estimated.

The particular listing and quantities will obviously vary according to such factors as: the actual age structure of the population; the particular local disease patterns (we have included malaria as being "typical", but this will not be so in many areas); the diagnostic capability of the primary-health-care workers; and national prescribing policies.

It is important that adequate supplies are regularly provided, and to assist with this a simple drug reordering form has also been devised.

This work has formed the basis for W.H.O./U.N.H.C.R. recommended emergency health kits for refugee populations.[11] The use of these kits will be evaluated over the next year.

Copies of the additional listing of drugs for health personnel supporting primary-health-care workers and the drug reordering forms referred to in the text are available from Emergency Relief Operations, World Health Organisation, Geneva.

Correspondence should be addressed to S. P. S.

TABLE III—BASIC DRUG REQUIREMENTS FOR A POPULATION OF 10 000 FOR 3 MONTHS

Drug	Pharmaceutical form and strength	Total required for 3 mo*
Analgesics (2):		
Acetylsalicylic acid	Tab 300 mg	17 000 tabs
Paracetamol	Tab 500 mg	5000 tabs
Antihelminthic (7·2):		
Piperazine	Tab 500 mg	2500 tabs
Piperazine	Syrup 500 mg/5 ml	10 litres
Thiabendazole	Tab 500 mg	3500 tabs
Antibacterial (7·3):		
Ampicillin	Syrup 125 mg/5 ml	400 bottles
Benzylpenicillin	Injection 0·6 (1 million IU)	500 vials
Phenoxymethylpenicillin	Tab 250 mg	5000 tabs
Phenoxymethylpenicillin	Syrup 250 mg/5 ml	300 bottles
Procaine benzylpenicillin	Injection 3·0 g (3 million IU)	300 vials
Sulphadimidine	Tab 500 mg	6000 tabs
Tetracycline	Tab 250 mg	9000 tabs
Antimalarial (7·6):		
Chloroquine	Tab 150 mg/base	2000 tabs
Chloroquine	Syrup 50 mg/5 ml base	10 litres
Antianaemia: (11·1)		
Ferrous salt and folic acid	Tab 60 mg iron with 0·25 mg folic acid	9000 tabs
Dermatological (14):		
Benzoic acid and salicylic acid	Ointment 25 g tube	100 tubes
Benzyl benzoate	Lotion 25%	25 litres
Gentian violet	Crystals	200 g (8 bottles)
Neomycin and bacitracin	Ointment 25 g	50 tubes
Antacid (17·1):		
Aluminium hydroxide	Tab 500 mg	5000 tabs
Cathartic (17·5):		
Senna	Tab 7·5 mg	500 tabs
Diarrhoea (17·6·2):		
Oral rehydration salts	Sachet 27·5 g/litre	5500 sachets
Anti-infective (21·1):		
Sulphacetamide (ophthalmological)	Ointment 10%, 5 g tube	400 tubes
Solutions (26):		
Water for injection	2 ml	500 amps
Water for injection	10 ml	500 amps
Surgical disinfectants (27):		
Chlorhexidine	Solution 5%	10 litres
Iodine	Solution 2·5%	5 litres
Vitamins (28):		
Retinol	Caps 200 000 IU	1000 caps

Figures in parentheses refer to W.H.O. classification.[9]
* Amounts rounded up to the nearest 500 for tablets and sachets.

REFERENCES

1. Lane NS. Ensuring supplies of medical equipment and drugs where really needed. *WHO Chron* 1977; **31**: 404–07.
2. Editorial. Drugs for the Third World – a double standard. *Lancet* 1979; i: 709.
3. Gish O, Feller LL. Planning pharmaceuticals for primary health care: the supply and utilisation of drugs in the Third World. Washington DC: American Public Health Association, 1979.
4. Medicinal products for all who need them: action programme on essential drugs. *WHO Chron* 1979; **33**: 203–08.
5. King M, King F, Martodipuero S. Primary child care: a manual for health workers. Oxford: Oxford University Press, 1978.
6. Petit PL. Management schedules for dispensaries: A manual for rural health workers. Nairobi: African Medical Research Foundation, 1979.
7. Schull CR. Diagnosis and treatment of common health problems of adults in Papua New Guinea: A manual for health workers in health centres and hospital out-patient departments. Madang: Kristen Press Inc, 1980.
8. World Health Organisation. The primary health worker. Geneva: W.H.O. 1980.
9. World Health Organisation. The selection of essential drugs. *Tech Rep Ser* no. 641. Geneva: W.H.O. 1979.
10. Department of International Health, Johns Hopkins University School of Hygiene and Public Health. The functional analysis of health needs and services. Bombay: Asia Publishing House, 1976.
11. White KL, Anderson DO, Kalimo E, Kleczkowski BM, Purola T, Vukmanovic C. Health services: concepts and information for national planning and management. *Publ Hlth Papers* 67. Geneva: W.H.O. 1977.
12. Casas AR, Vargas H. The health system in Costa Rica: towards a national health service. *J Publ Hlth Policy* 1980; 1: 258–79.
13. World Health Organisation/United Nations High Commissioner for Refugees WHO/UNHCR emergency health kit: lists of drugs and clinic equipment for 10 000 refugees for 3 months. Geneva: W.H.O. 1981.

Extract - From Paper on Health for All by 2000 A.D Resources
by Dr C.M. Francis Dean, STMC and President ISHA 85-2

Pharmaceuticals for Primary Health Care

One of the recommendations of the Alma Ata Conference has been with respect to the production, import, distribution and utilization of drugs and pharmaceuticals to ensure the availability of essential drugs at feasible costs.

Though some advances have been made by the Pharmaceutical industry in the country, India is lagging far behind in the provision of pharmaceuticals for the people. The amount that is utilised for the purchase of drugs and pharmaceuticals by a person in India is extremely small compared to what is used in the developed countries and even in some of the developing countries. While increase in expenditure of drugs is not an indicator of health it is necessary that a certain minimum amount is available for the purchase of drugs and pharmaceuticals to care for the sick. A look at the amounts spent by some countries is revealing.

Estimated purchase of human pharmaceuticals (1975)

	Per capita Average
West Germany	US$ 53.35
Japan	38.45
U.S.A.	35.05
U.K.	19.50
India	0.75

Not only is the consumption of pharmaceuticals low in India but even for the low consumption, the production of pharmaceuticals is not enough. The financial requirements for the manufacture of bulk drugs have been estimated to be Rs.720 crores for 1983-84, with a production of formulation of Rs.2,160 crores. The investment in the public and private sectors is of the order of Rs.150 crores and Rs.400 crores, leaving a gap of Rs.1,610 crores. We are still dependent almost entirely on other developed countries for these products. In the International trade in medicinal products there is a wide disparity between the developed countries and the developing countries.

International trade in medicinal products 1969-1974

	Imports		Exports	
	1969	1974	1969	1974
Developed market economy countries	62.4	67.1	94.2	92.8
Developing countries	37.6	32.9	5.8	7.2

RM

Ten countries in the world accounted for 86.8% of all the exports in 1969 and 84.4% in 1974. These countries are therefore in a position to control the production of drugs as regards the nature of the products, the priorities and the final prices. Modern drugs are mostly chemical substances derived from petro-chemical or fermentation industries. The German chemical industry was the only major international supplier before World War I. Later other developed countries joined them, especially when it was found that the Germans withdrew their supply of some of the more important drugs from the international market; the countries involved also put large duties on the imports discouraging the imports of these drugs and thereby helping the indigenous production of the drugs. The State acted as a facilitator in the growth of the pharmaceutical industries in the countries and was mediator between interests of the industry , the medical profession and the consuming public.

Large capitals, modern technology, expertise and extensive promotion activities are necessary in the highly sophisticated pharmaceutical trade and there is a concentration of these industries in the developed world. The Pharmaceutical industries are often a part of the activities of the firm which is mainly a chemical industry. Hoechst which ranked 2nd in world wide drugs was one of the 8 largest companies in the world of overall net sales in 1976. Bayers which was among the top 15 transnational companies in total drug sales was one of the most successful firms in the world, in regard to the overall net sales in 1976. Most of the leading transnational companies dealing with pharmaceuticals have widely diversified interests. A country like India has little chance to compete.

Research and Development: Research and Development are often geared to the needs of the more developed countries (because of the greater purchasing power) and carried out in the technologically forward countries. The developed countries have different prevalent disease patterns from those in the under-developed countries. There is a change from communicable and parasitical illnesses to chronic and degenerative such as heart disease, cancer and various stress-related diseases. This would mean that lines of research which could have yielded beneficial results in tackling health problems of countries like India by development of cheaper andefficacious drugs may not be followed up.

There is a possibility of a geographic redistribution of industry based research. This is evident in some of the countries like Mexico and Hongkong. It is because (1) certain development costs particularly for research personnel are lower in developed countries, (2) the requirements for testing human subjects are less formidable and (3) delays in registration of new products are shorter. Nevertheless this change in allocation of part of production and development of drugs has not affected the industrialised countries' disease orientation of the Transnationals.

Patent: The great majority of patents registered in the developed countries are in the chemical sector and among them a great majority concern drug products, but the nationals within the group of developing countries own only 6% of the total number of patents; a ll the remainder were by other countries. Very few of the patents registered by foreigners are actually worked in the developed countries. The Patent holders very often decide not to use them and therefore do not develop them and also prevent others from developing the product; the patent has worked adversely in providing the consumer with cheaper, effective drugs.

Promotion: Many of these drugs are given intense promotion by various advertising means when doctors become used to recommending the drug by its brand name, and not by the generic name. One drug may be known by a very large number of different brand names and depending upon the capacity to advertise and exploit, the same drug marketed by different firms may be sold at different levels in different countries. There are certain countries which are now insisting on purchases being made by generic names. Some of the developed countries like Norway have national formularies and purchases had to be restricted to the drugs found in the formulary. The total number of drugs in the Norwegian formulary comes to about two thousand whereas in India there are over 15,000 products in the market, most of them being duplicate products. It has been estimated that marketing expenses were equivalent to 15 - 35% of the sales and represent roughly 3 times the expenditure on research and development.

Pricing and Profitability: Only a small proportion of the selling price of the drugs represents direct cost of production. Even where the substance has been produced by the same manufacturer, costs vary greatly between the various distributors. The firms often get monopolies by various methods and therefore are able to fix the price. The US Trade Commission found that the first company to patent Tetracycline, Messrs. Pfizer, was directly responsible for "procurement by misrepresentation" of monopoly control over tetracycline. It was found that Pfizer and Cynamid had concluded a secret agreement by which Cynamid withdrew its application for patent for tetracycline after accepting an offer from Pfizer to divide up the market for the drug.

Pricing pattern is often higher in the developing countries. For 100 tablets of 10 mg librium the cost was

U.K.	-	0.83 US$
Mexico	-	4.42
Costa Rica	-	7.03

The transnational companies have charged whatever the national market would bear.

One of the ways in which the prices are manipulated is by transfer pricing. The prices of intermediate chemicals which are produced only by a few firms are fixed at different levels and supplied at different costs to imports by subsidaries or joint operations in developing countries.

U.K. has a system of negotiating profits with pharmaceutical firms. Hoffman La-Roche, the biggest manufacturer of drugs in the world, included the costs of active ingredient of Librium at £437/- per kilogram. When operations and overhead costs in the United Kingdom were computed the prices were set at a level that showed a profit of less than 5%. However the Monopolies Commission found that the cost of the active ingredient listed elsewhere in Europe was £9/- per kilo for Librium. Roche was using a much higher transfer price. After negotiations, Roche agreed to repay £3.75 million in excess profits and also agreed to fix the prices of the drug at half the earlier price. Transnationals declare prices in various countries at different levels, depending upon the tax situation, restrictions on repatriation of profits and regional requirements.

With a situation like this, India one of the poorest countries, cannot depend on these transnational companies for our requirements of essential drugs (which would really number less than 200) and we should see that they are made available to the people. This could bring about substantial savings in the health expenditure.

CHRISTIAN MEDICAL ASSOCIATION OF INDIA

PHARMACY WORKSHOP PAPER

PREPARATION OF INTRAVENOUS FLUIDS

Introduction The preparation of intravenous fluids has been undertaken in Christian Hospitals for many years with a varying degree of competence and exellence of product. In recent years due to accidents both in India and other countries more and more emphasis is being placed on the construction of the accommodation, equipment and chhemicals used in the manufacturing process.

This paper discusses the standards for which the Pharmacist should aim Many of these standards are the result of scientific observation and experiment and a few based on personal opinion.

Part I The Construction Standards f)epartment

These vary with the type of work to me and can be outlined as follows:

1) Wash-up Room This is the area where the containers are received and washed and also where the rubber liners and caps will be prepared for use. This room needs to comply with good standards of hospital construction. In it will be located sinks for soaking and washing of the bottles and a good water supply is essential.

2) Mixing Room In this room the chemicals will be weighed or measured and the mixing of the solution undertaken.

3) Filling Room This will be connected directly with the Mixing Room so that the solution can be taken into it. Also this room will have a connection with the Washing-up Room so that the bottles can be transferred easily. In the Filling Room the solution will be filtered into the final containers.

The construction of the Mixing Room and Filling Room will have to comply with high standards so that contamination of the fluid is reduced to the absolute minimum. The following are guidelines:

a) The floors and walls must be smooth and without cracks or joins This can be best achieved by using mosaic laid in a continuous form and not tiles which inevitable have to be joined with cement which in time breaks down leaving cracks which can accumulate dirt. The same material can be used for the benches unless formica is preferred.

b) All ledges and gaps in construction must be eliminated including windowcills.

c) All services such as water and e city should have the conduit outside the room, and where possibl itches should be outside or situated beneath the bench.

d) Ultraviolet light should be installed to help eliminate bacteria from the air. It must be remembered that UV light is of limited value and thorough cleaning methods are still essential.

e) The entrances and exits to these rooms should have an 'airlock' to reduce the entrance of unfiltered air

f) These rooms will need to be airconditioned. By this means clean air is admitted under slightly positive pressure which prevents the entry of unfiltered air through any appertures or when doors are opened.

4) Autoclave/Still Room Next to the Filling Room should be a room where the autoclave is installed and also the stills because it is a help to have all the heat generating equipment in one place. The distillate can usually be piped through the wall and if possible the waste hot water can be piped to the Wash-up Room to be used in the bottle washing work. The Autoclave/Still Room can be of normal hospital hospital construction with the addition of efficient extractor fans .

Part I The Construction Standards of the Department (contd)

5) Quality Control Section Intravenous Fluids are subjected to the following tests:

a) Chemical analysis
b) Bacteriological Tests
c) Pyrogen Tests

In each case a separate room will be required of normal hospital building standards. For the pyrogen testing the room where the test is carried out will need to be air conditioned or have facilities for keeping the rabbits for 18 hours before test is carried out. In addition an animal house will be need

6) Store Room A store will be esse for keeping a supply of bottles and other stock required in the preparation of the fluids and also one for the storage of the finished product with facilities for keeping batches separate until the result of the tests are known until which time issues cannot be made.

Part II Equipment

The choice of equipment is not an easy matter with so many companys manufacturing Pharmaceutical equipment. Quality should be the first consideration. Buying cheap equipment frequently leads to problems with servicing and as the makers insist on payment at the time of delivery if they default in any way it is almost impossible to get redress.

The following items are required:

1) Stills There are two types available in India, namely, the Barnstead type and the Kilburn type. The former is to be preferred although it is more expensive. The main problem with the Kilburn type is that any leaking of raw water is very likely to enter the distillate and leaking does appear to be a problem.

The principle of the still is simple and that is that there is a boiling chamber from which the steam is led to a condenser cooled with cold water which having absorbed some of the heat from the condenser passes into the boiling chamber. Generally for every litre of distillate there is 7 litres of cooling water wasted.

A reliable company for this equipment is Steel. There is a choice of capacities but one producing not less that 10 litres per hour is recommended. It is an advantage to have two stills so that if one is out of order the other will allow some production to continue.

2) Collecting Vessels For the collecting of distilled water stainless steel vessels should be used. The size will depend on the amount of intravenous fluid to be prepared. The vessels should be straight sided to enable thorough cleaning to be carried out. When purchasing care should be taken to ensure that any welded joints are smooth and free from pitting which will permit the collection of dirt.

The storage of distilled water for more than 3 to 4 hours is not recommended but this can be extended to about 7 hours by the use of a heated tank. Much longer storage is possible in tanks with Ultra-violet lamps but this is not practicable for most hospitals.

Mixing can usually be undertaken in one of the collecting vessels especially where small batches are prepared.

3) Balances One balance for weighing up to say, 2 Kgs will be required for the weighing of dextrose and other bulk chemicals and another two pan chemical balance for the weighing of small quantities of salts especially where electrolyte solutions are prepared.

Avorys prepare satisfactory coarse balances but care should be taken to specify stainless steel pans as the plated type may soon become spoiled.

Part II Equipment (cont'd)

Minor Equipment Stainless steel spatulas should be provided and glass measures. The measures should be of good quality and those from Corning Glass Ltd are to be recommended (distributed by Borosil). If possible obtain class A measures which have a certificate of accuracy. Never use plastic measures. Glass stirring rods will also be needed.

4) Filters Generally sintered glass filters are used although sintered steel are available from ove[illegible] The type preferred is the pipeline type which enables fil[illegible]ect into the final containers. The filter required s[illegible] capable of removing particles visible to the eye from [illegible]tion but not bacteria as this type filter very slowly. The g[illegible] required is Porosity 3 (sometimes called PG 3). Bacterial filters are porosity 5 or 5 on 3.

After each use the filters must be thoroughly rinsed with distilled water. Occasionally, say once a week, the filter should be washed chemically and the manufacturers instructions should be followed. In the absence of instructions the following may be used:

a) Allow to drip through under gravity concentrated sulphuric acid with 1% sodium nitrite at about 80°C.

b) Allow to drip through under gravity a chromic acid solution prepared as follows:

Potassium Bichromate	80 grammes
Acid Sulphuric Concentrated	120 mls
Distilled Water to	1000 mls

Method a) is much to be preferred because with thorough rinsing all traces of the chemical are removed. Chromic acid is very toxic and this solution should be kept for very dirty or contaminated filters. Large volumes of distilled water will be required for rinsing.

Sintered glass filters are available fro[illegible] Corning Glass (Borosil)

5) Vacuum Pump The system generally [illegible]sed is filtering under negative pressure and for this a vacuum pump i[illegible]eeded. Suitable pumps are manufactured by Pharmalab Industries [illegible]y.

6) Autoclave It is much to be p[illegible]r the Pharmacy to have its own autoclave. A shared autoc[illegible]gents problems for supervision in operation as well as [illegible]times it will be available. It is essential that the autoclave can give a temperature of 121.5°C (15 lbs/sq in pressure) and a thermometer and pressure gague must be fitted. If possible a record of the maintenance of temperature throughout the cycle should be attached. The capacity of the autoclave will relate to the production of the fluids but very small ones should not be purchased.

Satisfactory autoclaves are produced by NatSteel.

7) Clarity Checking Light All fluids must be checked after autoclaving and this can be done with a light source in a box with a back panel of white (to show up black particles) and black (to show up white particles). This box can be constructed locally.

8) Capping Machine Generally screw caps will be used on the bottles and these must be covered with a paper cap prepared by hand or a machine applied aluminium foil cap. The latter is to be preferred as this gives a professional finish. This cap indicates that a bottle has not been opened when it is in place thus providing a useful safeguard.

Part III Staff Arrangements

The following staff will be needed:

1) Pharmacists The work of the department must be under the direct supervision of a registered Pharmacists and should posess either the Degree or Diploma in Pharmacy. Some states insist that a degree Pharmacist should control this work. However the guiding principle must be competence and experience. The number of Pharmacists needed will depend on the work load.

2) Aides It will be a great time saver if an aide is trained to do such work as washing bottles, preparing rubber bungs and caps and keeping the department tidy. It must be remembered that his work is important and that he should have his responsibility explained to him.

If the work of pyrogen testing is undertaken another aide will be required to look after the rabbit house.

3) Dress When working in the mixing and filling rooms thestaff must cover their own clothing with provided sterile dress as follows:

a) Cap covering the hair
b) Mask covering the mouth and nose
c) A gown which covers the outdoor clothing.
d) If possible shoes should be provided and failing this the outdoor footwear should be removed.

This dress should not be worn outside the sterile work area. This clothing is similar to that worn inside the operating theatre and the Pharmacists should dress similarly to avoid contamination of the fluids which could have serious results.

4) Personal Health and Hygene This must be of the highest order. Staff suffereing from infections such as colds and coughs must not enter the area.

Part IV Theory and Practice of Intravenous Fluid Preparation

1) General Cleanliness The whole section must be kept very clean and there should be not accumulation of rubbish or rarely used items. The Pharmacist in charge must carefully supervise cleaning procedures which should be written down.

Cleaning staff who work in the wards should not be admitted to the mixing and filling rooms. These rooms should be cleaned with an antiseptic solution and the walls and benches with alcohol 70% if this is available.

Water for Injection Quality This is from distilled water prepared in a still which can produce pyrogen free water and then autoclaved immediately.

When water boils there is a tuburlent action on its surface which throws up droplets of raw water into the steam and are therefore carried over into the condenser and become part of the distillate. To prevent this carryover (technically entrainment) of water droplets baffles are introduced which allow only steam to enter the condenser.

Raw water may contain bacteria and therefore almost certainly pyrogens. Pyrogens are produced chiefly by Gram-negative bacteria and are lipidpolysaccharides the lipid part being the pyrogenic agent the action of which is enhanced by the polysaccharide. They have a molecular weight of about 1 million and are about the size of a small virus. It has been shown that even a small amount of pyrogen is injected a reaction results.

Part IV Theory and Practice of Intravenous Fluid Preparation (contd)

2) Water for Injection Quality (contd)

The presence of pyrogens is most serious in large volume injections because
a) a large volume injection will contain a correspondingly large amount of pyrogen
b) Large volume injections are normally given intravenously and the pyrogens will act quickly.
c) Patients receiving these injections are often seriously ill.

The pyrogen reaction is rather like a chill and the most serious symptom is a rise in body temperature which may be fatal for a patient already feverish.

The preparation of pyrogen free solutions is complicated by the nature of the pyrogens which are:

a) Not destroyed by the temperature at which solutions are autoclaved.
b) Water soluble and cannot therefore be removed by filtration
c) They are unaffected by the common bactericides

However they are non volatile and so the method of distilling water described eliminates them.

The Pharmacopoeias direct that the distilled water collected must be sterilised immediately. This is because on storage the water will become contaminated by bacteria leading to the formation of pyrogens. This instruction is generally taken to mean that distilled water may be kept for about 3 hours. To keep contamination to a minimum the vessel containing the water should be carefully covered. Some authorities state that distilled water may be kept about 6 to 8 hours in a vessel kept at 70 - 80°C but this should be avoided if possible. Water must never be stored overnight.

Distilled water must be free from dissolved salts and a well constructed still should ensure that this is so.

3) Preparation of Intravenous Fluid Bottles This is a very important job usually given to an aide. Poor work in this connection can result in the loss of a batch of fluids.

All bottles, both new and reused ones, must be examined carefully for cracks and other flaws and those so damaged must be rejected. The bottles are then put to soak in a detergent such as Iteol or Teepol. Soap must not be used as this leaves a film on the glass which may be detatched during the autoclaving. Preparations such as Vim and Surf should not be used as these tend to scratch the glass.

After soaking the bottles must be scrubbed either mechanically or by hand using a good quality brush which must be in good condition. The detergent solution is then washed away with plenty of tap water, allowed to drain for a short time and then rinsed with distilled water and drained. The final rinsing before filling must be with freshly distilled water.

In some hospitals the bottles are dried in a hot air oven after rinsing with distilled water as this reduces the possibility of pyrogens forming. In either case the bottles should be used as soon as possible after the cleaning procedure.

4) Weighings and Measurings These must be done with great care on a balance of suitable capacity and liquids measured in glass measures of suitable capacity. All weighings and measurings must be checked by another pharmacist and in doing so he must check not only the weights but also the source of the material on the balance pan. Even very experienced pharmacists have been known to make mistakes and in this work such mistakes are not only wasteful but also may be fatal to patients.

Part IV Theory and Practice of Intr[illegible]luid Preparation (contd)

5) Filtering Before filtering the f[illegible] old tubing and filter head must be rinsed through with fresh distilled water. The first 100 to 200 mls of the filtrate of the solution should be rejected because this will have been diluted by water remaining in the filter from the rinsing. After the filtering of the batch is finished the filter, tubing, etc., must be rinsed again with fresh distilled water.

6) Closures for the Intravenous Fluid Bottles Rubber closuers should be obtained from reliable manufacturers because poor quality rubber can impart chemical impurities to the solution on autoclaving.

The liners will need cleaning before use and the following procedure is suggested:

a) Boil for 15 minutes in a solution of 2% Sodium carbonateand 0.1% detergent.
b) Rinse thoroughly
c) Boil in fresh distilled water for 15 minutes
d) Rinse in fresh distilled water.

The liners are then ready for use. Only enough for immediate use should be prepared.

Opinions about this cleaning procedure vary but the less violent the cleaning procedure the better because this in itself will tend to release further chemicals from the rubber.

The aluminium caps should be washed thoroughly and boiled in [illegible] distilled water and finally rinsed in fresh distilled water.

7) Sterilisation As soon as the bott[illegible] filled they should be packed in the autoclave for sterilis[illegible] Do not overfill the autoclave as this tends to hinder the penetration of the load by the steam. Delaying of sterilisation will greatly increase the danger of pyrogen reactions and such delays must not be allowed to occur.

On closing the autoclave door steam is allowed to enter the chamber and as soon as the temperature reaches 121.5°C the cycle timing is begun. This temperature must be maintained for 30 minutes when sterilising 500 ml bottles.

At the end of the cycle the steam is turned off and the chamber pressure allowed to reach zero. Then the door can be opened cautiously a few centimetres to allow the bottles to start cooling. The door can then be opened fully after about 20 minutes. This procedure helps to reduce the charing of dextrose solutions. The bottles must not be removed from the autoclave for about an hour otherwise bottles may explode due to sudden temperature changes and such explosions are very dangerous as glass fragments and nearly boiling solution are blown across the room.

8)Examination of bottles for Clarity When the bottles are cool they should be examined using the light box and any with particulate matter present should be rejected.

9) Capping and Labelling Alumunium foil or paper caps should be applied Where foil caps are used it is best to have one colour for all solutions. Different colours tend to encourage staff to identify bottles by colour rather than by reading the label.

Printed labels should be attached and [illegible] should bear the following details

a) Volume of the Injection
b) Name of Injection and source of formula, e.g. BP
c) Strength where applicable
d) Milliequivalents where applicable
e) Sterility statement
f) Batch number or date
g) Name of Hospital
h) Clarity warning

Part V The Quality Control Testing of Intravenous Fluids

1) Clarity testing This is referred to in Part IV 6). above.

2) Chemical Analysis After the sterilising of the solution (and before if possible) the contents of the solution should be analysed both qualitatively and quantitatively and other tests carried out according to the Pharmacopoeial monographs.

3) Bacteriological Testing The absence of aerobic and anaerobic bacteria must be established by introducing samples into suitable media and controls should be set up. These tests require 7 days incubation before the results are known. Similar tests may be done for fungi.

4) Pyrogen Testing This test is designed to establish the absence of pyrogens in the solution. Unfortunately there is no reliable chemical test so a test based on rabbits is used. The principle of the test is to observe if there is any temperature rise on giving the fluid intravenously such solutions being rejected.

The details of the test is set out in the Pharmacopoeia. The test demands that three rabbits each weighing not less than 1Kg are used. They must not have been used for a pyrogen test in the previous three days and within the last 3 weeks if a pyrogen response was observed in a test. At least one day before the test they are checked with pyrogen free sodium chloride injection and if the body temperature rises significantly that animal should not be used.

For the test the animals are kept in a room which is within 3°C of their living quarters or failing this they must be kept in the test room for 18 hours. Food is withheld from the rabbits overnight and water during the rest. The material under test is injected into the ear vein and the temperatures recorded at 30 minute intervals for 3 hours. The temperature is determined by rectal thermometer.

The interpretation of the results is that the summed response of the group of three rabbits does not exceed that of the first column in the table the solution passes the test. If this lies between the two figures then the test is repeated on a further group of three rabbits if necessary up to a total of four groups being used. If at any stage the summed response exceeds the figure in the third column of the table the solution fails the test.

The results of all the above tests should be known before the intravenous fluid is released for use.

These tests are expensive to undertake, especially the pyrogen test, so it may be more economical to send the test material to a laboratory specialising in this service.

Table for Pyrogen Test Results

Number of Rabbits	Material Passes if summed response does not exceed	Material fails if summed response exceeds
3	1.15°	2.65°
6	2.80°	4.30°
9	4.45°	5.95°
12	6.60°	6.60°

A.Cranmer, MPS
Consultant Pharmacist.

Group Discussion on Prescribing Policy - Groups B1 & D1

Questions to be pondered about !

1. Can a Hospital devise a formulary of good quality, low cost medicines?

   Can this be common for all Voluntary Hospitals?

2. How can prescribers' compliance be ensured or is freedom of prescribing likely to make this impossible?

   Can we ensure Health Workers' compliance with their formulary (medicine list)?

   Will doctors also prescribe from this list?

   Is it possible to prevent prescriptions to medical shops being given?

3. Where simple low cost drugs will not be sufficient, how do we subsidise to all or those who need help most?

   Should all patients contribute to the cost of medicines? If so, how?

4. Will a Pharmacy Committee, including Doctors, Administrators and Pharmacists help in implementing cost control or quality control policy? (In most Hospitals medicines are the second largest item of expenditure!)

5. Have we asked our pharmacists to research costs? If so, does he know how to do so?

   Have we provided tools for the job? If so, what tools?

6. Are bulk drugs purchases possible on a group of Hospitals-base? What methods can we devise for obtaining low cost drugs either for one or many Hospitals?

7. Do we consider proper stock control, record keeping and auditing of medicines, purchase and distribution:

   a) unnecessary expenditure b) essential?

   What are our reasons for our attitudes?

8. In many Hospitals the Pharmacy is an important income producing section. Will a switch to low cost drugs raise cost or make it instead a burden on the Institution?

9. Is the production of medicines in the Pharmacy :

   a) too time consuming

   b) too costly in terms of personnel or equipment

   c) uneconomic?

   (Broadly thinking of two types: non sterile prescriptions and sterile prescriptions) How would you advise your Hospital Management?

CHRISTIAN MEDICAL ASSOCIATION OF INDIA

PHARMACY WORKSHOP PAPER

PHARMACY DESIGN AND ORGANISATION

The number of people seeking medical help will be large in many Christian Hospitals. From the patients attending outpatient departments admissions will be made and bookings taken for confinements and surgery.

From the O.P.D. the patient, after seeing the doctor, will proceed to the Laboratory, Pharmacy, dressing room, etc., for further health care. Therefore the siting of these service departments is important. In the smaller hospitals there will be one Pharmacy only and this should be sited centrally and if possible at the junction of the Outpatient and Inpatient departments. In larger institutions there will probably be an inpatient Pharmacy and one for out patients sited in that department.

Make sure that it is easy for patients to find the Pharmacy. Direction boards should be written in the Regional Language and English and in Hindi where this is appropriate. Remember not all patients can read so a colour and a symbol for the Pharmacy is helpful.

Design of the Pharmacy

In a medium sized hospital the department may be as follows:

a) Dispensing Section
b) Sterile Products manufacture which will be principally I.V. fluids.
c) Non sterile products manufacture - mixtures, ointments, etc..
d) Store
e) Office for the Chief Pharmacist

a) Dispensing Section If possible make the window arrangements for patients to collect their medicines so that at least two may be dispensed for at one time. In some areas it is an advantage to have one window for men and one for women. An arrangement whereby the nursing staff can obtain medicines quickly is appreciated by them. Try to make the queue system work by having barriers so that only one patient at a time can get to a particular window. It is very distracting to have patients waving prescriptions at you whilst dispensing.

Each Pharmacist should have reasonable working space. The benches must be high enough to work at without bending over and stools of the correct height should be provided so that a Pharmacist may sit and work. The bench tops should be of polished stone or Formica but remember chemicals such as silver nitrate and acriflavine stain these materials and so any spillage must be wiped up immediately.

Stocks of medicines for dispensing should be close at hand. Much walking is time consuming and tiring. Tablets of much domanded tablets can be stored on either side of the dispensing window in small compartments.

b) Sterile Products This section requires a washing up room for the bottle cleaning, a mixing and filling room and an autoclave room. In addition facilities for assay and pyrogen tests on the final product. (Further details are given in the Pharmacy Workshop Paper 'Preparation of Intravenous Fluids')

c) Non-sterile Products One room will probably be sufficient. It must be fitted with easy clean benches, water supply and good lighting. A high standard of cleanliness is essential because it has been established that many pathogenic organisms can be transmitted through these preparations.

Design of the Pharmacy (contd)

d) Store This must be of a size adequate for the work load of the Pharmacy. Adjustable steel shelving is the best but is expensive. Do not have the shelves too wide apart as this can waste much space. The store should be cool even in the hottest weather. A refrigerator must be available for heat sensitive medicines such as vaccines, oxytocin and insulin.

e) Office for the Chief Pharmacist An office should be available for the Chief Pharmacist and here the various clerical work and stock records can be maintained. Reference books and journals should be available for the staff and could be kept in the Office.

Day to Day Work in the Pharmacy

Try to organise the work load so that it is spread evenly throughout the day. In many hospitals the ward baskets come to the Pharmacy when it opens and this work is cleared before the ward and O.P.D. prescriptions are likely to be received.

Make sure that all the Pharmacists know what is required of them in their allocated duty and a written job description often helps to prevent misunderstandings. All Pharmacists, especially in smaller hospitals should undertake all the types of work so that during periods of sickness or annual leave the work will not be seriously interrupted. All duty changes should be notified in writing through the departmental notice board. The Pharmacist who is to attend to calls during the hours when the Pharmacy is closed should not leave the hospital compound and should inform the Doctor on call and the duty sister of his whereabouts if this is different from his quarters. Weekend and Sunday duties will also have to be arranged and some compensatory off duty time should be allowed.

Training Programmes Where the Pharmacy is well developed it should be possible for the senior members of the staff to give lectures to the more recently qualified Pharmacists. Juniors should also be encouraged to prepare papers and to listen to the constructive criticism of their seniors.

The postgraduate training for the Diploma in Pharmacy is 750 hours practical training. Well developed Pharmacy facilities are urgently needed for this purpose and the Drugs Controller for the State can give the necessary information on gaining recognition.

Dispensing of Medicines When taking the prescription from the patient make sure that it is written by one of the Hospital doctors. Read it through and if there should be any error do not show the patient by your expression or speech that there is anything wrong but check quietly with the prescriber. Do not do anything which might destroy the confidence of the patient.

Dispensing should be carried out as quickly as possible but without haste or omission of any checking, packing and labelling. Packing of medicines should be carried out in a professional manner. Never, never pack tablets in pages torn from old journals or newspapers, and never pack ointments in papers. Plastic bags and containers are available quite cheaply and proper pricing of medicines will cover the cost of these materials. It is better not to use medicine bottles brought by patients which may well be dirty and thus contaminate clean medicines. Provide bottles for the patients for which a small charge may be made.

Labelling should be clear and neat. It is preferable to use printed labels in suitable languages. Take time to explain the directions to the patient. It has been definitely established that patients do not remember what the doctor has told them and this is an important task for the Pharmacist. Never, never stick one label over another. This is potentially a very dangerous habit.

Prepacking of medicines Much time can be saved by the prepacking of medicines. This may be done in commonly used sizes for mixtures, ointments and tablets. Each packet should be labelled with the name of the contents and on dispensing a label must be attached giving the patient's name and directions.

Staff Matters

Provision should be made for hand washing in the Pharmacy and if at all possible with running water. It is surprising how many pharmacies are deficient in this respect.

Uniforms should be worn by all. They will normally be provided by the Hospital or an allowance made towards their provision. Uniforms help to identify staff, protect personal clothing, and protect the work being done from contamination bound to be brought in from outside.

Remember when the patient leaves the Pharmacy, which is usually the last department he visits, he takes away two things with him - his medicines neatly packed and labelled and his impression of the Pharmacist which should be one of a helpful, cheerful person.

A. Cranmer, MPS
Consultant Pharmacist
Christian Medical Association

777

85.5

CHRISTIAN MEDICAL ASSOCIATION OF INDIA

PHARMACY WORKSHOP PAPER

GENERAL ADMINISTRATION OF THE PHARMACY

Control of the Pharmacy Service

All hospital departments come under the control of the Medical Superintendent but in all but the smallest hospitals he will delegate his authority to a head of department for day to day control of its working.

General policy will be laid down for the administration of the Pharmacy but unfortunately this is rarely done in writing.

Pharmacy Sub-committee This Sub-committee will give guidance in the running of the Pharmacy and should have the following members:

a) Medical Superintendent (Chairman)
b) Medical Specialist (Vice chairman)
c) Chief Pharmacist (Secretary)
d) Administrative Officer
e) Another Specialist probably a pediatrician

Other members of the Hospital staff can be called to meetings where matters concerning them are to be discussed.

The functions of the sub-committee should be set out in broad terms as follows:

a) To help in the general administration of the Pharmacy
b) To publish a formulary
c) To set out general purchasing policy
d) To examine requests for medicines to be added to the formulary
e) Disciplinary matters such as professional misconduct. This will not interfere with the general discipline for dealing with serious misconduct which is in the hands of the Administration.
f) To deal with complaints and suggestions about the Pharmacy Service.

Meetings should be held about once a month and if possible the interval between meetings should be regular. Do not make the Subcommittee too large or it will be difficult to choose a time when most members can be present.

Pharmacy Budget In smaller Hospitals the Pharmacy will not have its own budget but medicines will appear as income and expenditure item with other hospital expenditure and income. Larger Hospitals will set down the expenditure as follows:

a) Staff salaries
b) Electricity ad water charges
c) Depreciation on equipment
d) Depreciation on buildings
e) Purchase of new equipment
f) Purchase of medicines
g) Write off of spoiled medicines

Against this will be set income erived from medicines plus any special grants.

When arriving at the amount to be budgeted for medicines the following must be remembered:

a) The average expenditure over the last three years is calculated
b) The number of inpatient days and outpatients over the last three years is noted. The trend of increase or decrease is calculated as a percentage and this taken as the increase/decrease to the figure arrived at from a).
c) Any anticipated increase in the prices of medicines and whether the trend is for the doctors to prescribe more expensive items.

Pharmacy Budget (contd)

d) The budgeted receipts for medicines and Pharmacy Services will reflect the same percentage above expenditure as in previous years.

The Pharmacy Sub-committee will be able to discuss this and offer suggestions for modification to the Management.

Some Hospitals donot stock medicines because of the very considerable outlay needed. However failing to keep adequate stocks had the following adverse effects:

a) Christian Hospitals are generally in need of all the income which can be generated and failure to keep stock puts money into the pockets of local business men.
b) The Hospital Pharmacy staff and equipment are not being put to full use. The waste of a Pharmacist's skills is a loss to the Hospital.
c) If patients bills are carefully prepared and presented on time money is collected quickly and company bills can be paid by the due date.

Billing of Patients

The billing of inpatients for medicines at the time of dispensing has been discussed in the Pharmacy Workshop Paper ' Distribution of Medicines to Patient Areas'. However a few additional procedures have to be considered.

Private Patients Patients who are paying high ward rent will probably not want to pay for their medicines at the time of dispensing. One of the following will avoid this whilst making sure that an accurate record is kept:

a) A cost sheet is added to the Patients chart. This is sent to the Pharmacy with the normal patient's special medicine requisition and when the Pharmacist prices this he also adds the details to the cost sheet. At the end of the period, probably one week, the office will total the value of medicines supplied and add the amount to the bill.
b) The prescription is written in duplicate one copy for the Pharmacy and one when priced for the office who will keep these to add to the patients bill.

Method a) is simple and saves a good deal of office time and takes very little Pharmacy time.

Special Fund Patients These patients treated free from some of the Hospital Special Funds such as the Leprosy and Village Community Health Funds.

Emergency Medicines When medicines are used from the Emergency Tray of life saving medicines kept on the wards they are replaced either by the nurse making out an indent form in the usual way, asking the patient to pay and then replacing the item on the Tray. In the case of death or discharge or death this cost is added to the final bill and the nurse must show the Pharmacist that the medicines have been used for before they can be replaced.

Dangerous Drugs and Ward Stock Medicines Stock medicines can be paid for in one of the following ways:

a) Daily Charge. Throughout the wards over a period of at least six months the value of medicines issued as stock is calculated at the patient charge rate. From the record office the total number of inpatient days (not inpatients) is obtained, which is divided into the value of medicines issued giving the amount spent per patient per day. On discharge the patient is charged the number od days of his stay multiplied by the daily charge. This method is quick and easy to administer and allows a collection to be made against exponsive antiseptics and disinfectants often overlooked in charging patients.

Dangerous Drugs and Ward Stock Medicines (contd)

b) Medicines Listed from Chart. This method requires the sister to prepare a list of ward stock medicines given to the patient at the time of discharge. This is then priced by the office and added to the bill. This method suffers from two disadvantages, firstly the making of lists is often inaccurate and secondly it takes a good deal of nursing and office time.

Night Emergency Cupboard Medicines. Payment for these is either raised by the Pharmacist reporting to the ward sister the medicines used and an indent being raised for the replacement in the usual way or the amounts used, which will be fairly small, are added to the patients final bill.

Outpatients In a few cases outpatients will not pay for their medicines at the time of dispensing. These will have to be billed and this can be done by the Pharmacy. A copy of a bill book page is attached. This bill must be sent to the Office for the official account to be made.

This book can also be used for staff purchases if the Pharmacy Offers such items as baby foods and tonics. These amounts will normally be collected from the salaries so the bills must reach the office well before pay day.

Outpatients Free Medicines When medicines are supplied free the Pharmacy account must be credited and this can be done by one of the following methods:

a) Charity receipt book. This is an ordinary receipt book for which no cash is taken but the amount is credited daily to the Pharmacy
b) Pharmacy keeps a record book in which all free medicines are listed and valued and the amount added to the Pharmacy account at the end of a suitable period.

Refunds On occasions patients will be advised to stop taking medicines already prescribed and purchased from the hospital. In this case although it is not obligatory it is a help if the Pharmacy takes the medicines again and arranges for a cash refund. This is done as follows:
a) The patient takes the medicines to the Pharmacy together with his cash receipt and the Pharmacist completes a form for the Office stating the medicines received and the value and receipt number.
b) The patient goes to the office and signs for the refund.
c) The Pharmacist replaces the medicines in stock making the necessary entries in the records.

It is normal practice not to accept parts of bottles of liquid or loose tablets and in any case the value of these will probably be low.

Pricing of Medicines

Medicines Purchased and Dispensed Unchanged This is a very important matter because it involves the contribution the Pharmacy can make to the income of the institution and also some legal obligations. For the past few years the Government authorities have set the maximum retail price for the medicines of all companies which is printed on the container together with the statement 'Local Taxes Extra'. These taxes are Sales Tax and octroi. The method of calculating the price is given in the following example:

Maximum Retail Price	Rs 12.00
Sales Tax at 8%	96
	12.96
Octroi at 2%	26
Price to patient	Rs 13.22

For convenience the price is normally rounded to the nearest five paise i.e. this case Rs13.20.

Medicines Purchased and dispensed Unchanged (contd)

This pricing will allow a margin of income over expenditure of about 12½, and from this departmental costs have to be covered. The icome may be increased where special contracts are arranged. It is permissable to charge lower prices when desired.

Non Sterile Preparations These are items prepared in the Pharmacy and include such items as mixtures, ointments and lotions. The price of these is calculated in much the same way as that for intravenous fluids set out below. At least 12½% above cost should be charged and reasonably more because professional skills are involved.

Sterile Preparations The biggest part of this will be intravenous fluids and the following example will give an idea of how to calculate cost and the amount to be charged.

Salaries (estimated at 4/5 Bpharm Pharmacist and ½ aide)	742.00
Chemicals (based on 5% Dextrose solution = 25.35 Kg @ Rs14/- x Kg)	390.00
Labels, celophane, rubber bands at 2 p per bottle	23.00
Rubber liners	190.00
Electricity	1000.00
Water	10.00
Depreciation on equipment (10% per annum)	100.00
Depreciation on buildings (2½% per annum)	44.00
Bottles at Rs4/- each (used average of six times)	769.00
	3268.00
+ 10% rejects	327.00
Rs	3595.00

This is the total cost for a monthly average production of 1154 bottles.

Each bottle costs to produce Rs 3.12

Suggestd price to the patients Rs 6.50 per bottle

The suggested price may seem high compared with the cost but it must be remembered that at least 12½% is added and also that quite a number of bottles will probably be given free to patients. Also in the near future it will probably be obligatory to have the bottles assayed and pyrogen tests carried out. The retail price of manufacturers' bottles is not less than Rs7.50 at present.

777

A.Cranmer, MPS,
Consultant Pharmacist
Christian Medical Association

85.6

CHRISTIAN MEDICAL ASSOCIATION OF INDIA

PHARMACY WORKSHOP PAPER

MEDICINES - PROCUREMENT AND STOCK CONTROL

Part I Purchase of Medicines

Sources The cheapest sources are not always the best. The major Indian and International companies have quality control and research laboratories to ensure that the products are of a high standard. Their prices may be a little higher than some but there is the assurance of good quality.

Criteria for Purchasing these are:

a) Good quality. This can be decided by
   i) Quality Control tests carried out in the Hospital but these will not be possible for most institutions
   ii) The Pharmacists experience in selecting companies
   iii) By listening to the comments made by your doctors
   iv) General reading and comments by other Pharmacists

b) Continuity of Supply This is not easy to ensure but the Pharmacist's general experience will be a help.

c) Company Dispatching Orders Quickly

d) Company giving maximum discount There are several methods of obtaining discounts
   i) Bulk orders - see below
   ii) By negotiation of terms. Sometimes a local distributor will forgo some of his profit to gain business or he may agree to pay some of the taxes such as Octroi. It is important to ensure that the correct company rates are charged.
   iii) Seeking quotations from company offices. This may be done through a representative. As competition grows with more companies making the same medicines the larger firms can often be persuaded to give some special discount.

Methods of Purchasing Bearing in mind what has been said above the following are possible:

a) From the Manufacturer. This ensures the correct rate being charged as well as availability of stock and is the best method for all large purchases. Do not change companies frequently but rather try to build a good business relationship with those you choose. Many of them are sympathetic to the needs of Christian Hospitals.

b) Bulk Purchasing This will normally be from the manufacturer who is often ready to give discount for a guaranteed purchase of an item during a year. Usually it will be agreed that the goods can be delivered an paid for in anything up to 12 deliveries a year. It must be remembered that when such a contract is entered in to the Hospital must take the agreed quantities to get the concession rate.

When taking contracts be careful about the amount of money required for each payment. Remember that money tied up in stock is not earning any return. The discount given must at least equal the interest which could be earned by placing the money in the bank.

Placing of Orders This must be the job of the Pharmacist who will know the company details outlined above. All Pharmacists must make sure that they are competent in this respect.

The Indian Pharmaceutical Guide is a help in selection of companies but it is only a list and is not necessarily a guide to quality.

When orders are written the Medical Superintendentor Chief Pharmacist may sign them. In many hospitals it is the former as he likes to know the amount of bills likely to be received in the near future.

It is an advantage to have a printed order book rather that to have to write letters. It should be in duplicate so that the Pharmacist can keep the carbon copy. (More copies can be made if other Hospital departments require them) On the order form the following details should appear:

1) Hospital name and address including the pin code
2) The Railway Station
3) Order number
4) Conditions under which the order is placed
5) Quotation number
6) Space for name and address of company
7) Items, size and quantity required
8) Signature

It is not wise to use company order forms because these are of varying size, require filing, and have no Hospital order number.

Company Representatives Many companies employ representatives to detail their products to doctors and pharmacists. Representatives are trained with impressive sales talk and great care must be taken not to over order the items they are pressing you to purchase. Do not be taken in by, 'If you purchase this I will see that the doctors prescribe it'. It is best to make it a rule not to place orders with representatives bu rather send them direct to the company which gives you time to think. Similarly doctors should not so place orders. All orders must go through the Pharmacy order book.

Representatives can take a lot of your time and very rarely do they have a new, important medicine to tell you about. It will help you to keep control of the situation if you see them at certain days and times in the week. It is fairly easy to end an interview by standing up and saying, 'Thank you for coming'.

Special Orders These are orders for Narcotic Drugs and for Spirit. Make sure that you know the procedure for obtaining the transport passes and for the renewal of the licences in your State. Do not forget to start the renewal in plenty of time and at least 2 months before expiry.

Payment of Bills This is not normally the responsibility of the Pharmacist. However, watch when payments fall due and if necessary ask the office to pay on the due date. The Hospital's relationship with the companies is greatly influenced by this matter and a good name once lost is hard to recover.

Part II Receipt of Goods

Receipt of Documents The company will usually send the documents that is the carrier's way bill and invoice by one of the following methods:

a) Through the Bank. The documents are sent to the Bank and the Hospital's representative has to go to the bank and pay the invoice amount plus a fee for their release. They are then taken to the carrier's godown where the goods can be collected. Where there is an octroi charge the octroi office release the good only after payment of this tax.

b) Direct. In this case the Company sends the Way Bill and invoice direct to the Hospital whose representative can go direct to the carrier's or octroi office as in a)

Method b is obviously to the advantage of the Hospital because the goods are received on credit and 15 to 30 days is allowed for payment. Method a is used by a few companies for all customers and by most companies when customers delay payment beyond the due date.

Payment for Transport Charges Almost all companies will pay the cost of transport when the invoice amount is above a certain figure - often Rs300/-. The amount will be set down in the Company's terms of business and it is a good policy to read these. If a way bill is received 'Freight to Pay' make sure that the amount is deducted from the invoice.

Taking Delivery of the Goods At the carrier's office all boxes and other packages must be carefully examined for damage or signs of pilferage. The suspect boxes must be weighed and compared with the weight recorded on the way bill. If the weights differ or their is any doubt whatever take 'Open Delivery'. This means that on opening you reserve the right to complain and call the carrier to see the damage as you may wish to make a claim on him. Otherwise the signature of acceptance implies that you are satisfied and release him of responsibility.

Unpacking the Goods On arrival at the Hospital the goods are unpacked either in the Pharmacy or at a central receiving point. The idea of a central receiving point for all types of hospital purchases is a good one provided that it is efficiently run and at the same time it is remembered that staff have to be provided for it. In practice because of the special nature of the medicines it is usual for the Pharmacist to have opened the parcels and then these are placed on a bench and carefully counted. The items with pack size and quantity should be listed in the Goods Received Book under the company's name. This book should have numbered pages so that reference can be made to it on the invoice and stock card. The goods are then placed in the store.

Part III Store

The Store should be neatly in one of the following ways:

1) Alphabetically under generic (official) names so that all the items of one medicament are together. e.g. Under tetracyclines the items on the shelf would be - capsules, intramuscular injection, intravenous injection, ointment, vaginal tablets.

2) Alphabetically as in 1) but the store divided into sections for Chemicals, Injections Tablets, Ointments, etc.

3) Pharmacological groups. This method is difficult to organise satisfactorily so is rarely used in store keeping.

There will probably have to be a separate section for bulk items such as disinfectants and some chemicals.

Part III Stores (contd)

When placing new supplies in the store the new stock must always be put behind the older stock to ensure strict rotation of use. Make sure that the store is always clean and tidy.

Invoices These will be received at the same time or shortly after the goods. The details of the quantity received must be written on the stock cards (see below). The invoice is checked against the Goods Received Book and the book entry number written on the invoice. The invoice number is written on the Goods Received book entry. The invoice is then signed and sent to the office for payment. It is useful to have a Pharmacy seal for the invoices and a suitable design is given below.

Hospital Name

Rec by	Entered on cards	Price checked
Date Rec	GRB No	Order checked
Passed for payment	Date passed for payment	

PART IV STOCK RECORDS

Stock Cards These are the centre of Pharmacy stock control and must be kept carefully especially with regard to keeping up to date with issue and receipt entries. Stock cards are preferable to bound ledgers because of the ease with which they are operated and economy in space. Separate cards for receipts and issues is an advantage for the same reason. To ensure security each new card can be numbered and signed by a senior officer. The following are the details needed on the cards:

Receipt Card

1) Name of medicine (generic)
2) Pack size
3) Card folio number
4) Manufacturer's name
5) Suppliers names
6) Date of Order
7) Order number
8) Quantity ordered
9) Date of receipt
10) Order number
11) Goods received book number
12) Suppliers number
13) Invoice number
14) Quantity received
15) Total cost including Sales Tax
16) Expiry date
17) Unit rate

In addition the card may show
18) Monthly consumption rate
19) Lead time
20) Buffer stock
21) Reorder level

Issues Card

1) Date
2) Amount issued
3) Stock balance

and in addition may show
4) Amount received
5) Issued to (dept name)

It is useful to have a bin card in the stores for each item so that as quantities are removed an immediate record is made. This is a check on the stock cards. For this purpose an issues card can be used.

Medicines for Low Income Groups

□ ALAN CRANMER, M.P.S. □

INDIA is still in the early stages of the industrial revolution with 80 per cent of the people living in rural areas. As industrialisation grows, urbanisation will make supply of medical care easier in respect of distance from health care centres and provision of facilities for a larger percentage of people.

At present urban areas have many advantages in medical care facilities. Both Government and voluntary agencies provide clinics and hospitals, sometimes of a highly sophisticated nature. However, the majority of people who want to obtain even simple care are put to great expense over travel and loss of working time to utilise them. A real problem is getting medicines to the people where they are, rather than forcing them to come to towns. For the urban poor the problems are similar but distances less; medicines need to be taken to where they live, often in the most unattractive localities.

Patients naturally want their prescriptions dispensed as soon as possible. However, persuading pharmacists to set up in villages is very difficult. Like all health service personnel they want to live at the standard to which they are accustomed, educate their children, and see a reasonable return on the investment in their own education, pharmacy facilities and stock. It is doubtful if many places would be able to support a medical shop. Its viability is even more doubtful whilst the majority of doctors, for similar reasons, practice in urban areas. How then can the provision of medicines be made possible?

The complex nature of this problem has been tackled and different answers tried in different places. A three-tier structure consisting of a basic health worker, a health centre, and a referral hospital is the most likely to succeed in giving an adequate medical service.

Basic Health Worker: The basic health worker, who in some areas is exposed to other disciplines such as simple agriculture, sanitation, etc. is being trained to provide health care treating a high percentage of patients who do not need more highly trained help. Such workers are best selected from the community they are to serve and could be teachers or post office officials for example.

Following training in simple diagnosis and the medicines to be used, a medicine kit is supplied consisting of simple medicines to treat common illnesses. Such a list might be:

1. Malaria : quinine, chloroquine.

2. Colds : aspirin, paracetamol, a decongestant.

3. Coughs : a cough tablet or perhaps a simple mixture, although supplies of the latter are more difficult to get.

4. Fevers : aspirin, paracetamol.

5. Diarrhoea : kaolin powder, a simple tablet.

6. Worm treatment : piperazine tablets for round and thread worms. A treatment for hookworm, very often the cause of severe anaemia.

7. Iron tablets : Ferrous sulphate. Ferrous fumerate. (The latter said to be less of an irritant to the stomach).

8. Vitamin tablets : Vitamin B Complex and multivitamins.

9. Antiseptic : perhaps dilute savlon for wound cleansing.

10. Eye lotion : either boric acid lotion or a locally prepared normal saline solution.

11. Salt solution : a mixture of sodium chloride with some other salts, in dry form, to be mixed in water to save dehydration, especially in children with diarrhoea.

Cheap to Maintain

Such medicines would be cheap to maintain and could be given either free or at low cost to patients. It is better to make a charge because frequently free medicines are not much valued by the recipient. These medicines would be supplied to the health worker from the nearest health centre. He would have a working relationship with the

centre because it would be to these that he would refer patients needing to be examined by the doctor and this doctor would also be responsible for supervising the basic health workers. Additionally, the health worker would arrange for clinics for immunisation of children, and give advice on family planning.

This medicine list has the advantage that all the medicines may be handled by unqualified persons and do not need a doctor's prescription. One problem with staff trained at this level is that they often want to have more medicines as their knowledge and experience grows. This must be firmly resisted because they have neither the diagnostic skills nor the facilities to observe patient reactions to the treatments or to deal with them. This trend in the past has led to compounders and nurses setting up as doctors in rural areas with many attendant problems such as the incorrect use of antibiotics, leading to the development of resistant strains of bacteria, etc.

Health Centre : A wider range of medicines will be needed at the next level of medical care so that serious conditions such as tuberculosis, hypertension, etc., can be treated on a long-term basis with some monitoring of the patient's response to treatment. Records and treatment for leprosy patients can also be maintained. At this level will be found health centres serving a number of villages but not more than about eight kms from any one of them. There would preferably be a resident doctor, nurse, and para-medical worker. If it is not possible to maintain a doctor in residence then regular and frequent clinics should be available. During his absence it would act in a manner similar to that of the basic health worker and the availability of medicines would be the same.

A number of medicines would be necessary for use by the doctor and some decision has to be made about the type of cases to be treated at health centres. Specific guidelines for medicines are difficult to describe briefly; but the items would not include any which are not found in the World Health Organisation's 1979 List of Essential Medicines[1]. This List gives proven medicines for many illnesses but avoids expensive and doubtful remedies. The stock available would need to be revised from time to time in the light of experience. Payment by patients will probably be necessary for medicines, so the simpler these are the better. Most treatments will be more expensive than at the health worker level so it may be necessary to subsidise medicine costs.

At health centre level the provision of medicines on the prescription of a doctor comes under the provisions of the Pharmacy Act. One important Section of the Act (Section 42) states that "any person who is not a registered Pharmacist shall compound, prepare, mix or dispense any medicine only on the prescription of a medical practitioner". The one exception to this rule is that a doctor may dispense his own prescriptions and is exempt from registration under the Act. This is almost certain to cause staffing problems at health centre level; so if a doctor travels to various clinics it will be helpful if a registered Pharmacist goes with him. It has to be clearly understood that nurses and para-medical workers are not permitted to dispense nor to undertake dispensing under the supervision of a pharmacist.

Referral Hospital : The referral hospital will have a proper pharmacy service with the widest range of medicines; but again, those to be stocked should be based on the 1979 WHO List of Essential Medicines. The policy of the hospital should be to hold in stock enough medicines to provide at least 90 per cent of the medicines prescribed.

Provision of Medicines

In considering the problem of obtaining and prescribing medicines, it is necessary to look at their availability, prescribing habits and the expressed needs of patients. Each of these factors has a considerable influence on what is promised or prepared in the hospital pharmacy. Inevitably the major demand will be for solid dosage forms such as tablets and capsules as these have simple storage requirements and need no skilled person for administration.

There is a growing number of pharmaceutical companies in India producing thousands of items which are mainly combinations of several medicaments in solid dosage forms. Many of the formulations produced by different companies are almost identical and it is rarely that a new drug is introduced. Products are generally promoted by high pressure salesmanship by both Indian and multinational companies. These methods on occasion include the offer of

discounts on purchases of a certain number of units or total value which require careful scrutiny to ensure that the products are really required and that the discount will in fact be helpful and not involve the purchase of unprofitable quantities resulting in overstocking and possibility of time-expired drugs being left on the pharmacy shelves. Some inducements to purchase are intended unduly to influence officers with powers of ordering and these include personal gifts of saris and suit lengths of material, or refrigerators and fans, and should not be permitted by the rules of the purchasing organisation. Usually these offers are made in connection with the purchase of multidrug formulations which, as suggested, will not feature largely in purchasing policy.

Types of Medicines

Medicines available on the market are of two types and the value of each needs consideration. Basic drugs are usually preparations of single drugs and include analgesics and antipyretics, antihypertensives, antibiotics, diuretics, etc. From such preparations the majority of patients can be treated economically. There are however also multidrug formulations.

The advantages and disadvantages of including more than one drug in a dosage form should be considered :

Advantages :

— A few combinations are synergistic, e.g. co-trimoxazole in certain illnesses.

— Reduced side-effects, e.g. Isoniazid with pyridoxone.

— Compliance with treatment. A patient may understand and remember how and when to take a single medicine whereas he may default on a number of different ones. (This also raises the question of how many conditions to attempt to treat at one time).

Disadvantages :

— In multidrug formulations the dosage ratio is fixed and does not permit the physician to adjust dosages.

— Adverse reaction to any of the ingredients cannot be identified.

— Inappropriate combinations are found e.g. anti-inflammatory drugs with prednisolone; simple analgesics with diazepam.

— Ignorance. Prescribers are frequently unaware of the constituent drugs. A Montreal survey[2] showed that the most frequently prescribed of 23 combinations was correctly identified by only two-thirds of the physicians and for seven of the 23 not a single prescriber answered correctly. Hospital pharmacists did slightly better.

Cost is probably a variable factor but, not infrequently, combination drugs are more expensive partly because they include drugs not required by the patient's condition.

Costly Formulations and Food Products

Some simple medicines are available in more costly formulations which are not significantly more active. For example, ferrous sulphate tablets cost a few paise each but some sustained release formulations are available on the market at many times the price with no significant advantage to the patient.

Tonics are very often part of the drug companies listed products and profit margins are high. These are normally based in a malt or aqueous alcohol base which makes them pleasant to take. In almost all cases a balanced, not expensive diet will provide sufficient minerals and vitamins of the types included in tonics. Some tonics include the glycerophosphates which have been incorporated presumably because lecithin contains phosphorus in the form of the glycerophosphates radical and therefore would be more easily assimilated by the tissues. There is no evidence to support this assumption[3], and therefore to pay for such ingredients is wasteful. Except in cases of severe illness, when swallowing is difficult, the prescribing of tonics is economically unsound.

Nutrition is an essential part of reducing dependence on tonics and other food products. As stated earlier, this need not mean an expensive diet. Health workers can and are being trained in teaching the selection of locally available foods so that adequate quantities of minerals, vitamins, carbohydrates, fats and proteins are included in the diet, especially for children. Food habits and taboos die slowly and teaching requires a sensitive and patient approach by all levels of staff. Health workers in the community must set the example themselves, and here dedicated women workers with children can achieve great improvements.

Baby foods prepared artificially

have often been condemned and are not to be recommended, except in exceptional circumstances, because of the problem of preparation and administration. Often the mother does not understand the mixing technique and, for economic reasons, over-dilutes the food with serious consequences for the baby. Bottle cleaning and sterilisation present problems in rural areas. Teaching about weaning and weaning foods would prevent many of the malnutrition cases seen at clinics and hospitals.

Various Pressures

The prescriber is subject to great sales pressure from the industry which, like other industries, survives, develops, and satisfies its shareholders by maintaining and increasing sales. The prescriber is the one who will ultimately shape the pharmaceutical industry, and education for doctors in prescribing and resisting pressures is essential. They need orientation in prescribing essential, proven treatments for sufficient periods and basing such prescriptions on such lists as that provided by WHO, thereby avoiding the costly items so often promoted. Working closely with an experienced pharmacist can help to minimise the stocking of unsuitable medicines; but efforts by both doctor and pharmacist are required.

The prescriber is also subject to pressure from patients who, with very little knowledge, often try and dictate the medicine they want to have. This pressure includes:

— Demands for injections. Patients assume that an injection will cure all conditions rapidly. The problems of maintaining sterility of syringes is considerable in busy clinics; so injections should be prescribed only where there is a problem of patient compliance with treatment or the oral route is unsuitable.

— Quick results are expected or desired by all and the prescriber should resist changing treatments for this reason. The treatment of tuberculosis and leprosy are particularly difficult in this respect and patience is required in explaining the need for taking medicines regularly.

— Costly formulations appear attractive in multi-coloured capsules or specially shaped tonic bottles. So these should be kept out of sight of patients even if they are part of the stock.

— Education is an essential part of the programme so that all from the doctor to technicians and health workers will not themselves expect such treatment and thus guide patients into a more reasonable acceptance of simpler medicines.

Pricing and Selection of Drugs

Prices charged for medicines have to be calculated in accordance with Drug Price Control Orders by the manufacturers and submitted to Government for approval. The approved price is that printed on the container and to that sales tax and any other local taxes may be added. There is therefore reasonable uniformity in prices. The retail pharmacist must keep to this price structure and is forbidden to add anything to it for his services. The purchaser has every right to a receipt for his payment on which must be written the name and quantity and price of the medicine supplied. The patients most likely to suffer from deliberate over-charge are the illiterates; so for them a receipt is even more important as evidence to show what they have purchased. Any over-charge should be brought to the notice of the pharmacist and if he refuses to correct the situation, a complaint to the Drug Control authorities in the State is in order, and an investigation will be ordered if evidence can be supplied to support the complaint.

In the matter of selection of suppliers of medicines, quality should be the first consideration. Here, the knowledge and experience of the doctors and pharmacists are very important. It is wise in the case of each durg to list the names of, say, two manufacturers who have shown reliability, in terms of quality, pricing and supply and to keep to those. It is possible to find in certain markets antibiotics and other drugs at much below the average price. Generally they are unbranded and there is the risk that they may contain adulterated or spurious drugs and so should be avoided.

The supply of medicines to rural and urban low income groups needs careful thought and systematic action to ensure that patients get the medicines really needed and at prices which they can afford. The prescriber has a very important role to play in moulding manufacturing policy and public opinion.

Almost all medicines are pro-

(*Contd. on page 76*)

PART V STOCK ANALYSIS AND ORDERING SYSTEMS

Deciding on the amount of stock to be kept and the amount and time to order are very important if over and under stocking are to be avoided. The first step is to find out the pattern of investment.

A B C Analysis For this analysis the following steps have to be followed:

1) The cost of each item is multiplied by the number used during the year giving the total expenditure.
2) The items are listed in descending order of total expenditure.
3) The percentage of the cash investment for the first 10% of items is established. This will be found to be about 70% (A items)
4) The percentage of cash investment for the next 20% of items is established. This will be found to be about 20% (B items)
5) The remaining 70% of items will be found to take the remaining 10% of the investment (C items)

The method of Stock Control in the Pharmacy Dispensing Area as well as stock levels can be derived from this Analysis as shown in the table below.

Category of Item	A	B	C
Number of items as % of the inventory	10%	20%	70%
Value of items expressed as a percentage of the whole	70%	20%	10%
Stock	minimum	medium	large
Buffer Stock	small	medium	large
Turnover	fast	medium	medium or slow
Admin. Control in Dispensing Area	individual record	individual or general record	general record

From this table it will be seen that the items where the most money is invested should be held in comparitively small amounts (A). A small amount of excess stock will tie up large sums of money. Items in C category will be held in large quantities because the investment is small. Orders for A items will be placed frequently and for C items much less often.

The use of all items will be carefully recorded in the store but in the Dispensing Area only on category A and some B items individual records will be required. This is fully dealt with in the paper 'Distribution of Medicines from the Pharmacy to Patient Areas'

Following this analysis the next step is to decide on the ordering method which will be one or a combination of the following methods:

Cyclical Ordering System This is a time based system which usually involves an annual review of the stock level of all items and the requirement for the following year is calculated taking into account the amount used in the previous year and the stock in hand. From this information the orders are placed either annually of up to four times a year regardless of the stock position. There are certain disadvantages in the use of this system, namely

Cyclical Ordering System (contd)

1) Unforseeable fluctuations in demand cannot be controlled
2) Advantage cannot be taken of special contracts except at the revue time
3) Placing of orders is concentrated at a few periods of the year

Fixed Quantity Ordering System This system is based on the quantity of stock of the items held. A point is fixed below which the stock is not allowed to fall. The advantage of this system is that the stock level is the guide for ordering and that orders are spread out in time. However if the lead time and usage fluctuate too much a new re-order level has to be fixed.

To operate this system the following must be understood:

1) Lead Time This is the time taken expressed in weeks between the Pharmacy writing the order and the goods being received in the store.

2) Buffer Stock This is the stock kept to cover fluctuations in demand. For example, there is often a season of Typhoid when more than usual chloramphenicol is prescribed. It is difficult to decide exactly when that season will begin so extra stock must be held to cover such emergency situations.

The buffer stock is calculated by multiplying the difference between the maximum and average issue rate by the lead time (all expressed in weeks):

Buffer stock = (max demand - aver demand) x lead time

Example:

Maximum demand	=	20 vials/week
Average demand	=	14 vials/week
Lead time	=	2 weeks
Buffer Stock	=	(20 - 14) x 2
	=	12 vials

3) Re-order Level This is the level at which the new order has to be placed. It is not the same as the Buffer Stock because no account is taken of the useage during the lead time. The Reorder Level is calculated by the addition of the Buffer Stock to the expected demand during the Lead Time

Re-order Level = Average Demand x Lead Time + Buffer Stock

Example from above:

Re-order Level = 14 x 2 + 12

= 40 vials

4) Maximum Stock Level This is generally taken to be twice the Re-order Level.

It is obvious that one of the two systems alone will probably not be satisfactory for all items in the store although the Fixed Quantity Ordering System will be the most used but if rigidly applied would not permit the taking up of contracts. These systems need to be applied with common sense so that the best use can be made of them to ensure adequate but not excessive stock levels.

A.Cranmer
Consultant Pharmacist
Christian Medical Association

25577/AC

1. the dispensing and supply of drugs shall be carried out by or under the supervision of a qualified person.

2. the premises where drugs are supplied or stocked shall be open to inspection by an inspector appointed under the Drugs and Cosmetics Act who can, if necessary, take samples for test.

3. The drugs shall be stored under proper conditions.

The key word here is SALE

In the Act and Rules we have

- a license to sell, stock or exhibit for sale required of retailers and wholesalers - defined and governed.

- a license to repack for sale - defined and governed.

- a license to manufacture for sale - defined and governed.

The exemption in Schedule K in effect, if not in intent, negates the whole of the Pharmacy Acts and Rules in regard to the hospital pharmacy. The hospital pharmacy does not sell, nor manufacture for sale - it compounds and dispenses. NO Sale - therefore, NO LICENSE.

The definition of 'manufacturing' in the Act is ambiguous. Manufacturing in relation to any drug or cosmetic includes any process, or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to it's sale (there's that word again) and distribution - but excludes the compounding or dispensing of any drug, or the packing of any drug or cosmetic in the ordinary course of retail business, and to 'manufacture shall be construed accordingly'. The word SALE excludes the hospital from the role of a manufacturer.

Hospital pharmacy has no legal definition at this time in India. The hospital pharmacists are seeking a definition and subsequent control. Until that time we have to act responsibly, ruled by norms and behaviour accepted by all who are dealing with human.

-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-oOo-

Renu/
5.1.1978

85-8

PHARMACY

Introduction:

> "that profession which is concerned with the art and science of preparing from natural and synthetic sources suitable and convenient materials for distribution and use in the treatment and prevention of disease. It embraces a knowledge of the identification, selection, pharmacologic action, preservation, combination, analysis, and standardization of drugs and medicines. It also includes their proper and safe distribution and use whether dispensed on the prescription of a licensed physician, dentist, or veterinarian, or in those instance where it may be legally done, dispensed or sold directly to the consumer."

HOSPITAL PHARMACY AND ITS IMPORTANCE:

The practice of pharmacy in a hospital setting: In the average hospital, the pharmacy will fill thousands of prescriptions and disperse as many ward orders and requisitions in a single year Purchase of drugs and the value of the annual inventory run into many thousands of rupees. A fairly high percentage of the total annual expenditures of the hospital go for pharmaceutical services. This emphasizes the need for very careful attention to the effect that pharmaceutical services have on the efficiency of both clinical and administrative services in every size hospital.

The idea of the hospital pharmacy with a well qualified pharmacist in charge has been accepted by the larger hospitals as a necessity. Small hospitals have not taken this position largely because of the fear of increasing their operating deficits hospitals which fail to employ a pharmacist with proper training, experience, and talent are seriously lowering the efficiency of their services and operations. A well organized pharmacy will function effectively in its own sight and also contribute to the whole integrated hospital organisation.

In hospitals where pharmaceutical services do not appear to be of sufficient volume fully to utilize the time of a competent registered pharmacist, several alternatives are employed to maintain good services without undue cost. It has been traditional to assign to the pharmacist other duties, particularly those relating to general administration, such as purchasing. Most pharmacists, by experience, are well qualified in this regard. Recently there has been a movement to retain the pharmacist in professional medical fields. Examples of division of time between limited pharmacy duties and others include laboratory or x-ray functions, or supervision of central sterilizing and supply services. Another alternative which probably will gain in favor in coordinated hospital programs is the employment of a qualified pharmacist on a part-time basis by two or more small hospitals where travel time is not too great.

The Pharmacist incharge, with the approval and cooperation of the director of the hospital should initiate and develop rules & regulations pertaining to the administrative policies of the department. The professional policies of the department should be formulated by the pharmacist and the Pharmacy & Therapeutic Committee and approved by the administration.

...../-

RESPONSIBILITIES OF THE PHARMACIST:

The pharmacist in charge shall be responsible for: (a) the preparation and sterilization of injectible medication when manufactured in the hospital, (b) the manufacture of pharmaceuticals, (c) the dispensing of drugs, chemicals and pharmaceutical preparations, (d) the filling and labeling of all drug containers issued to services from which medication is to be administered, (e) necessary inspection of all pharmaceutical supplies on all services, (f) the maintenance of an approved stock of antidotes and other emergency drugs, (g) the dispensing of all narcotic drugs and alcohol and the maintenance of a perpetual inventory of them, (h) specifications both as to quality and source for purchase of all drugs, chemicals, antibiotics, biologicals, and pharmaceutical preparations used in the treatment of patients, (i) furnishing information concerning medications to physicians, interns and nurses, (j) establishment and maintenance, in cooperation with the accounting department, of a satisfactory system of records and book-keeping in accordance with the policies of the hospital for (1) charging patients for drugs and pharmaceutical supplies, (2) maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies, (k) planning, organizing and directing pharmacy policies and procedures in accordance with the established policies of the hospital, (l) maintenance of the facilities of the department (m) cooperation in teaching courses to students in the school of nursing and in the medical intern training program, (n) implementing the decisions of the Pharmacy and Therapeutics Committee, (o) the preparation of periodic reports on the progress of the department for submission to the administrator of the hospital.

EDUCATION OF THE PHARMACIST:

- Diploma in Pharmacy Course

  One year basic sciences - Chemistry, Physics, Anatomy, Physiology, Hygiene, English, Biology.

  One year professional - General Pharmacy, Dispensing Pharmacy, Pharmaceutical Chemistry, Pharmacognosy, Pharmacology, Forensic Pharmacy.

  Internship - 750 hourse in an institution approved by the Pharmacy Council of India.

- Bachelor in Pharmacy Degree

  I year - English, Mathematics, Physics, Biology, Chemistry.

  II year - Mathematics, Physiology, Pharmaceutical Chemistry I and II.

  III year - Pharmacognosy, Pharmacology and Toxicology, Pharmacy Administration and Industiral Business Management, Pharmaceutical Engineering, Pharmaceutical Chemistry III, Pharmaceutics I.

  IV year - Pharmaceutical Chemistry III and IV, Pharmaceutics II and III, Pharmaceutical Engineering, Forensic Pharmacy.

  Internship - 750 hours in an approved institution (only if registration is sought)

FACILITIES:

Adequate pharmaceutical and administrative facilities should be provided for the pharmacy department. In addition to the equipment needed for the compounding dispensing, and manufaeturing of pharmaceuticals, these facilities should also include (i) an adequate library and filing equipment to make information concerning drugs readily available to both pharmacists and physicians, (ii) special locked storage space to meet the legal requirements for storage of narcotics, alcohol and other drugs, (iii) a refrigerator for the storage of thermolabile products (iv) adequate floor space for all pharmacy operations and the storage of pharmaceuticals at a satisfactory location provided with proper lighting and ventilation.

PERSONNEL:

The number of pharmacists required for any particular hospital varies with the program, policies, responsibilities, services and their utilization for inpatients, outpatients, employees and the public.

The workload consists of both measurable activities and those which do not easily lend themselves to quantification. In general each category requires about one-half of the time of the pharmacist. More readily measured items include filling of prescriptions, issues to patient care areas, including outpatients, compounding, and pre-packaging.

THE PHARMACY AND THERAPEUTICS COMMITTEE

- an advisory group of the medical staff which serves as the organizational line of communication or liaison between the medical staff and the pharmacy department. This committee is composed primarily of physicians and the pharmacist and is selected under the guidance of the medical staff. It also is a policy recommending body to the medical staff and to the administration of the hospital on all matters related to the use of drugs.

- Functions and scope

1. To develop a formulary of accepted drugs for use in the hospital.
2. Advise on all matters pertaining to the use of drugs.
3. Advise on selection or choice of drugs.
4. Evaluate clinical data on new drugs.
5. Prevent unnecessary duplication of drugs.
6. Recommend additions and deletions of drugs from list accepted for use.
7. Develop a basic drug list and provide for its constant revision.
8. Recommend policies regarding safe use of drugs in the hospital.

...../-

9. Study problems relative to dispensing and administration of drugs.

10. Review Adverse Reaction Reports.

11. Evaluate periodically medical records in terms of drug therapy.

THE HOSPITAL FORMULARY

- a continually revised compilation of pharmaceuticals which reflects the current clinical judgement of the medical staff.

- A system whereby the medical staff of a hospital, working through a Pharmacy and Therapeutic Committee evaluates, appraises, and selects from among numerous available medicinal agents and dosage forms those that are considered most useful in patient care.

Purpose of the Formulary:

The Pharmacy or Therapeutics Committee should develop or adopt a suitable formulary of selected medications. This serves two main purposes: it promotes rational therapeutic, and it prevents unnecessary duplication, waste, and confusion, and thus promotes economy to both the patient and the hospital. There is a loss to the patient and the hospital when many brands of the same drug are stocked and prescribed. Economy in medication does not mean the use of inferior remedies. A formulary must be sold to the medical staff on its merits—, sound therapeutics and quickly obtained quality drugs for every condition or disease entity. The economy of a formulary is a corollary or result of this system in effect.

The use of a formulary has many advantages, but should not be so inflexible as to restrict the physician. Its content and pharmacy procedures should be reviewed periodically by the above committee.

Guiding Principles

1. The hospital formulary system shall be sponsored by the medical staff based upon the recommendations of the Pharmacy and Therapeutic Committee.

2. The medical staff shall adopt written policies and procedures governing the hospital formulary system as developed by the Pharmacy and Therapeutic Committee. These policies and procedures shall afford guidance in the evaluation or appraisal, selection, procurement, storage, distribution, use, safety procedures, and other matters relating to drugs in the hospital.

3. The Pharmacist, with the advice and guidance of the Pharmacy and Therapeutics Committee, shall be responsible for specifications as to quality, quantity, and source of supply of all drugs and chemicals, biologicals and pharmaceutical preparations used in the diagnosis and treatment of patients, and for assuring that quality is not compromised for economic considerations.

..../-

4. Prior agreement by the prescriber must be obtained to permit the pharmacist to dispense upon prescriptions and medication orders, formulary drugs without reference to brand identity.

Recently the HATHI COMMISSION has recommended to the Government that all life saving drugs be sold by generic name at a reduced price rather than by brand name.

PURCHASE AND INVENTORY CONTROL

Drug stocks in nursing units should be standardized and be kept at a useful minimum and should be inspected by the pharmacist, accompanied by the nursing supervisor, at least monthly.

The pharmacist's principal function in purchasing is to establish standards and specifications for medication and equipment. He alone is responsible for sub-standard or dangerous items reaching the patient. The pharmacist is familiar with the pharmaceutical and chemical manufacturers, their distribution system and discounts. He is also familiar with firms which furnish other professional supplies. It is his duty to have in stock at all times an adequate supply of the proper quality. A sound purchasing and control system is essential.

A purchase record card on each item stocked in the pharmacy is necessary. The purchase when recorded with the date, quantity and price, will reveal when reordering the product the need for obtaining larger or smaller quantities. Quantity discounts may be taken advantage of, dependent on business conditions, and over-stocking is prefented. Control of prices to be charged is easily effected, cost changes are noted and the selling price adjusted at the same time.

Purchase of drugs and pharmaceuticals should be on a bid basis where practicable.

CONSIDERATIONS:

R.O.L. - 'reorder level' - the minimal holding, or stock, of an item that has been determined from a study of tiem required to obtain that item from the source of supply.

E.O.Q. - 'the economic order quantity' - the optimum quantity of an item to be ordered at any one time taking into consideration the following factors: normal flow rate, the cost of ordering, the cost of holding, relative availability.

Three methods of establishing E.O.Q. in ascending order of efficiency.

1. Replenishment System - the purchase is made on fixed ordering times rather than quantities. Inventory is reviewed at periodic intervals, an order is placed to replenish the withdrawals.

...../-

2. The Fixed Order Quantity System - the R.O.L. is established and an order is placed when the stock reaches this level. The E.O.Q. is fixed on an annual turnover basis.

3. The Exponential Smoothing Technique - a sophisticated scientific approach to determine the E.O.Q. so as to achieve maximum economy.

ABC Analysis - a computation of the annual rate of consumption of items, by value, and arranging a list in descending order. The items which contribute 70% of the consumption is classified as A, the next 20% as B, and the remaining 10% as C. Rigid control of the A items is a decided economic advantage, minimal control of B items narrows the task, and negligible control of the C items would result in an efficient operation.

Manufacturer or Supplier Ledger - an individual ledger maintained on each manufacturer, or supplier, that permits a permanent register of all transactions with same.

Purchase order - a triplicate, preferably, order form used to requisition drugs, or chemicals from the manufacturer and/or supplier.

G.R.N. - 'goods received note', in duplicate recording the receipt of all drugs and chemicals ordered on the purchase order.

Invoice - document usually sent separately by post for the drugs of chemicals supplied by the manufacturer, and/or supplier indicating amounts sent and values attached.

Stock register - a perpetual inventory maintained on all items by means of individual 'stock cards', and suitable stock ledger.

Indents - an indenting form used to requisition drugs or chemicals from the pharmacy stores.

Record of Dated Pharmaceuticals - R of D.Ph. - in every pharmacy there will be drugs remaining in stores which will soon become useless in the near future because of the expiring date. The pharmacist should list these drugs and inform the medical staff so that they can prescribe the same.

A practical application of the above is possible in all hospitals regardless of size. The main prerequisite is a separate store room, that is, separate from the dispensing operation.

Drug stock in nursing units should be standardized and be kept at a useful minimum & should be inspected by the pharmacist, accompanied by the nursing supervisor, atleast monthly.

DRUG DISTRIBUTION

GENERAL CONSIDERATION

Prescription - the term refers either to an order for medication or to the medication dispensed by the pharmacist as a result of the order. A prescription order issued by a

..../-

physician is specific in character in that it designates a particular medication for a particular individual at a particular time.

The Label - assures the specificity of the prescription for a particular patient by a physician. It indicates the directions for utilization of the prescription.

Pre-packaged prescriptions - prescriptions packaged at a prior time in anticipation of dispensing.

Ward Stock - drugs that are kept at the nursing station issued to the patient as directed on the medication order written in the patient's chart.

Dangerous Drugs - Opium and its derivatives, natural or synthetic; pethidine, cocaine, methadine require special attention to record their distribution, accountable to the government authorities.

Protected drugs - those drugs that are kept in reserve to combat organisms resistant to ordinary therapeutic agents.

Emergency drugs - drugs kept ready for immediate use on patient in extreme distress.

Free drugs - those drugs which may, at the discretion of the clinician, be given free to an indigent patient.

Prescription charge - prescriptions are dispensed and not sold. The dispensing charge recovers the cost of the drug plus a service charge for handling plus a contribution to the maintenance of the institution.

PROCEDURES FOR DISTRIBUTION

In order to systematize his work, the pharmacist's daily work schedule is coordinated with the activities of the other departments of the hospital. The systematic collection and delivery of floor baskets to the nursing units each morning saves nurses' time by reducing requisitioning to a minimum, making frequent trips to the pharmacy unnecessary, and by avoiding delays in the daily nursing program with prompt deliveries.

A requisition system is essential in saving the time of all departments served by the pharmacy. The requisition for special medication should contain all needed information whether written by a physician, intern or supervisor. This includes date, floor and room number, patient's initials; whether medication is for oral or hypodermic use when both are available size of dose and frequency of administration.

Methods of distribution -

Out-patient - on a doctor's prescription, from a pharmacy dispensing unit.

In-patient - 1. Ward stock

Advantages: Ready access.

Disadvantages: Duplicate inventory, little control, responsibility on nursing staff detracting from their time for patient care.

..../-

2. Main dispensing unit

   Advantages: Maximum control of drug flow, one inventory, dispensing by licensed pharmacists.

   Disadvantages: Time lag due to distance in large hospitals.

3. Combination ward stock and dispensing unit.

   Advantages: Adequate control of drug flow, dispensing primarily by licensed pharmacists, minimizes ward drug holdings, bulk supply of common drugs reduces 'handling' expenses, minimizes time disadvantage of (2), minimizes duplication of inventory.

Observations:

1. It is false economy to insist that the patient supply his own prescription container. He must purchase it somewhere, why not from you? The containers brought by the patients are not clean, usually uncapped, cracked, etc. Few drugs can withstand contamination, exposure to the atmosphere and still maintain their integrity.

2. In the United States of America where the literacy rate is probably 99% plus, the incidence of patient error in reading label directions is in the neighbourhood of 12%. Think of the patient error in this country with prescriptions dispensed without labels. LABEL ALL PRESCRIPTIONS IN THE VERNACULAR AND INSIST at the point of delivery that the directions be explained in detail to the patient.

Drug Pricing

Hospital Pharmacy Dispensing is an income producing department. The medication cost per patient day is reduced by proper management. The charges for medication to patients is established on a business like basis, usually above cost. It must maintain the pharmacy department as a whole as well as return an amount to the institution which will help offset the administrative costs and extend its charity to the community. An exception to this may be made on the ordinary drugs stocked in the floor medicine cupboards which are often dispensened without charge to the patient. This avoids irritating and time consuming accounting of charges.

To do this an adequate price schedule must be derived -

Three basic types -

1. Straight percentage - Cost of Goods sold plus a fixed percentage

   Disadvantage - Low cost drugs do not carry their proportion of costs. High costs drugs carry too much - puts too great a burden on the patient.

...../-

The written policies should specifically cover the writing of prescriptions and charges for drugs to hospital employees. The pharmacy must co-ordinate its services with the business office in pricing & promptly submitting all charges & credits.

Partly-Used Drugs

A definite policy is needed in relation to unused portions of prescriptions, particularly for discharged patients. Approval of the attending physician, with adequate instructions for continuing use by the patient, should be provided in situations where the remaining portions of a prescribed drug are to be taken home upon discharge. All other unused portions of specific prescriptions should be returned to the pharmacy for appropriate disposition, usually destroyed. Modification of charges, if indicated, should be reported to the business office.

2. Graduated percentage - Low cost drugs - higher percentage Mark-up

   High cost drugs - low percentage Mark-up

3. Professional fee + Cost of goods sold

Consideration:
1. Government Price Order
2. Needs of the Institution
3. The competition
4. Own expectations

LEGAL ASPECTS OF HOSPITAL PHARMACY

A. Legislations of Government of India:

Some of the Acts promulgated by the Government of India are :

1. The Drugs Act of 1940
2. The Drugs Control Act of 1950
3. The Drugs Rules of 1945
4. The Drugs and Cosmetics (Amendment) Act of 1963
5. The Pharmacy Act of 1948
6. The Drugs and Magic Remedies (Objectionable Advertisements) Act of 1954
7. The Dangerous Drugs Act of 1930
8. The Dangerous Drugs (Import, Export and Transhipment) Rule of 1957
9. Opium Act of 1878
10. The Poisons Act of 1919
11. The Medicinal and Toilet Preparation (Excise Duties) Act of 1955
12. The Medicinal and Toilet Preparation (Excise Duties) Act of 1956
13. Drug Price Control Order 1970

B. Narcotics:

The Dangerous Drug Act, 1930, of the Government of India defines dangerous drugs and delegates powers to the State to make rules permitting and regulating-import, export, transport, possession and sale of "manufactured drugs" that are under this act. Therefore, each hospital should familiarize itself with rules and regulations governing the handling of dangerous drugs in its own State (for example, the Madras Manufactured Drugs Rules, 1932 for Tamil Nadu).

Permits must be obtained for purchasing and dispensing of narcotics, dangerous drugs and alcohol. These permits are to be renewed annually. Narcotics and dangerous drugs must be kept in a separate locked cubboard.

C. Daily Control:

An absolute perpetual inventory must be maintained by the pharmacy department for the receipt and issuance of each narcotic. This is accomplished by maintaining a narcotic stock register which will have a separate sheet in the register for each item.

To complete the record for doses administered on the ward, a record of narcotics must be maintained. In all cases, issues at the ward level should be approved only after the ward supervisor has satisfied herself that the ward record has been compiled and completed in all details for former issues.

This Record of Narcotics must be kept by every ward the OPD, operating and delivery rooms and returned to the pharmacy at regular intervals for checking.

If the hospital pharmacy has an analytical section, records of analytical reports about I.V. & raw materials purchased must be maintained. The Drugs controller checks these reports at intervals.

D. Spirits

A perpetual inventory must be maintained also for receipts and issues from the storeroom for rectified and methylated spirits. This inventory will be checked annually by the local excise and taxation officers before another permit is granted.

All the above records must be kept on file for a minimum of five years and are subject to government inspection at any time.

E. Legal implications of Hospital Pharmacy

Section 123 of the drug rules (The Drugs and Cosmetics Rules, 1945) states that the hospitals are exempt from the provisions of Chapter IV of the Drugs and Cosmetic Act, 1940, to the extent and subject to the conditions specified in the Schedule K. Schedule K, paragraph 5A, gives the exemptions as the provisions of Chapter IV of the Act and the Rules thereunder which require them to be covered by a sale license, subject to the following conditions,

...../-

DRUG PUSHERS OR HEALERS?

"The greatest danger to Health in India is the over medicalising of our Health Care System. Eternal vigilance is required that the Doctor-drug producer axis does not exploit the people and that the 'abundance' of drugs does not become a vested interest in health".

- ICMR/ICSSR study on 'Health for All' -an alternative strategy

The problem of Drug Policy and low cost drugs encompasses a very wide spectrum of issues-multinationalism, industrial policy, medical advertising, research, drug production, medical education, price control and so on. The recent upsurge in interest in this important area of health policy has led to the publication of numerous reports, books and papers and many seminars and workshops have and are being organised. In the final analysis any collective action in the form of policy, analysis, research or education can only result from an individual understanding of the related issues translated into a prescribing policy to be accepted voluntarily by doctors, nurses, para-professionals and others in their attempt to contribute to a solution of the problem.

Readers of this bulletin are requested to think over the following facts, observations, conclusions taken from WHO, ICMR, ICSSR, Earthscan, VHAI, Govt. of India and other sources of information. Can we collectively accept as many of these 9 -points as possible?

(1) 15000 branded drugs are on sale in India but a Government Committee believes that Health needs would be met by only 116 drugs.[2,3]

There is now an overproduction of drugs (often very costly) meant for the rich and well to do, while the drugs needed by the poor people (and these must be cheap) are not adequately available!

WHO in its report on selection of essential drugs has prepared a list of 200 drugs needed for health care.[5]

The real purpose of an essential drug list must be seen as taking drugs to those who need them most, not as reducing the drugs bill.[2]

Could we accept an essential drug list for our practice in which cost would be an important criteria in selection in addition to efficacy, safety and quality?

(2) All UN agencies and governments involved in preparing a list of essential drugs are convinced that prescriptions should be through the generic names of drugs only.[6]

Generic name is not chemical name but official, international, non-proprietary name e.g., not Acetylsalicylic acid but Aspirin.[2]

Branded named products cost higher because they include promotional costs and cost of claims of additional ingredients in formulation e.g., Librium by Roche is available for Rs.16/- per 100 tablets but generic equivalents are available for Rs.1.50.[6]

A study of UNCTAD has shown that bio-availability argument for branded drugs i.e., therapeutic difference

....2.

based on formulation is not very valid for most drugs.[6]

Could we accept Generic prescribing? i.e., Rx Aspirin not Blusprin, Disprin, etc.

(3) In India 60 firms with Foreign shares accounted for 70% of the country's total drug sales in 1973-74. The remaining 30% was shared by 116 large and 2,500 small manufacturing companies.[2]

Drug industry in India is an offshoot of development of the industry in the Western World ..... is in private hands which produces mainly for profit.

ICMR/ICSSR and the Mathi Commission have recommended that the small scale sector, cooperative sector should be encouraged. Hospital and dispensary based formulations should be promoted.

Can we prescribe drugs which are Indian rather than foreign, Government rather than private industry, small scale and cooperative sector rather than large sector?

(4) One of the most distressing aspects of the present health situation in India is the habit of doctors to prescribe glamorous and costly drugs with limited medical potential.

The drugs required by the poor are not produced on the main grounds that there is no profitable market and adequate demand for them, while the country continues to be flooded by plethora of costly and wasteful drugs meant for the minor illnesses of the rich and well to do.

Multiple drug combinations often containing drugs in amounts far in excess of what is required are presently marketed in India. There is a collosal national wastage of drugs because of such combinations.[3]

Packaging increases the cost of drugs very greatly because the trend is to make it attractive and highly elegant and to add cosmetic embellishments to promote sales.

The drugs Consultative Committee examined 34 categories of fixed dose combinations and concluded that in the case of 23 categories of these formulations, there was no therapeutic rationale for their marketing.[6]

Could we stop prescribing drugs whose only additional advertised values are -

a) cosmetic embellishment

b) Elegant packing

c) Irrational combination

d) Imitative drugs

e) Inadequate evidence of greater value?

(5) 25% of a total production of Rs.700 crores in 1976 as analysed by a Task force of the Planning Commission was on vitamins, tonics, health restoratives and digestive enzymes.

An ICMR/ICSSR study observed that production of INH and Dapsone are a third and a quarter respectively, of the

....3.

minimal requirements of the country. On the other hand, tonics and vitamins which are mostly alcoholic preparation and spin money are produced in wasteful abundance![1]

A NIN study on tonics has shown that most of the high potency or 'Forte' preparations of multi-vitamins are a sheer economic waste.[4] These are not only a drain on the patients' purse but also help only to vitaminise our sewage systems.

Can we stop this 'tonic' practice?

(6) A WHO report notes that drug advertising and contacts with representatives of pharmaceutical firms are often the main sources of information for a physician on drugs and sometimes the only one. Such information is largely influenced by commercial interest.[6]

Drugs are often being prescribed by doctors not because they think a particular one is best suited for the situation but because the company which produced it gives the maximum monetary and material advantages and inducements to them. These range from free samples (often sold in practice), pens, calendars, diaries, teas, lunches, travel and conference attendance costs.[1,6]

Medical training in Colleges does not train future physicians to judge a preparation critically ..... nor does it include conscious immunization against the half truths of persuasive industrial advertising.[6]

Can we stop accepting physicians samples and other forms of inducements from Medical Companies?

(7) Many medicinal herbs and roots that are used by grandmothers, local dais and village medicine men have been scientifically tested and researched and known to have therapeutic value. Their descriptions in journals collect dust in reference libraries.[2,6]

Herbal medicines and home remedies are not only low cost and easily available but their popularisation will help in breaking the doctor-drug producer axis for over 80% of the common minor ailments which are now being over-treated.

China has integrated over 50 herbal medicine and home remedies in their armamentariums not only as a drug policy but as an expression of local participation in health care.[2,6]

Can we propagate simple home remedies and locally available herbal medicine after studying their efficacy?

(8) A very large number of techniques of healing are being researched today in which diseases are tackled and cured without drugs. Non-drug therapies include Yoga, Pranayama, Meditation, Accupuncture, Acupressure and Chiropractice among others. Traditional systems of Medicine such as Ayurveda, Unani, Homeopathy which use drugs but of a different sort are being researched in various places and the therapeutic effectiveness of many of their products are being discovered and documented.

Can we adopt a more open policy of enquiry and use of traditional medicine and non-drug therapies?

.....4.

(9) Health Care is becoming increasingly a quest for priorities. "Clean water before antibiotics, food before vitamin pills, vaccination before kidney machines, mothers milk before powdered baby foods mixed with dirty water, health for villagers and slums before more hospitals for the affluent suburbs of capital cities".[2]

Inspite of our preoccupation with Drug Prescribing policy could we commit ourselves to other more important Health Care Priorities?

- ravi narayan

References:

1. Health for All - an alternative strategy ICMR/ICSSR Report (1980)

2. Drugs and the Third World, Anil Aggarwal Earthscan publication, 10 Percy Street, London W1P0HB (1973)

3. Hathi Committee Report of the Committee on Drugs and Pharmaceutical Industry, Ministry of Petroleum and Chemicals, Govt. of India (1975)

4. In Search of a Diagnosis MFC book containing reprints from bulletin

5. The Selection of Essential Drugs, WHO Expert Committee, WHO TRS No.615(1977) and 641(1979)

6. Medicines as if people mattered - Health for the Millions (VHAI bimonthly) Vol.VII No.283, April-June 1981.

35-10

D-10/344
MS:k:27/2/84

MISUSE OF DRUGS AND OUR ROLE AS SOCIALLY CONSCIOUS HEALTH PERSONNEL

Aspects of the drug problem requiring our attention and understanding

Health needs and medical care

Principles of Rational Drugs Therapy and Medical Education:

* Drug Policies which encourage misuse of Drugs in medical care
* Number of drugs - Confusion propounded by 30,000
* Kinds of drugs - Combination drug
  - Substandard
  - Hazardous and irrational
* Drug Control - How ineffective
* Drug prices - trends - medical care - health institution
* Impact of Drug prices on Voluntary health institutions
* Disease patterns and the drug needs and actual drug production patterns
* Shortages of essential and life saving drugs - the case of anit-TB drugs
* Drug information, the lacunae
* Adverse reaction

How and Why misuse of drugs occurs?

Commonly misused drugs

Principles of Rational Drug Therapy

Role of Socially conscious health personnel

Recommended reading for self education.

Health Needs and Medical Care

/better Today there is/understanding of HEALTH as well as the recognition of the implicit relationship of disease with UNMET BASIC NEEDS OF FOOD, CLEAN AND ADEQUATE DRINKING WATER, CLEAN ENVIRONMENT. All that goes on in the name of 'Medical Services' at constantly increasing costs, is being increasingly questioned by more and more people today.

For approximately 60-70% of Indians below or around poverty line no amount of medicines 'modern' or 'traditional' can deal effectively with most of their health problems having their roots directly or indirectly in poverty.

(The well off can afford adequate care for themselves and don't really need us.)

We, the health personnel realize the limitations of our role even as 'deliverers of curative and medical care', We are unable to help with, and ensure consistent supply of adequate nutrition even after we have made an accurate diagnosis of second or third degree malnutrition with multiple vitamin deficiencies. Even while we go on diagnosing and dealing with serious and fatal diarrhoes, (the childhood killer number 1,) we somehow cannot ensure adequate supply of clean water.

On looking back we realize that we were never trained to be "facilitators of health." in the real sense of the word. Actually some of us sincerely believed in the importance of health education, in prevention of disease. Unfortunately we found that much of the health education 'given' in all good faith does not necessarily result in changes in 'attitudes or behaviour. The subtle but crucial difference between "giving of health education" and "being able to communicate, be listened to, be 'heard' and understood was painfully realized only with experience in the field.

Realization of this, as well as realization

- The pressing health needs of the people who needed us most
- The limitation of our training which does not equip us to deal with their problems effectively
- The expected and traditionally accepted role of voluntary health institutions
- The obvious need for the changing role of health institutions, towards more relevant functioning, leaves many of the more sensitive and socially conscious health personnel from service oriented health institutions facing a moral crisis and dilemma.

For the time being let us accept, that voluntary health institutions (like others) are geared only to "deliver medical care" and they do so with commitment and sincerity. Medical care as it exists today is based mainly on 'use of drugs,' whether it's in a big teaching hospital, health centre or even in most community health programmes.

When accusations are made that health personnel all over misuse drugs, and are "pawns in the hands of the drug industry" and "part of an exploitative medical industry complex" - the allegations are very serious and cannot be rejected without as analysing them.

Principles of Rational Drug Use in our medical education

It is a very well recognized (but an unfortunate) fact that our medical education has not equipped us adequately to deal effectively with the problems as they exist in the field. Our teaching of pharmacology and Therapeutics is from Ivory towers for Ivory towers. Principles of 'Rational therapeutics are not taught keeping in mind the conditions under which the

health personnel will have to be functioning in the field - ie.

- With limitation of diagnostic facilities and of supportive staff
- With heavy workload and pressure of time & diversity of function
- With financial constraints with ever increasing deficits
- Shortages of drugs
- Little or no referral facilities or help in consultation
- Long distances and hopeless transports facilities involved which make revisits by patients for reports and followup difficult

To deal effectively with all these constraints calls for constant innovativeness, initiative, skills, concern and commitment. It is a fact that those "undrained brains" meeting all these challenges in the field to the best of their ability are worthy of deep respect.

Unfortunately in many cases as the different constraints increase, the situation deteriorates in the absence of authentic need based drug information with no facilities for meaningful ongoing medical education to certain lacunae begin to occur - unwittingly. Our medical education never geared us for dealing with these lacunae.

Insptite of the encylopedic knowledge of pharmacology we acquired, we find ourselves totally foxed when confronted with hundreds of unheard of drugs. We are unable to critically evaluate, from amongst the hundred of brands of the same product, - the most rational product to stock our pharmacies/with and to prescribe.

Our entire medical education is based on the use of generic named drugs and that too mostly single ingredient drugs. The medical journals also use non-proprietary generic names and then we walk into the world of Brand names - of which there are 30,000 in India. Many health personnel don't see the unreasonableness of the brand names - till confronted by a critically sick patient with numerous prescription slips full of unfamiliar brand names. The realization that most of these are combination drugs with varying contents of ingredients makes it all the more complicated to figure out what was prescribed and actually consumed.

Out education does not equip us with a thorough understanding of:

- our country's health & drug policies
- our people's health needs & health priorities
- the rationale behind generic drugs over brand names
- the existing drug control mechanism and its ineffectiveness
- concept of essential drug list and its relevance for a developing country like ours
- irrationality of most combination drugs

- the various hazardous drugs banned in various countries which should not be allowed to be manufactured, marketed and prescribed
- the half truths and biased drug information fed by the drug industry on which the health personnel tend to depend in the absence of EASY ACCESS TO UNBIASED MEDICAL DRUG INFORMATION.

According to the working group on Rational Drug Therapy of WHO, out of 17 ways in which doctors misuse drugs, the commonest is overuse. Over use of Drugs means:

- too large a quantity of drug
- for too long
- prescribing of an unnecessary drug
- prescribing of many drugs adding no additional benefit for the same purpose

Factors leading to overprescribing

1. Inadequacy of time and facilities for diagnosis.
2. Lack of knowledge of drugs and prescribing principles (over prescribing to avoid risk of underprescribing)
3. Pressures exerted by patients
4. Heavy and often unethical practices, marketing by drug companies and distribution of samples.
5. Desire to retain patients good will.

Another problem for Failure on part of the patient in taking drugs properly; ie. right drug given to the right patient with INADEQUATE or NO appropriate drug information may not be taken properly. Reasons being -

1. Failure to understand and follow the prescribers instructions/given too vaguely or not at all.
2. Treatment by more than one doctor often of more than 1 system of medicine.
3. Self medication by patient.
4. /Premature cessation of drug is due to financial reason, fear of harmful effects (most allopathic drugs are considered hot), and because of some unacceptable mild side effect.
5. Drug substitution at the chemists.
6. Illegible prescription.
7. Chemists own vested interest.

/which may have been

/Stopping

Principles of Rational Drug Therapy is based on "Rational prescribing - the right drug for the right patient at the right time at the right amounts and with due consideration to relative costs." (Dept. of Health Education Welfare, 1969).

Rational Therapeutics is based on -

a) As accurate a diagnosis as possible under the constraints of diagnostic facilities and supportive staff and costs. (Relative contributions of history taking, physical examination and lab investigation to diagnosis and management of medical outpatients, B.M.J. 2, 486-89).

(In 83% new hospital outpatients the final diagnosis was reached on history and referring doctor's note. Only 5% diagnosis was reached after investigations).

Hamptom, J.R., Harrison, MJG,, Mitchell, JRA, Pritchard, J.S. and Seymore C. (1975).

b) Appropriate use of Drugs

Drugs available should be:

1) Effective
2) Safe
3) Economical
4) Essential
5) Easily available
6) Acceptable (culturally and socially to the patients)
7) With little scope for misuse
8) Easily administered

(See article on Rational Drug Therapy - Drug Issue - April June 1982 - HfM). Therapeutic Guidelines, Upanda, J. Yudkin, G Brown, AMREF.

c) Effective Communication to the patient about usage of drugs

Various studies have shown that between 10% to 90% patients with an average of 50% do not take prescribed treatment, they forget or reject their doctor's advice. (Ref. Psychological studies of doctor-patient communication in contributions to medical psychology Ed Rachmann, Oxford Pergamon Press, Page 9-42). Dr. George J Caranasos et al in the Journal of the American Medical Association (JAMA))talking about lack of communication between Doctor and patient says:

> "Patients also cannot identify correctly 60% of their medicines. Forty percent of patients receive drugs prescribed by 2 or more physicians, increasing the possibility of drug interactions. Twelve percent of patients take drugs prescribed for someone else and 60% of the patients consider their drugs completely safe."

Coranasos, George J et al, Drug Induced Illness Reading to Hospitalization, JAMA, 228 - 713-717, 1974.

Dr. Hulka an epidemiologist at the University of North Carolina and others revealed that 58% of the total number of patients studied made mistakes in the way they took their medication - they took either too much, not enough or at the wrong time.

ive

In our Indian context, effect/communication with illiterate, often ignorant patients, for whom what we consider superstitions is a reality, requires special skill and on this depends whether the drug will be taken

- at the times suggested
- in correct amounts
- in a correct way
- for the correct duration and that the patient would be able to report back any serious adverse reaction and not consider it worsening of the disease or consider the diagnosis to be wrong.

Most of our rural patients who are used to home remedies, traditional systems of medicine - western medicine is alien - even though it is often associated with the "awe" and "mystery" accorded to white man's medicine. The dangers of these medicines and the importance of taking it properly is often underestimated. In this social context our responsibility as effective communicators, and educators obviously increases. The need to shoulder, and appropriately delegate some of these responsibilities to other trained staff is very pivotal in rational drug therapy.

What Encourages Drug Misuse?

1. Drug Policies which allow hazardous and irrational drugs to flood the market, which allow their heavy promotion and creation of false needs are very much to blame. Even concerned Health Personnel have so far never felt the need to express their opinion in all this ... power of the drug industry is obvious from some of the following examples:
Eg. Lifting of price restriction on category III drugs by the Govt. in return of dissolving of the foreign equity shares by certain multi-national from 70% to 40% and having/demand met. /their Finding more and more unessential but profitable drugs flooding the market is but a natural outcome. (For categorise of Drugs & Drug Price Control Order see Drug Situation in India.)

Another example is the enability of the Govt. to ban the 23 irrational combination drugs which the Drug Consultative Committee recommended for withdrawal, because of vested interest (list available with VHAI).

The drug companies getting a stay order:

- on Govt. decision to allow sales of 5 single ingredient drugs only under generic names

- on Govt.'s decision to ban high dose estrogen-progesteron combinations involved in the hormonal pregnancy test scandal (the tests were officially banned since 1976).

The fact that Bangladesh heavily dependent on foreign drug imports/could manage to ban 1707 hazardous and irrational drugs /but makes our indifference and apathy all the more pathetic.

2. Number of Drugs

There are 30,000 drugs in the market. Hathi Commission recommends 116 essential drugs while WHO recommends about 200 essential drugs to deal with 90% of the problems in most hospitals. Studies based on information recall showed that it was not possible to remember important information of more than 100 drugs - this being the highest estimate. Most of us can remember much less.

A survey of 92 hospitals conducted by a Chruch Agency indicated that 25 drugs were adequate to take care of most of the problems according to WHO working group on Rational Drug Therapy.

WHAT /ARE THE DECIDING FACTORS GUIDING THE CHOICE OF THE DRUGS THAT WE PRESCRIBE?

Many times it's not the principles of rational drug therapy, but the subtle influence of the drug representatives and their biased medical literature. When confronted with too many diverse unfamiliar drugs, with each drug being sold under 50 to 200 different names - confusion and misuse is the expected end result.

3. Combination Drugs

Kinds of drugs with expected misuse potential are Combination Drugs. 60-70% of the brand products in the market are not single ingredient drugs but combinations of 2 or more. Less than 5% of drugs in the WHO's Essential Drug List are combination drugs. In combination drugs many of the most important ingredients are in sub-therapeutic doses or the combinations are totally irrational and non-sensical.

- the cost of combination drugs is any day more than cost of single ingredient drugs.

- what is probably worst is the potential for adverse reactions it is known that chances of drug interactions increase with the increase in number of drugs prescribed. The chances of drug interaction increases by 40% when 6 or more drugs are prescribed. The fact that 2 or 3 combination drugs may easily contain 6 or more known or unknown ingredients is often overlooked.

ADVERSE DRUG REACTIONS

Problem of adverse reactions with too many drugs another serious concern. In States adverse drug reactions kill more victims than does cancer of the breast - They rank among top 10 causes of hospitalization alone, they are held accountable for as many as 50 million hospital patient days a year. They may interfere with diagnostic tests, causing a missed or errouneous diagnosis.

They may spare a patient's life but leave him blind or deaf, afflicted with kidney liver or brain damage, bone necrosis, ulteration of the bowel, intestinal haemorrhage, skin scars,

extreme sensitivity to sunlight or other disabilities that may last for months or years (Ref. Dale G. Friend - Adverse Reactions to Drugs Clinical Pharmacology and Therapeutics 5: 257, 1964) (AMA Drug Evaluations 1971).

"Only during the past 10 years have we begun to recognize the magnitude, seriousness and complexity of the problem. Today it is only too obvious that adverse drug reactions represent a major public health menace of alarming proportion" (Pills Profits and Politics - Milton Silverman and Philip R Lee).

Adverse Drug Reactions are not a rarity. In States where the Drug Control Authority is very strict, where drugs are not prescribed by RMP's and untrained personnel or freely available over the counter without prescription, the extend of adverse drug reaction is fairly significant. The following reports should act as a timely warning for us - as we set out to find new drug markets in our villages - in the name of development of medical services with little or no controls and checks.

According to Dr. Louis Sherwood and Dr. Edith Pauis in New England Journal of Medicine "18-30% of all hospitalized patients end up with drug reaction which often double their stay in hospital." (Preventable Drug Reactions, Causes and Cures, NEJM 284: 1361-1368, 1971).

Dr. Hersehel Jick of Boston Collaborative Drug Surveillance Programme one of the most comprehensive drug monitoring organizations of the world. Say, "We have reported that in 30% of hospitalized medical patients atleast one adverse drug reaction develops during hospitalization and using the estimate that about one third of the approximately 30 million people admitted to the US general hospitals per year are admitted to general medical services, we may estimate that about 3,000,000 hospital patients suffer an adverse drug reaction in medical units each year".

Jick Hershel "Drug - Remarkably nontoxic, NEJM, 291: 824-829, 1974). Some US hospitals have reported that as many as 20% of their patients were admitted because of drug induced disease.

Miller, L.C. "How Good are our Drugs?"

Distinguished lecture delivered December 30, 1969 before the American Association for Advancement of Science, Boston, Mass

Am J Hospital Pharm. 27: 367-374, 1970.

"Serious drug reactions anywhere from 15% to a high 40% have been reported in hospitalised patients." Gotti, E.W. "Adverse Drug Reaction and the Autopsy" Arch. Pathol 97: 201-204, 1974.

Over the counter drugs which don't require a prescription are considered safe by most people. A study entitled "Drug Induced Illness leading to Hospitalisation" reported that OTC drugs were implicated in 32 out of 177 (i.e. 18.1% admissions"
Caranasos, George J et al. Drug Induced Illness leading to Hospitalization, JAMA 288: 713-717, 1974).

The drug adverse reaction reporting system is highly undeveloped in India. Recognition of adverse drug reaction can only be possible if the health personnel are aware of the various associations of interactions, toxicity and sick effects of drugs.

/cogni- tion. This was ob- vious in

The tendency to underplay side effect & toxicity of drugs by drug companies has led to underestimation & almost total dere-/ Our attempts at finding out about the understanding and awareness of the clioquinol (Mexaform & enterovioform) induced toxicity —— the SMON syndrome. The story of the clioquinol controversy has been hitting the headlines. The crippling of more than 11000 Japanese with these drugs being the biggest drug scandal of the century — as bad as the Thalidomide disastor. We found that very rarely was the history of ingestion of hydroxyquinolines was taken, when dealing with a patient with neurological problems. Since there are more than 90 brands, a doctor could hardly be expected to remember them, or the patient recall the name, specially if it had been taken over the counter. "Scientific" conclusions of the medical establishment — there is no SMON in India, is therefore unacceptable.

Substandard and Spurious Drugs and Drug Control.

(52% of the drugs in the Indian market are assessed to be substandard - Anil Aggarwal in Drugs & the Third World). The accepted official figures are 30%. According to the Estimates Committee Report Nov. '83 only about 20%. We have very poor drug control mechanism and grossly inadequate numbers of drug inspectors Right but substandard, non quality controlled drugs - is just as wrong.

Why have the health personnel not raised their voice against this and demanded better quality control. mechanism, when it is so crucial for quality of health care? The bigger and better known drug companies taking advantage of the situation have been able to successful push their products because of the alleged better quality control. Unfortunately most of the spurious and imitation drugs are imitations of precisely these expensive popular brands. Ensuring that all the drugs in the market meet a certain standard and are quality controlled is the responsibility of the Govt. and the Drug Industry. Putting this added responsibility on the shoulders of the prescribing doctor is incorrect and the prescribing by health personnel of expensive brand drugs, to their poor patients to deal with the problem is equally incorrect & unjustified. A coordinated and coherent demand for adequate and effective drug control mechanisms, adequate numbers of efficiently functioning quality control labs and drug inspectors should be made by all socially conscious health institutions. An unhealthy dependence on the multinationals to as a solution, is actually not the most appropriate solution.

Hazardous and Irrational Drugs

Our last Drug Workshop in Jaipur focussed precisely on this. There is absolutely no reason why any sensible health institution should continue to stock any of the hazardous or irrational drugs. The list of 23 combination drugs recommended for weeding out by our own Drug Consultative Committee.

Bangladesh's list of 1707 banned drugs as well as the 16 Criteria for withdrawl which are entirely in keeping with WHO's recommendations for Rational Drug Therapy, are available.

All health personnel believing in Rational Therapeutics should voluntarily BOYCOTT dangerous and useless drugs - the above 2 to start with. The Govt. ban on these drugs may come too late, and because of the pressure and vested interest never come at all. The Gazette notification by Drug Controller of India banning 22 categories of drugs on 23rd July 1983 is either not known, nor implemented. Outrageously sales of these products containing Phenacetin, Amidopyrine, Paediatirc Letracyclin continue.

The boycott by 3000 doctors and veterinary doctors led by Dr. Olle Hansson in Sweden against all Ciba Geegy products was because Ciba Geigy continued to produce and sell clinoquinals (mexaform and Enteroviaform) in the third world, inspite of the fact that 11000 cases of SMON (Sub acute Myelo-Optic Neuropathy) had been identified in Japan and reports from all over the world have been coming 43 cases of SMON have been identified in Sweden itself from where subsequently Clinoquinols like in most other countries is banned. The boycott was because of continued sales in the 3rd world countries like India and not in Sweden, where it was already banned.

What are we, the health personnel from the 3rd world doing about sales of hazardous products to our people?

Some of the problem drugs are:

- Hormonal Pregnancy tests
- Anabolic Steroids
- Amidopyrines, Phenacetin
- Butazalidine
- Diethylstilbaestrol and hormones in pregnancy
- Lomotil in infants
- Paediatric Tetracyclines
- Ancoloxin in Pregnancy for Nausea
- Clinoquinols
- Steroids being used indiscrimenately
- Antibiotics being used indiscrimenately for viral infections in wrong doses etc. & incomplete courses
- 2nd line anti TB drugs
- anti hypertensive, antidiabetics
- Tranquillizers

Drug Information - The Lacunae

Charles Medawar in "Drug Disinformation" compared the drug information given in MIMS (Monthly Index of Medical Specialities) from UK and in Ireland. Discrepencies in the drug information given by the same drug companies in the 2 different countries showed their double standards. Comparing MIMS (UK) with MIMS (India) would make our hair stand on end - and demonstrates the triple standards followed by the drug companies.

- How come Anecoloxin durg company, an antinausea drug is specifically indicated for morning sickness when it is contra indicated in pregnancy in States?

- How come we have so many more indications and such few contra-indications and side effects for anabolic steroids, for drugs like the butazoledines .

- How come dosages of lomotil for children and Syp. Lomotil are still available when they are banned for use in kids due to associated respiratory arrest paralytic illness and toxemia?

- How come drugs containing amidopyrines were allowed to be produced and marketed without giving all the information which led to their being banned in most countries.(while attempting to compile information on it, we found hardly a paragraph devoted to it in Goodman Gillman in the Pharmacodology Text Book because in most countries it had become obsolete). Cibalgin and Ergopyrin have known high popularity- all amidopyrines sales have been officially BANNED from 31st October 1982 prescribing and selling them is illegal

Talking about Drug Information it is a well recognized fact that the Drug Industry spends a lot on doctors. Dr. Yudkin in his study in Tanzania 1978 calculated that "£1000 per year is spent on providing information to a single doctor - a very calculated investment which has always paid well."

In UK which consumes much more drugs than us there is one drug representative for 30 doctors while in developing countries like Tanzania there is one drug representative for 4 doctors.
/1 In Phillipines there is/drug representative for 2 doctors.

In the absence of any alternative source of unbiased information the prescribing practices of most doctors are highly influenced by these interactions. I am not mentioning the inticing role of samples, cut backs and other incentives. This lack of unbiased and authentic drug information is one of the most important causes of drug misuse. Since we believe that health personnel in the voluntary health sector are above all this.

Drug list and Drug Prices

Drug prices are increasing and going to increase. With increasing drug doctor dependency and heavy marketing of nonsensical and inessential drugs - drug use is going to increase. With our training of VHW's - we have ensured inadvertantly that the pills reach the remotest corners.

Eventhough an average Indian spends much less on health care than his counterparts in the West, he SPENDS A MUCH LARGER PERCENTAGE OF HIS ANNUAL INCOME. A study done by Health Workers in Piaxtala, Mexico showed that people spent 40 - 60% of their annual income on medicines. The cost of drugs in many third world countries is increasing between 30-50% each year (Yudkin 1978; Pichard 1980). The impact on Voluntary Health Institutions of these increasing drug prices is going to be twofold:

- they will either incur higher and higher deficits
- or become unreasonably high priced and out of reach for the majority they set out to serve. It will be a question of 'service without survival' or 'survival without service'.

Traditional selection, purchase, stocking and prescribing of drugs are needed by the health institution with the patients and their own present and future in mind. Rational selection of drugs is good economics.

The Health Status, Health Needs and Drug Needs of our People

For a country with such a large medical manpower and medical technological know how in terms of drug production* the health status of our people specially the women and children - is disappointingly poor.

(*We are the biggest producers of Drugs in the third world)

The most important health parameter reflecting the development of a society as a whole is the Infant Mortality Rate i.e. number of children who die before they reach one year of age per 1000 live births.

Our figures are 120/1000 while Sri Lanka, our little neighbour has managed to achieve 45/1000. 50% of the Indian children get ½ the calories they require. 60% of the children under 6 suffer from severe anemia and protein calorie deficiency. 40,000 children become blind each year because of Vit. A deficiency and about 3 million children suffer from other forms of Vit. A deficiency i.e. nigh blindness, dry eyes and dry skin. 24% of all deaths are due to non-immunization for diseases like such TB, whooping cough, diphtheria, measles, polio. 48% of the children below 5 years suffer from moderate to severe forms of malnutrition.

Women

Where women are concerned their worsening health status is reflected in the declining sex ratio

1946	1971
950 Females/1000 males	930 Females/1000 males

Our maternal mortality figures are 163/1000 delivery. 50% of the pregnant mothers are found to be anemic. 14% of all deaths are related to pregnancy, childbirth and early infancy though in terms of % they constitute only 4% of all diseases. 56% of all deaths are preventible.

Where some of the major health problems for the country are concerned. About 2% of all the Indians have T.B. and 10million ie. ½ of the worlds 20 million TB patients are Indians. 2.5 million of these being infectious and 1/3 of the worlds 10 million leprosy patients are also ------ here. Diarrhoeal diseases kill 1.5 million Indians mainly children each year. 1.2 million e.e. 40% of the 3 million new malaria cases each year die because of it. Waterborne diseases like malaria (including infection with plasmodium, falciparum (cerebral malaria), Filaria, polio, kalazar, Japanese B Enephalitis has shown an increasing trend.

Basic needs of water and sanitation have to be met.

1/3 of the 5.8 lakh villages covering a population of 160million (out of 680 million) still have no access to potable water. 1/3 of the 40 million households night soil is still collected and disposed off manually (Gandhi had seen not merely decreased chances of pollution of water source and food but also the emancipation of the sweeper - the Bhangi). The health

personnel as well as the policy makers know that with improved water supply and sanitation programmes 80-85% of all illnesses specially the water borne ones CAN BE PREVENTED.

*56% of all deaths are preventable.

- Mukarram Bhagat
in Aspects of Drug Industry.

Source: Centre for Monitoring Indian Economy CMIE Bombay

Most of these are diseases of poverty and therefore realization that 60% of the Indians live below (or on the margin of the poverty level is very significant (poverty level - as assessed in relation to average calorie requirement ONLY - a level which does not take clothing, housing, schooling, medical expenses into account).

If fulfilling of their basic minimal needs of food, water, sanitory living — is not given a priority, by the health services - we would atleast expect to see the curative care services for the majority to be functional and appropriate.

It is the LOPSIDEDNESS in even this, which apparently forms the basis of our health care services that makes it all the more painful.

75% of the Indians have no access to even essential life saving drugs. So 20% or so basic drugs are available and it is only to 5% of the economically well off that all modern drugs are available. Production of drugs is NOT in relation to the health needs and people's health priorities.
Of the 636.9 crores worth of drugs sold in 1980

19% were antibiotics
10.21% vitamins
4.41% tonics
4.24% antianaemic preparations
4.71% cough & cold (the increase in growth within last 5 years has been i.e. 137 crore worth of vitamins 70 items sold in 1980.

Source: Dr. A. Patwardhan as quoted in VHAI's Drug Situation in India, Jan. '82.

Our National Formulary has over 60,000 drugs and chemicals ie. about 15-20,000 brand drugs, out of these 68% are obsolete and unessential only about 5000 are useful and 2500 of marginal use.

In 1979-80, only Rs.350 crores worth of drugs out of Rs.1260 crores worth manufactured were essential and life saving the rest were tonics, digestive, enzymes, formulations of medicines with marginal benefit. Many vital bulk drugs in huge quantities have been wasted which could have been utilized for manufacture of essential drugs.

Source: J.S. Mazumdar in Drugs Industry Instruments of Policy.

Since the Government Health Authorities and the Drug Industry has failed to ensure provision of atleast the basic essential life saving drugs to the people who need them - the time has

now come for the people to ensure that the National Health and Drug Policies are made in accordance to their health needs and not according to the dictates of the drug industry.

Things would have been different if 80% of our medical manpower was not concentrated in the urban areas and serving mere 20% of the population; if their western model training and the unfortunate present reliance on the drug industry and sophisticated medicine had not ensured that they lose touch with the socio-economic reality of the 80% of the Indian population living in rural areas, and urban slums.

Some of the glaring examples of the contradictions existing in the care of our priority health problems are dealt with below:

Malnutrition and Anaemia: We are taught their ideal management, but very few know of what nutritional advice and treatment to give to a pregnant woman whose husband gets less than minimum wages which feeds a family of five, including underfives, and sick aged parent. Why is it difficult to obtain single ingredient Ferrous sulfate, Folic Acid Thiamine or B12 which patients need and can afford. On the contrary there is a gay abundance of expensive Vitamin Fortes often in ridiculous combinations and tonics. An article "Tonics - an economic waste?" by Kamla Jayrao of M.F.C. deals very appropriately with this subject.

Diarrhoea: We are taught about antidiarrhoeals, but very few can very accurately and easily prepare ORT, nor confidently prescribe only oral rehydration therapy without feeling a compulsion to prescribe anti-diarrhoeals. The fact that many of the Commercial ORS packets are not even in the keeping of WHO recommendations seems to be of little concern. According to WHO most of the popular antidiarrhoeals have little or no role (HFM - Special issue on Diarrhoe, Dec. '83).

Shortages of essential and life saving drugs reflect that it is the drug industry which decides which drugs to produce and the motive is 'PROFITS' and not 'CONCERN' for PEOPLES HEALTH!.

Shortages of anti TB is a perfect example of a profit oriented industry taking on the decision making role, while the health personnel of the country passively watch on, the worsening of the health and drug situation - where the poor and the majority are concerned.

Shortages of Essential and Life saving drugs eg. TB drugs. Some of the painful facts about the Public Health Enemy No.1 is TB, a major killer. We have ½ of world's TB patients i.e. 10 million patients, of which 2.2 million are highly infectious and 5 lakhs die annually because of TB. A survey report from Bombay recently indicated a 4 fold increase in infectious cases of TB within 1 year.

NTI Bangalore and TB Centre Delhi which have been involved in longitudinal studies of TB in areas with much better developed infra structure than most places do not indicate ANY CHANGE IN TB incidences. This is inspite of the drugs, doctors and medical advances.

D-10/344
MS:k:27/2/84

The only thing that is deceasing steadily is the production of anti TB drugs inspite of the increase in total numbers of TB patients. One would think that the health personnel all over would be up in arms and atleast demand to know the reason of this downward trend and shortages. This is when many of them have felt the shortages in their areas themselves. TB authorities refuse to admit there are shortages of anti TB drugs. The answer to our requests to our member institutions to let us know if they have faced anti TB drug shortages for proof, has been - evidence mainly silence.

Talking of TB it is known that 92% of the infectious TB cases are AWARE OF THEIR SYMPTOMS and 52% seek medical help on their own. 90% of these come away with cough syrups and tonics. The fact that our case finding and case holding is as hopeless as it is, makes the whole story of rational TB care - a tragic one.

Misuse of 2nd line drugs and steroids does occur, with increasing numbers of infectious TB cases, emerging resistance and known limitations of BCG - TB picture is bound to get gloomier. TB patients continue in the meantime to consume gallons of different types of tonics cough syrups, gulp down different coloured vitamin pills, steroids or something to improve appetite or bring down fever.

The fact that the medical establishment has failed to deal effectively with a problem like TB could mean that without realizing

- we are beginning to lose touch with the actual health needs of the people.

- with our silence we've allowed the Drug industry to subtly control our prescription practices and our decision making

Story of leprosy care is not too different while 1/3 of world's leprosy patients live or should we say struggle for survival in India, our drug industry produces ⅛ of the minimal requirement of Dapsone. While some health personnel in remote areas treating leprosy patients cry themselves hoarse about the shortages of this cheapest antileprosy drug — the medical community comes up with a better way of treating leprosy patients — the multi drug regimen.

Ensuring that adequate essential drugs are produced and made available is the responsibility of the socially conscious health personnel -- specially those in the voluntary sector.

If we could realize that production of unessential nonsensical drugs is at the cost of production of essential and life saving drugs - we'd be more aggressive in getting the former thrown out and no longer extend the tolerance which we have done in the past.

There has been enough talk about issues related to drugs, but why does drug misuse still continue? those misusing drugs fall into one of the following 3 categories:

(Rio Note)

Category 1: Those that misuse them, and do so knowingly for vested interest and couldn't care less.

Category 2: Those misusing them, but do so out of ignorance because of inadequate or biased information available to them.

Category 3: Those that are aware about the true nature of drugs and would not like to prescribe them, but find themselves prescribing these drugs for various reasons. The most common reason being 'patient demand'.

Unfortunately after graduation we have the licence to practice as we please, with no checks, no controls, and sometimes in some cases with no sense of medical ethics. Till malpractices and misuse of drugs remain unchallenged by medical colleagues consumer groups, peoples organizations and the patients themselves - they will continue and increase.

Where category 2 and 3 are concerned what is needed is creation and development of alternate channels of information. It is true that socially conscious health personnel from institutions in the field, could easily teach the medical graduates and doctors in the more privileged medical institutions what Rational Drug Therapy in the field, with all its constraints is all about. Specially when supported with authentic need based information, and their own experience and that of others in the field.

Some of the important roles of the health personnel in the field are:

1. Deliverer of rational health care to the patients.
2. Facilitator for the people in their obtaining the necessities for their health needs eg. water, work, wages etc.
3. Educator in the real sense of the word where colleagues, and patients, are concerned.
4. Participator in analyzing major policy decisions at macro level which has an impact on peoples health, and always attempting to ensure that health and drug policies are socially just and that they enhance health and not jeopordize it.
5. Researcher - creating alternatives based on observations, clinical studies, atleast identifying areas requiring exploration and research.

The pioneering effort towards Rational Drug use and towards changing role of health personnel will necessarily have to come and will come from the voluntary health sector. We offer our support and solidarity to such courageous pioneers. We extend them a warm welcome, to the drug action network. Constituting socially conscious individuals and organisations.

(Dr. Mira Shiva, MD)
Coordinator
Low Cost Drugs and Rational Therapeutic

(Prepared specially for Andhra Pradesh VHA & West Bengal ... General Body Meetings on Rational Drug Use)

CSE

CENTRE FOR SCIENCE AND ENVIRONMENT
807 Vishal Bhawan, 95 Nehru Place, New Delhi-110019

INFORMATION SERVICE ON
Science and Society-Related Issues

TOWARDS HEALTH AND FAMILY WELFARE FOR ALL VII

PRESCRIPTIONS AND THEIR PRESCRIBERS

Everytime a patient goes to a doctor he wants a prescription. But do doctors always prescribe right ? Do they sometimes overprescribe ? The enclosed article analyses two common prescriptions.

Author Dr Ulhas Jajoo is a Reader with the department of medicine in the Mahatma Gandhi Institute of Medical Sciences at Sevagram.

The Centre for Science and Environment is a non-profit, non-governmental, quasi-academic research organisation that has been set up to increase public awareness of the role of science and technology in national development. The information service issues news and feature items in six languages—English, Hindi, Marathi, Bengali, Malayalam and Punjabi—prepared by a research team consisting of professionals qualified in science and technology.

Director : P. Dasgupta

Director of Research : Anil Kumar Agarwal

PRESCRIPTIONS AND THEIR PRESCRIBERS

By Dr. Ulhas Jajoo

Everytime a patient goes to a doctor, he goes with an element of faith. He expects two things from the doctor : one, the doctor will diagnose the cause of the problems; and, two he will prescribe some medicines to get rid of the cause.

But do doctors always prescribe right ? Do they sometimes overprescribe ?

Let us study a few prescriptions usually given by qualified doctors. The following are actual prescriptions for two common problems for which we often visit doctors.

Case I : The disease is acute diarrhoea. The history of illness is loose motions 3-4 times a day from first day; no fever, no abdominal pain and no vomiting; and, passed urine five times in last 12 hours. The treatment given is Lomomycin syrup two teaspoonful six hourly; Lomotil tablet one with each stool; Pecto-Kab two teaspoonful six hourly; Baralgan twice a day; Flagyl syrup two teaspoonful three times a day; and Pentalmine one tablet twice a day for three days.

Let us analyse this prescription. Firstly, most acute diarrhoeas are self-limiting. They do not require antibiotics (Lomomycin). Secondly, Lomotil is a drug of the morphine group which may reduce the frequency of motions but hides the fluid loss which continues within the gut. In the false security of diarrhoea being controlled, the child may land up with severe dehydration. Thirdly, Bismuth Kaolin (Pecto-Kab) has no role in treatment of diarrhoea. It creates a false impression of

/more...

diarrhoea being controlled as it solidifies stool. Fourth, unless pain is severe, Baralgan like drugs do not have any use. They should never be given in twice a day dose but only as a single dose, when required, to relieve pain. Fifth, Flagyl is a drug used for amoebiasis and giardiasis. Unless stool examination reveals these organisms, addition of this drug to a prescription of bacterial diarrhoea (antibiotics are being given already) is not ethically justified. Sixth, Pentalmine is a drug used against worms. It is the costliest wormicide available in market. Rationale of adding this drug to the prescription, cannot be explained without carrying out a stool examination.

The Conclusion is : this is a 'shot-gun' therapy. All the drugs against the common causes of diarrhoea have been prescribed. Some drugs are not ethically justified. The most important part of the treatment of diarrhoea is oral rehydration (to avoid the dehydration) is totally missing. One glass full of water with a pinch of salt, sodium bicarbonate and two teaspoonful of sugar is all that is required which is available with everybody at home. Most diarrhoeas of this type are self-limiting and get cured by the third day. The cost of such a minor ailment has been alarmingly raised by visiting a doctor.

Case-2 : The disease is common cold. The history of illness is running nose for two days; cough for one day; throat pain, one day; and, mild fever one day.

The treatment given is tablet septran twice a day for seven days; Otrivin nasal drops thrice a day for seven days; tablet Cosavil, one tablet thrice a day for seven days; tablet Crocin one tablet twice a day for seven days; Benedryl cough syrup, one teaspoonful three times a day; Injection B-complex; throat lozenges; and, syrup B-complex one teaspoonful twice a day.

/more...

Common cold is a self-limiting viral infection which responds within seven days if treated and takes a week if not treated. Role of a potent antibiotic like 'Septran' which can sometimes harm the patient cannot be justified. Otrivin contains ephedrine nasal drops to dry nose. It is the costliest preparation in the market. Cosavil contains aspirin and an antihistaminic drug which also helps in drying the nose. Combination of Crocin - a pain and fever relieving drug - when aspirin is already being given is not justified. To suppress the irritating cough of common cold, one does not need a Benadryl syrup (which has antihistaminic drug as an ingredient), but codein syrup or tablet. Addition of benadryl syrup to the drug list only helps in increasing the cost of the prescription. Use of injection B-complex and Syrup B-complex is unwarranted except to help pharmaceutical firms or the doctor to fetch money out of an injection. Throat lozenges are costly. They help only to suppress the cough by their local action. The age old remedies like "Harada", "Jesthamadh" or throat paint application are better.

The simple conclusion is : the prescription is mainly to provide "bread and butter" to the prescriber and to the drug industry. The real therapy — repeated saline gargles or steam inhalation - is totally forgotten. The repetition of the same drug in different forms has increased the cost of treatment.

There can be innumerable such examples. The observations from the prescription can be summarised as follows:

1. Unscientific prescribing: Many prescription reveal combination of incompatible drugs. Many times the doses of the drugs prescribed are inadequate. This reflects poverty of the knowledge of the prescriber.

/more...

2. The prescription is aimed at early relief of symptoms even if it is likely to harm the patient in the long run. For example : doctors have a shotgun therapy their prescription which covers all possible causes for a particular clinical symptom so as to avoid efforts required for a careful diagnosis. This tendency exposes a patient unnecessarily to many drugs and their side effects. It reflects the inferiority on the part of a doctor to properly diagnose the cause of illness.

Secondly, potent drugs have been used when they should normally be preserved for desperate situations. For example: (i) use of broad spectrum potent antibiotics even for an illness which does not require them, exposes the population to the problem of developing resistance against these drugs. (ii) Corticosteroid preparations like Betnelan, Wymisone, etc, though good drugs are like double edged sword. If not used at a proper time and in proper conditions they can harm the patient in the long run.

3. Many prescriptions are aimed at earning money. Most illnesses that a private practitioner deals with are self-limiting. Once a patient has come to a doctor, he feels it obligatory to prescribe some drugs even if not necessary. Most doctors do not charge consulting fees separately. They dispense drugs from their dispensary at an exorbitant cost, which includes their consulting charge. The charge depends on the paying capacity of the person. The name of the drug dispensed is never told to the patient because if the patient knows it, he may try to compare the cost with the market rate. The more the number of drugs prescribed / the bigger is the profit. The big list of drugs, thus, is a mechanism to earn money without the patient being aware.

Doctors have conditioned the minds of the people to drugs so much that now if a doctor does not prescribe, for instance, an injection, the patient starts demanding it.

The burden is on the patient's pocket — in India, usually a poor person — who spends all that he has in blind faith. It is not the doctor alone who earns in this business, but also the pharmaceutical industry. A doctor's knowledge is enriched from time to time by pharmaceutical agents, who try to convince him that his company's product is the best available. A heap of physician's samples is usually enough to convince those who are hesitant. The free samples are then sold. It is unusual to see a doctor who refuses this bribe. The sufferer is the patient. The doctor hardly ever knows anything about that the ingredients in the brand drug that he is prescribing, nor does he have knowledge of other similar brand drugs which may be cheaper.

Why is all this happening in a noble profession that is concerned with human suffering ?

The root of the malady lies in our value system. The medical profession has unfortunately been commercialised. If this goes on too long, the faith in the healer may cease to exist.

/------

85-12

CONSUMER ALERT!

Phenyl butazone - oxyphenbutazone

HAZARDOUS DRUGS

Prepared for:

Drug Action Network core group meeting at Sevagram

30 - 31 July 1984

Dr. Mira Shiva, VHAI

U. K.:

On 6th March 1984, U K banned Phenylbutazone.
On 3rd April 1984 Ciba Geigy withdrew Oxyphenbutazone, a breakdown product of phenylbutazone from U K market.

In Germany 65 such drugs have been banned, and use of another 206 severely restricted.

In Finland, manufacturers have been asked to withdraw these drugs.

In U S the Public Citizen Health Research Group has asked the department of Health and Human Services for an imminent danger ban.

Japan has severely restricted the use of these drugs.

IOCU has sent world wide consumer alerts. Norway, Federal Republic of Germany, Italy, Australia, Sweden, Finland and Bangladesh have severely restricted their sales.

It is not that, we have not been concerned about the misuse of these antiinflammatory agents and their irrational combinations, prior to the knowledge of these bans. We feel that after receiving unbiased authentic information about the extent of the adverse effects related to these drugs, it is our responsibility to alert others. The public needs to be informed of their dangers realizing that a significant number of patients to buy the drug over the counter unwarned and uninformed.

We are using this as yet another case where, double standards have existed in the drug information given to doctors in the West and to our own doctors.

The total annual turn-over of the two products of phenylbutazone and Oxyphenbutazone (BUTAZOLIDIN & TANDRIL of Ciba Geigy's) fetch 200 million Swiss-France ie. £ 65 million ie. Rs 1170 million and these drugs have been in the market since 1952 and 1960 respectively and are well known). It is very unlikely that, Ciba Geigy will withdraw these products from the third world, specially after having already stated their decision to withdraw Mexaform(Clioquinol) and Dianabol(anabolic Steroid) from the world market. Withdrawing Butazolidin and Tandril at this point would lead to a financial set-back. It is unlikely that Ciba Geigy will give in very easily toconsumer pressure- a stand already made clear by the makers of Butazolidin and Tandril.

What are these drugs used for?

Phenylbutazone and Oxyphenbutazone are non-steroidal antiinflammatory drugs which also have mild anti-pyretic and analgesic properties. They give only SYMPTOMATIC RELIEF and

COMMUNITY HEALTH CELL
47/1, (First Floor) St. Marks Road
BANGALORE - 560 001

in no way ALTER the course of the illness. In the U.S. the labelling indicates the drug for "acute gouty arthritis", "active rheumatoid arthritis", "active ankylosing spondylitis", "short term treatment of acute attacks of degenerative, joint disease of the hips and knees, and not responsive to other treatment and painful shoulders". Ciba Geigy warns that Tandril should not be given to children below 14 years(The Physician Desk Reference, U S A).

Similarly, warning for elderly patients is given, that every effort to discontinue the use of those drugs after a period of 7 days should be made as there is "exceedingly high risk of severe fatal toxic reactions".

In Malaysia, dose packages for children as small as 12 months carry inserts. Ciba Geigy states, that in elderly patients as also in long term therapy, smaller maintenance doses are indicated.

In West Germany, the use of the 2 drugs is severely restricted to:
1) ankylosing spondylitis; and
2) gout for the maximum of 7 days.
(In a personal communication from Dr Olle Hanssen, January 6, 1984).

In the third world it is indicated for minor ailments including joint stiffness of muscles and joints lumbago, headache, viral infection and fever and for long term treatment.

Phenylbutazone was introduced into India in 1949 strictly for treatment of rheumatoid arthritis and allied disorders. The drug is more of an OTC product in India being freely consumed by public, often without prescription, for aches, pains and fever.

Phenylbutazone with its equally potent relative oxyphenbutazone needs to be taken more seriously. IT IS A BAD BET TO GAMBLE WITH IT IN NON-RHEUMATIC DISORDERS.

" In India, oxyphenbutazone is being used for treatment of fractures, post operatively, in dental practice; ordinary common joint pains; bodyaches and backaches" according to Pune Journal of Continuing Health Education, June 1981.

Dr W V Rane of Arogya Dakshata Mandal talking about oxyphenbutazone has pointed out that it is being promoted for quicker post operative healing. Not only is this unethical but it is also unscientific and irrational. More painful is the fact according to him that a study was conducted by a Professor of an Orthopaedic Department for bone healing and that too on a Paediatric patient. The paper was presented to an August gathering and most probably, received its quota of applause and mutual back scratching from the Conference sponsors. No one in that scientific gathering questioned the rationale and ethics of conducting the study on children, when in the U.S/ Medical Pharmacology books the use of these drugs in those below 14 is contraindicated.Probably the drug company sponsoring the study preferred not to give this dismissable bit of information.

/in the

"Phenylbutazone and oxyphenbutazone should not be used unless the urine had been examined for protein and a blood examination and had shown that white cells and platelet counts were within the normal range. B M Ansell, Prescribers Journal, 1969, 8, 120 in Martin dale- the extrapharmacopia, 28th edition, 1982. A routine urine and blood test prior to usage of the drug is recommended. In view of the additional costs this may not always be possible forthe poorer patients. An extra caution and restrain in the utilization of these drugs is therefore, indicated.

In India the drugs have been recommended by certain manufacturers for minor problems and feeble conditions. Gifford 1973 has been quoted in MIMS editorial, November 1982 that according to Pharmacology books "Phenylbutazone as an antipyretic and an analgesic is relatively inferior to aspirin" Phenlbutazone as an antiinflammatory agent, is effective, but serious toxicity limits its use in long term therapy. In rheumatoid arthritis, phenylbutazone has a limited role and should be used primarily for acute exacerbations not relieved by other measures.

WHAT ARE THE DANGERS ASSOCIATED WITH THE USE OF PHENYLBUTAZONE OXYPHENBUTAZONE?

Bone Marrow Toxicity:

Aplastic anaemia or pancytopenia ie. total bone marrow shut down which is fatal in over 50% cases. Agranulocytosis, which is a severe depression of white blood (granulocyte cell production - fatal in about 35% cases). Leukaemia which is a cancer of bone marrow; Gastro intestinal bleeding or peptic ulceration - fatal in about 20% cases.

Other risks are liver damage Hepatitis in less than .1% cases access to liver. It is mainly hepato-cellular necrosis. Hepatitis usually starts within 4 weeks of starting treatment but in 20% cases can be started upto or even after 1 year. Cholestatic jaundice occurs in less than 3% cases. Serum sickness type of hyper-sensitivity, ulcerative stomatitis, nephritis(kidney failure) thrombocytopenia(depletion of platelet count) are other serious side effects, though some of these are much rarer.(Ref: Phenylbutazone and hepatitis-Fowler P D Woolfe D, Alexander S Rheum Rehabilitation, 14, 17, 1975).

MIMS editorial adds that "because of its sodium and chloride retention properties, phenylbutazone can increase plasma volume by as much as 50%, thus straining cardiac functions and occassionally causing acute pulmonary edema. Since, toxic effects are more pronounced in the senior citizens, the drug is contraindicated for use in geriatic patients.

The seriousness of the Problem:

A STUDY IN SWEDEN OF DRUG INDUCED BLOOD DYSCRASIAS ATTRIBUTED PHENYLBUTAZONE AS THE DOMINANT CAUSE.(Drug induced dyscrasias in Sweden Battinger L E & Westerholm N, Bratish Medical Journal, 3 339 1973).

Incidence of bone marrow aplasi due to phenylbutazone and oxyphenbutazone is assessed as 1 in 33000 to 1 in 99000. Aplasic anaemia or agranulocytosis were quoted as underlying or contributing causes of death. In 376 death certificates in the year October 1974 to September 1975, the mortality rate was estimated as 2.2 per 100,000 cases.

The study of fatal bone marrow depression with special reference to phenylbutazone and oxyphenbutazone- Inman W H W, British Medical Journal I-1500 (1977). The effect of bone marrow depression is serious. Drug induced agranulocytocis-phenylbutazone. Pisciotta A V Drugs 15 132 (1978) Drug induced bone marrow depression by phenylbutazone, British Medical Journal 4, 490 (1973).

Ciba Geigy's adverse effects department at its head office in Basle in one its internal memos in February 1983, gave its findings of 1182 reported deaths from these drugs [illegible] 2724 detailed patient reports of other adverse effects. Well over ½ of these deaths were from bone marrow toxicity including leukemia, gastro-intestinal bleeding or perforated ulcers. Of the 6716 cases of undesirable side effects reported on the drug, 777 persons have known to have died with Butazolidin between 1952 and 1981. Of 4165 cases of side effects reported with Tandril, 405 persons are reported to have died. 199 cases of serious undesirable effects and 18 deaths have been reported in Japan.

After 12 years, the receipt of the first report of adverse reaction to Butazolidin from Great Britain, came from West Germany indicating that identification of adverse reactions come along only with experience and a high degree of alertness and suspicion about possible adverse reactions. In third world countries, adverse reaction reporting is depressingly inefficient, as are the controls on potentially hazardous drugs. Double standards in giving the drug information to the health personnel makes matters worse.

Phenylbutazone and oxyphentubazone is poorly tolerated by many patients. Even if diarrhoea, nausea, nervousness, insomnia are associated with the drug, it is ignored that the potential fatality cannot be overlooked. Some type of side effect is noted in 10 to 45 % of patients and medication may have to be discontinued in their cases. Its use should be limited to short term therapy of not more than a week during any one treatment period. Even then, the incidence of disturbing the side effects is about 10%. Phenylbutazone has a limited role in the therapy of rheumatoid arthritis. It is primarily used for relief of acute exacubations of the disorder that are not relieved by the other measures.

Goodman Gillman; 5th Eidition
Chapter- 17.

According to Martindale : "Although phenylbutazone is effective in almost all rheumatic disorders including ankylosing spondylitis, osteo arthritis, rheumatoid arthritis and reitusdeseas, it is GENERALLY RESERVED FOR USE IN THE TREATMENT OF RHEUMATIC DISORDERS where less toxic drugs have failed.

- Martindale; 28th Edition

In 1975, a study was done in U.K. to determine the true incidence as opposed to the reported incidence of deaths due to aplastic anaemia, and agranulocytosis in people using phenylbutazone or oxyphenbutazone. In U.K. even where all death certificates mentioning a drug have to be reported to the Government Drug Authority, only 1 out of 4 deaths due to drugs were found to have been reported. It was only because of the study, that the relationship of the drugs and death could be found. According to Oldver Gillie, medical correspondent, Sunday Times, states "In Britain where the 2 drugs have been used comparitively cautiously, 512 deaths associated with them have been recorded between 1964 and 1980. But, the real total is probably at least double that world-wide, as reported in the Ciba Geigy internal report (Ref: Dr Hanssen) which records 1182 deaths associated with the drug upto 1982.

Since it is impossible that almost half of these deaths occured in Britain alone, many deaths must have gone unrecorded in other countries and the actual figures would certainly run into many thousands, giving Butazolidin and Tandril amongst the highest death total for any drug".

Scrip. No. 854; December 12, 1983; pg.18.

In U.K. the death rates were found to be 22 deaths per million users of phenylbutazone, and 38 deaths per million users of oxyphenbutazon. Dr Sidney Wolfe uses the companies own estimates of patient exposure world-wide ie.75 million users of phenylbutazone, 66 million users of oxyphenbutazon to estimate the number of patients that must have been affected. Using the U.K. study result and their mortality rate due to these drugs as the basis, he estimates the following;

with phenylbutazone, about 75 million people exposed by 22 deaths per million ie. about 1650 deaths.

with oxyphenbutazone, about 60 million people exposed by 38 deaths per million ie. 2280 deaths. Total= 3930 deaths(ie. 1650+2280)

World wide from aplastic anaemia and agranulocytisis; 3930 deaths must have occured many of which went unreported. The internal document shows that aplastic anaemia and agranulocylosis constituted 37.8% of the deaths. If 3930 deaths constitutes only 37.8% of total deaths, then the total number of the deaths due to these drugs would be approximately 10,400 ie. 10,400 deaths world-wide merely due to use of 2 drugs. If we try to extend this to other brands that are available in the market, then there would definately be more deaths. By mid 1982, 311 deaths in U.S. were reported. It is known that only one in ten deaths due to these drugs get reported. In other words total deaths would be over 3100.

According to Dr Olle Hanssen another Ciba Geigy's internal memo has stated in light of the dangers of the drugs and "the presence of many newer equally effective non-steroidal anti-inflammatory drugs now available in the market with comparatively less toxicity, that it is reasonable and necessary that the risk and benefit ratios of Butazolidin and Tandril should be carefully reassessed for the indications of all forms of inflammatory and degenerative arthritis as promoted, to see if such promotions are justified".

Malaysia:

Consumer association of Penang report based on discussions with University Hospitals, Pharmacologists reports that phenylbutazone and oxyphenbutazone are amongst the 5 drugs accounting for the majority of the adverse drug reactions suffered by patients, admitted into the hospital. Consumer Association of Penang has demanded an immediate recall of the drug from the market for the safety and health of the Malayasian Consumer.

Japan:

Mainichi Daily News which is a Japanese newspaper dedicated to International understanding covered the news in its headlines on 9th February, 1984. Ciba Geigy's antiinflammator pain killing drugs killed 1182 in the world.

INTERNAL DOCUMENTS OBTAINED : BAN IS CALLED FOR

The newspaper covered the issue daily in its morning as well as in the evening issue, including a strong editorial. The headlines on February 11, stated that the Government ignored findings of courts in drug poisonings. Apparently, two litigations took place about 10 years ago. Investigations should have been done. About 15 deaths in Japan due to these drugs have so far been recorded. [redacted] pharmaceuticals Co. stocking preparations of Ciba Geigy's declared withdrawal according to Mainichi, February 10. February 12th- Mainichi; "Documents of side effects ordered severe restrictions being decided and [redacted] is possible for all drugs containing these drug".

India:

Pune Journal of on-going Education : In this issue no. of 37, June 81, in a letter to the Managing Director of Ciba Geigy, the Journal had raised strong objection against their new product parazolandin (parasolandin being a combination of paracetamol and phenylbutazone) for indicating it for conditions like fever.

C E R C:

CERC prepared a document on irrational and hazardous anti-inflammatory agents including phenylbutazone and oxyphentazone combination with amidopyrines. They had submitted this to the Drug Control Authorities and demanded their ban. It is important for us to be constantly aware that the situation in India is more serious than the countries mentioned earlier.

1. We have these drugs available over the counters in any dosage for any duration of time with our (falsely conditioned to believe in the sanctity and magic of western medicine).
2. Patients are rarely given any warnings by their doctors and if they buy the drugs over the counter they can rarely make head or tail of the medical literature inserts.
3. Phenylbutazone and oxyphenbutazone have been available often in deadly combinations with amidopyrine, analgin, paracetamol, diazepan, Vitamin B, dextrapropoxyphene acetominophen which makes the combination.

Phenyl butazone and oxyphenbutazone are dangerous drugs.

CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE
HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED
OR NOT APPROVED BY GOVERNMENTS

First Issue

PHARMACEUTICALS

PRODUCT NAME / IDENTIFIER	HORMONAL PREGNANCY TESTS	CAS NUMBER	

LEGISLATIVE OR REGULATIVE ACTION :

Country	effective Date	Description of Action Taken/Grounds for Decision
AUT	1978	Withdrawn in view of their apparent association with birth defects.
BEL	1978	Withdrawn from the market following consideration of the evidence associating their use with birth defects.
GBR	1977	Owing to evidence of congenital abnormalities, these products were withdrawn by the manufacturer.
GRC	1980	All preparations containing estrogens and progestogens intended for pregnancy testing were withdrawn.
ITA	1978	Withdrawn from the market.
NOR	1970	
NZL		Voluntarily withdrawn from the market.
SAU		In view of their association with birth defects, all such estrogen/progestogen preparations are not recommended for use.
SGP	April 1978	Banned for importation.
VEN		Not approved for use and/or sale.

CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE
HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED
OR NOT APPROVED BY GOVERNMENTS

First Issue

PHARMACEUTICALS

PRODUCT NAME IDENTIFIER	TETRACYCLINE(PEDIATRIC)	CAS NUMBER	60-54-8

LEGISLATIVE OR REGULATIVE ACTION

Country	effective Date	Description of Action Taken/Grounds for Decision
BGD		Under the provisions of the Drugs(Control) Ordinance, tetracycline syrups have been banned as they are harmful to children and pregnant mothers ; they disturb bony growth of children up to 12 years of age and discolor teeth.
DNK		Products currently available on the market.
IND		Liquid oral dosage preparations have been prohibited for manufacture and sale for reasons of health risks associated with use and/or questionable therapeutic value.
	1975	Preparations for rectal use withdrawn from the market owing to their non-constant absorption. Since 1979, labels of concentrated liquid preparations have warned about possible dischromic effects on tooth enamel.
JOR	1973	The Ministry of Health withdrew syrup formulations of tetracyclines (mixtures, suspension or drops) particularly intended for pediatric use on the grounds that tetracyclines interfere with the growth of bones and teeth in infants.
NZL		Pediatric preparations have been voluntarily withdrawn.
PER	1974	The package insert and/or label for this product requires a warning that its use may be dangerous in nursing infants, children under 3 years of age and pregnant women, due to the drug's well known effects on bone formation.
PHL	1978	Preparations containing chlortetracycline, oxytetracycline, tetracycline, demeclocycline, rolitetracycline, methacycline, dexycycline, minocycline, and other tetracycline derivatives in the form of syrup (mixture or suspension) or drops particularly intended for pediatric use are no longer acceptable by Administrative Order No.342.

CONSOLIDATED LIST OF PRODUCTS WHOSE CONSUMPTION AND/OR SALE
HAVE BEEN BANNED, WITHDRAWN, SEVERELY RESTRICTED
OR NOT APPROVED BY GOVERNMENTS

First issue

PHARMACEUTICALS

PRODUCT NAME IDENTIFIER	ESTROGEN-PROGESTOGEN PREPARATIONS FOR SECONDARY AMENORRHEA	CAS NUMBER	

LEGISLATIVE OR REGULATIVE ACTION :

Country	effective Date	Description of Action Taken/Grounds for Decision
DEU	1980	The Federal Health Office has withdrawn from the market relatively high-dosage combination products containing estrogens and progestogens indicated for the treatment of secondary amenorrhoea. An expert committee had emphasized the need to exclude pregnancy before such products are used, having regard to their propensity to induce abortion.
DNK	Oct. 1974	Use of high-dosage products has been cancelled.
SAU		The Drug Committee has advised using these combination products only after pregnancy has been ruled out. Relatively [illegible]ge products are restricted for use.
VEN		Combinations for this indication are not approved for use and/or sale.

RM/29/9

Voluntary Health Association of India

C-14, Community Centre
Safdarjung Development Area
New Delhi-110016

Telegrams : VOLHEALTH
New Delhi-110016
Telephones : 668071
668072

Graded Essential Drug list

Explanatory Note:

These are the guidelines to help Community health programmes and health institutions draw up their own essential drug list.

This is a compilation of various drug lists and it emphasises the concept of Essential drugs. For those believing in and for those involved in alternative health care, the concept of Essential drugs is an integral part of health work.

The format used for this compiled list is based on WHO's Essential drugs list , Technical Report Series 685. An outline of it is given. It should be noted that certain drugs are repeated as they are used more than one disease entity.

The various drug lists as they appear in the compiled form are as follows:

EMRO(Eastern Mediteranean Regional Office)- WHO

List A - for 8th class passed
List B - for that are class 10 passed and have had training

Bangladesh drug list:

Category I - for village level workers
Category II - for Primary Health Care up to Thana complex level

CMC - Christian Medical Council list - Contact No.63, August 1981, "Getting Essential Drugs to the People"- Stuart Kinsma.

Locost:- Low cost standard therapeutics a collective voluntary enterprise for rational therapeutics
C/O Amrl, G P O Box No.7, Vadodara 390001.

PU:- Essential drug list drawn up by sub-group dealing with this at VHAI's Pune Workshop "The Drugs Issues - seeking feasible alternatives".

PGI:- Formulary of Post Graduate Institute of Medical Education and Research.

SL:- Sri Lanka graded Drug list included here is list of drugs recommended for doctors incharge of Peripheral health centre.

G:- Gambia restricted drug list based on their national formulary.

Echo An English NGO supply equipment and drugs to Charity Hospitals overseas.

AM:- Action Medeor. Our humble recommendations
A) for trained village health worker level
B) for trained Paramedic or middle level workers
C) for doctors involved in primary health care

Those drugs included in the Hathi Committee have been underlined. This drug list is meant to be a guideline to help health care institutions in the voluntary health sector to select their own essential drug list. It is up to us to show it to the government and Our medical colleagues who believe in commercialisation of medical care that good health care does not necessarily depend upon the length and variety of the drugs used.

COMMUNITY HEALTH CELL
47/1, (First Floor) St. Marks Road
BANGALORE 560 001

It is extremely difficult to go against the current created by the market forces. It is a true test of our conviction and our capability to convince others.

NOTE: * - Alternative substitute from the same therapeutic group can be selected based on comparative cost and availability of equivalent products. eg. Hydrochlorothiazide: any other thiazide type diuretic currently in broad clinical use.

Numbers in the Paren thesis following the drug names indicate:

1) Drugs subject to international control under the Single Convention on Narcotic Drugs(1961) and the Convention on Psychotropic substances(1971)
2) Specific expertise, diagnostic precision or special equipment required for proper use
3) Greater potency
4) In renal insufficiency, contraindicated or dosage adjustments necessary.
5) To improve compliance
6) Special pharmacokinetic properties for purpose
7) Adverse effects diminish benefit/risk ratio
8) Limited indications or narrow spectrum of activity
9) For epidural anaesthesia

Letters in the parentheses following the drug names indicated the reasons for the inclusion of compelementary drugs

A. When drugs in the main list cannot be made available
B. When drugs in the main list are known to be ineffective or inappropriate for a given individual
C. For use in rare disorders or in exceptional circumstances.

The criteria of selection of essential drugs, Steps to be taken to implement such a programme. Provision of information on essential drugs as recommended by WHO have been dealt with earlier. In the text of the paper the format of the drug list is as follows:

Revised model list of Essential Drugs - a WHO Expert Committee Report - Technical Report Series 685

1.	anaesthetics	1.1 general anaesthetics and oxygen
		1.2 Local anaesthetics
2.	Analgesics, antipyretics, nonsteroidal antiinflammatory drugs and drugs used to treat Gout.	
		2.1 non - opioids
		2.2 Opioid analgesics and antagonists
3.	Antiallergics	
4.	Antidotes and other substances used in poisonings	
		4.1 general
		4.2 specific
5.	Antiepileptics	
6.	Antiinfective drugs	6.1 anthelmintic drugs
		6.2 antiamoebic drugs
		6.3 antibacterial drugs
		6.3.1 penicillins
		6.3.2 other antibacterial drugs
		6.3.3 antileprosy drugs
		6.3.4 antituberculosis drugs
		6.4 antifilarial drugs
		6.5 antifungal drugs
		6.6 antileishmaniasis drugs
		6.7 antimalarial drugs
		6.8 antischistosomal drugs
		6.9 antitrypanosomal drugs.

Comparative Essential Drug List

Main List	Complementary List	Route of administration dosage forms and strengths	List A Emro	List B	CMC	Low Cost	PU	PG	SL	G	E	AM	ABC	I	II
	1. Anaesthetics														
	1.1 General anaesthetics and Oxygen						•			•					
ether, anaesthetic (2)		inhalation											C		
thiopental (2)		powder for injection, 0.5g, 1.0g (Sodium salt) in ampoule											C		
	1.2 Local anaesthetics														
*Lidocaine		.5% inj, 1,2 (hydrochloride) in vial					•		•	•	•		B		•
		inj. 1%, 2% + epinephrine 1:100000 in vial													
		topical forms 2-4 (hydrochloride)													
	2. Analgesics, antipyretics, Nonsteroidal antiinflammatory Drugs and drugs used to treat Gout.														
	2.1 Non-opioids														
acetylsalicylic		tablet 100-500mg, suppository, 50-150mg poed Aspirin	•	•	•	•	•	•	•	•	•	•	A	•	
*ibuprofen		tablet 200mg					•	•							
indometacin		capsule or tablet 25 mg						•				•			
paracetamol		tablet 100-500mg, suppository 100mg + syp	•	•	•	•	•	•	•	•	•	•	A		
	2.2 Opioid analgesics and antagonists														
(Phenylbutazone)/Oxyphenbutazone													A		
morphine (1)		inj 10mg (sulfate or hydrochloride) in 1 ml ampoule					•	•	•	•					
pethidine Hcl 5ml/ml							•	•	•	•					•
	3. Antiallergics														
*chlorphenamine		tablet 4mg (maleate)					•	•	•	•			A		•
		inj 10mg in 1ml ampoule					•	•	•	•					
epinephrine		inj 1mg (as hydrochloride in 1ml ampoule					•	•	•	•	•		A		

Main List	Complementary List	Route of administration dosage forms and strengths	List A Emro	List B Emro	CMC	Low Cost	PUR	GI	SL	G	E	AM	A B C	I	II
		4. Antidotes and other substances used in poisonings													
		4.1 General													
charcoal, activated		Powder										•	A		
		4.2 specific													
atropine		inj 1mg(sulfate)in 1ml ampoule					•	•			•	•	A		
diazepam		inj 5mg/ml in 2ml ampoule				•	•		•		•	•	B		•
		5. Antiepileptics													
phenobarbital(1)		tablet 50mg,100mg,syp 15mg/5ml capsule or tablet 25mg,100mg(sodium salt) inj 50mg(sodium salt/ml in 5ml vial				•	•	•	•	•	•	•	B		•
phenytoin							•	•	•	•		•			
inj Paraldehyde(Hathi)													C		
		6. Antiinfective drugs											C		
		6.1 Anthelmintic drugs													
mebendazole		tablet 100mg	•	•	•	•	•	•	•	•		•	A		
piperazine		tablet 500mg(citrate or adipate)	•	•		•	•	•	•	•	•		A	•	
senna tablet (Levamisol) II tablet elexir.		Elexir or syp(as citrate)equivalent I to 500mg hydrate/5ml		•					•	•			B		
tetrachloroethylene(Hathi)			•						•	•			A		
		6.2 Antiamoebic drugs													
chloroquine		tablet 200mg(as phosphate or sulfate)				•	•	•	•	•	•	•	A	•	
diloxanide		tablet 500mg(furoate)			•				•				B		
metronidazole		tablet 200-500mg		•	•	•	•	•	•	•	•	•	B		•
	dehydro emetine(B),1,7)	inj 60mg(hydrochloride)in 1ml ampoule					•	•	•						
furazolidine		inj 60mg					•	•					B		
pthalyl sulphathiazole(Hathi)											•		A		

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emro	List B	CMC	Low cost	PU	PG	HSL	G	E	AM	AG	I	II
	6.3 Antibacterial drugs														
	6,3.1 Penicillins														
*ampicillin(4)		Capsule or tablet 250mg,500mg (annydrous) I		.	.	.				.	.	.	B	.	
		powder for oral suspension 125mg (anhydrous)/5ml													
		powder for inj 500mg(as sodium salt) I in vial							.						
benzathine benzylpenicillin(5)		inj 1.44mg benzylpencillin											B		
fortified benzyl penicillin		procaine benzyl penicillin 30000 u/ml + benzyl pencillin 10000 u/ml											B		
benzylpenicillin		powder for inj 0.6g							.	.			B		
		1million IU) 3.0g(=5million IU)(as sodium or potassium salt)in vial													
		tablet 250mg(as potassium salt)I													
phenoxymethyl penicillin		powder for oral suspension 250mg (as potassium salt)/5ml				.			.		.		B	.	
procaine benzyl penicillin(7)		powder for inj 1g(=1million IU) 3g(=3 million IU)											B		.
	6. Antiinfective Drugs														
	6.3.2 other antibacterial drugs														
*chloramphenicol(7)		capsule 250mg				.	.	.	.	.	.	.	B		
		powder for inj 1g(as sodium succinate) in vial													
erythromycin		capsule ortablet 250mg(as lactobionate)/5ml											B		
		powder for inj 500mg(as lactobionate) in vial					.	.	.						
*gentamycin(4)		inj 10mg,40mg(as sulfate)/ml in 2ml vial					.	.					C		
metronidazole		tablet 200-500mg					.	.	.	.	.	.	B		.

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emro	List B	CMC	Low Cost	PUP	GI	SI	G	E	AM	A B C	I	II
		inj 500mg in 100ml													
		Suppository 500mg, 1g													
*Sulfadimidine(4)	(sulphadiazine)	tablet 500mg, oral suspension 500mg/5ml	.	.	.	.	.	.	.				A		
		inj 1g(sodium salt)in 3ml ampoule													
*sulfamethoxazole+trimethoprim(4)		tablet 100mg+20mg,400mg+80mg		.		.				.	.	.	B		.
*tetracycline(4)		capsule or tablet 250mg(hydrochloride)			.	.	.	.	.	.	.	.	A		.
	doxycycline(B)(5,6)	capsule or tablet 100mg(as hydrochloride)													
		inj 100mg(as hydrochloride)/5ml in ampoule													
	nitrofurantoin(A,B)(4,7)	tablet 100mg				.	.	.		.	.	.			
Hydroxyquinolines						.		.							
Furazolidine		100mg tablet				.	.	.	.				B		
	6.3.3 Antileprosy drugs														
clofazimine		capsule 100mg									.		C		
dapsone		tablet 50mg,100mg				.	.	.		.	.	.	A		
rifampicin		capsule or tablet 150mg,300mg					.	.			.	.	C		
	6.3.4 Antituberculosis drugs														
ethambutol		tablet 100-500mg(hydrochloride)						.	.		.	.	C		
isoniazid		tablet 100-300mg			.	.	.	.	.				B		
pyrazinamide		tablet 500mg				.	.						C		
rifampicin		capsule or tablet 150mg,300mg				.	.	.			.	.	C		
streptomycin(4)		powder for inj 1g(as sulfate)invial			.	.	.	.	.	.	.	.	B		.
thiacetazone*isoniazid		tablet 50mg+100mg,150mg+300mg				.	.	..				.	B		.
Thiacetazone						.		.					B		
	6.4 Antifilarial drugs														
diethylcarbamazine		tablet 50mg(citrate)			.	.	.	.	.	.	.		C		
	6.5 Antifungal drugs														
nystatin		tablet 500000 IU					.	.					C		.

Main list	Complementary list	Route of administration dosage forms and strengths	List A Euro	List B Euro	CMC	Low Cost	PU	PGI	SL	G	B	AM	A B C	I	II
		6.6 Antileishmaniasis													
sodium stibogluconate		inj 33% equivalent of 10% antimony in 30ml											C		
pentamidine		powder for inj 200mg in vial											C		
		6.7 Antimalarial drugs													
*chloroquine		tablet 150mg(as phosphate or sulfate)	.	.		.		.	.				A	.	
		syrup 50mg(as phosphate or sulfate)/5ml													
		tablet 75mg(as phosphate)													
primaquine		tablet 15mg(as base)							.				B		
quinine		tablet 300mg(as bisulfate or sulfate)											B		
		inj 300mg(as dihydrochloride)/ml in 2ml ampoule											B		
	pyrimethamine				.					.		.	B		
	sulfadoxine+pyrimethamine(B)	tablet 500mg+25mg								.					.
		7. Antimigraine drugs													
ergotamine(2,7)		tablet 2mg(as tartrate)											B		
		10. Blood drugs affecting the blood													
		10.1 Antianaemia drugs													
ferrous salt	A	tablet equivalent to 60mg iron (as sulfate or fumarate)	.	.		.	.	.	.	.	.	.	A	.	
		oral solution equivalent to 15mg iron(as sulfate)in 0.6ml													
folic acid(2)		tablet 1mg			.		.	.	.	.	.	.	A		
		inj 1mg(as sodium salt)in 1ml ampoule													
*hydroxocobalamin(2)		inj 1mg in 1ml ampoule						.				.	C		
	*iron dextran(B)(5)	inj equivalent to 50mg iron/ml in 2ml ampoule					.	.	.	.	.				
		12. Cardiovascular drugs													
		12.1 Antianginal drugs													
glyceryl trinitrate		tablet (sublingual)0.5mg							.				C		

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emrc	List B	CMC	Low Cost	PPU	PGI	SI	G	E	AM	List C	I	II
tetracycline ointment															
chloramphenicol															
	13.3 Antiinflammatory and antipruritic drugs														
*betamethasone(3)		ointment or cream 0.1%(as valerate)				.		.	.				B		
*calamine lotion		lotion					.		.				B		
*hydrocortisone		ointment or cream 1%(acetate)					.	.	.	.			B		
	13.5 Keratoplastic and keratolytic agents														
salicylic acid		solution topical 5%							.				B		
	13.6 Scabicides and pediculicides														
benzyl benzoate		lotion 25%	.	.	.	.			.		.		A	.	
	14. Diagnostic agents														
tuberculin, purified protein derivative (PPD)		injection					.						B		
fluorescein	14.1 Ophthalmic drugs	eye drops 1%(sodium salt)					.						C		
	15. Disinfectants														
*chlorhexidine		solution 5%(gluconate)for dilution.		.	.				.				B	.	
*iodine		solution 2.5%	.	.			.	.	.	.	.	.			
	16. Diuretics														
*furosemide		tablet 40mg inj 10mg/ml in 1ml ampoule				.	.	.	.	.	.		B		
*hydrochlorothiazide		tablet 50mg				.	.	.	.			.	B		
	17. Gastrointestinal drugs														
aluminium hydroxide(a)		tablet 500mg oral suspension 320mg/5ml	.	.	.	.		.	.	.		.	A		
magnesium hydroxide		oral suspension equivalent to 550mg magnesium oxide/10ml					.	.	.	.	.		A		
	tab. antacid(a+b)														
*promethazine(d)	17.2 Antiemetic drugs	tablet 10mg,25mg(hydrochloride)	.	.	.	.	.	.	.	.	.		A		
chlorpromazine		elixir or syrup 5mg(hydrochloride)/5ml													

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emrc	List B	CMC	Low Cost	PP	UP	GI	SI	G	E	AM	EC	I	II
tetracycline ointment																
chloramphenicol																
	13.3 Antiinflammatory and antipruritic drugs															
*betamethasone(3)		ointment or cream 0.1%(as valerate)				•			•	•				B		
*calamine lotion		lotion					•			•				B		
*hydrocortisone		ointment or cream 1%(acetate)					•	•		•		•		B		
	13.5 Keratoplastic and keratolytic agents															
salicylic acid		solution topical 5%								•				B		
	13.6 Scabicides and pediculicides															
benzyl benzoate		lotion 25%	•	•	•	•				•		•		A		•
	14. Diagnostic agents															
tuberculin, purified protein derivative (PPD)		injection					•							B		
fluorescein	14.1 Ophthalmic drugs	eye drops 1%(sodium salt)					•							C		
	15. Disinfectants															
*chlorhexidine		solution 5%(gluconate)for dilution.		•	•					•				B		•
*iodine		solution 2.5%	•	•			•	•	•	•	•	•				
	16. Diuretics															
*furosemide		tablet 40mg inj 10mg/ml in 1ml ampoule				•	•	•	•	•	•	•		B		
*hydrochlorothiazide		tablet 50mg				•	•	•	•				•	B		
	17. Gastrointestinal drugs															
aluminium hydroxide(a)		tablet 500mg oral suspension 320mg/5ml	•	•	•	•		•	•	•			•	A		
magnesium hydroxide		oral suspension equivalent to 550mg magnesium oxide/10ml						•	•	•	•	•		A		
	tab. antacid(a,thi)															
*prometh azine(d)	17.2 Antiemetic drugs	tablet 10mg,25mg(hydrochloride)	•	•	•	•	•	•	•	•	•	•		A		
chlorpromazine		elixir or syrup 5mg(hydrochloride) /5ml														•

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emcc	List B	PMC	Low cost	PU	PG	SL	G	L	M	Key	I	II
	17.3 Antihaemorrhoidal drugs														
*local anaesthetic, astringent and antiinflammatory drug		ointment or suppository	•	•									C		
Oxyphenonium bromide				•				•					C		
*atropine(Hathi)	17.4 Antispasmodic drugs	tablet 1mg(sulfate)				•	•	•			•	•	B		•
		inj 1mg(sulfate in 1ml ampoule													
*codeine(1)	17.6.1 Antidiarrhoeal (symptomatic) drugs	tablet 30m (phosphate)							•				B		
oral rehydration salts(for glucose-salt solution)	17.6.2 Replacement solution		•	•			•				•		A		
ipecacuanha	antiflatulent														
activated charcoal															
gamma benzene hexachloride(1)		solution		•								•	A		
	18. Hormones														
	18.1 Adrenal hormones and synthetic substitutes														
*dexamethasone	Hydrocortisone	tablet 0.5mg,4mg						•				•	C		
		inj 4mg(sodium phosphate)in 1ml ampoule													
*prednisolone		tablet 5mg				•		•	•			•	C		•
*ethinylestradiol	18.3 Estrogens	tablet 0.05mg							•	•			C		
	18.4 Insulins and other antidabetic agents														
*glibenclamide		tablet 5mg					•						C		
insulin (M.A.)							•	•	•	•			C		
Tolubutamide		injection					•	•	•	•			C		
	Chlorpropamide								•						
	18.5 Oral contraceptives														
*ethinylestradiol *levonorgestrel		tablet 0.03mg+15mg+0.25mg				•							C		

Main list	Complementary list	Route of administration dosage forms and strengths.	list A Emrb	list B	CMC	Low Cost	PU	PGI	SL	G	E	AM	A B C	I	II
		18.8 Thyroid hormones and antihydroid drugs													
levothyroxine		tablet 0.05mg, 0.1mg (sodium salt)											C		
potassium iodide		tablet 60mg											C		
*propylthicuracil		tablet 50mg											C		
		19. Immunologicals													
antivenom sera	19.1 Sera and animal globulins	inj) all plasma fractions should comply with WHO requirements											C		
diptheria antitoxin		inj) for the collection, processing and quality control of human blood and blood products											C		
		inj) 10000 IU 20000 IU in vial													
tetanus antitoxin		inj 50000 IU in vial											B		
	19.2 Vaccines														
	19.2.1 for universal immunization														
BCG vaccine (dried)		inj) all vaccines should comply with											B		
diphtheria pertussis-tetanus vaccine		inj) the WHO requirements for biological substances.											B		
diphtheria-tetanus vaccine		inj)													
measles vaccine		inj)											B		
poliomyelitis vaccine (live attenuated)		inj/oral solution											B		
tetanus vaccine (WHO, Hathi)		inj											B		
	19.2.2 cholera TABC, small pox														
		21. Opthalmological preparations													
silver nitrate	21.1 antiinfective agents	solution (eye drops) 1%											B		
sulfacetamide		eye ointment 10% (sodium salt)											A		
*tetracycline chloramphenicol		solution (eye drops) 10% sodium salt													
		eye ointment 1% (hydrochloride)													
	21.2 Antiinflammatory agents														
hydrocorizone															

Main list	Complementary list	Route of administration dosage forms and strengths.	List A Euro	List B	CMC	Low cost	PU	PGI	SEG	E	AM	A	B	C	I	II
21.4	21.4 Miotics															
pilocarpine		solution(eye drops)2%,4%(hydrochloride or nitrate)					•	•								
	21.5 Mydriatics															
physiostigmine(Hath)																
homatropine(A)		solution(eye drops)2%(hydrobromide)														•
	22. Oxytocics															
*ergometrine		tablet 0.2mg(maleate)		•	•	•			•							
oxytocin		inj 0.2mg(maleate)in 1ml ampoule					•	•		•					•	•
		inj 10 IU in 1ml ampoule														
	24. Psychotherapeutic drugs															
*chlorpromazine		tablet 100mg(hydrochloride)					•	•	•	•	•					•
		syrup 25mg(hydrochloride)/5ml														
		inj 25mg(hydrochloride)ml in 2 ml ampoule					•			•	•					
*diazepam		tablet 5 mg														
	25. Respiratory tract, drugs acting on															
*aminophylline	25.1 antiasthmatic drugs	tablets 200mg	•		•	•	•	•	•	•	•		B			•
		inj 25mg/ml in 10ml ampoule		•												
epinephrine		inj 1mg(as hydrochloride)in 1ml ampoule														
*salbutamol		tablet 4mg(sulfate)			•	•	•	•	•	•			C			
		oral inhalation(aerosol)0.1mg per dose														
		syrup 2mg(sulfate)/5ml														
adrenalin tartarate maliate in 1000							•	•	•	•			C		•	
P E T- phenobard 5mg, ephedrine 10mg, theophyline 125?(Hathi)													B			
noscapine(cough suppressant)																
	ephedrine(A)	tablet 30mg(as hydrochloride)				•			•				B			,

Main list	Complementary list	Route of administration dosage forms and strengths.	list A	list B Euro	CMC	low cost	PU	p	GI	SL	G	E	AM	I	II	WHO C
26. Solutions correcting water, electrolyte and acid-base disturbances																
26.1 oral																
oral rehydration salts	(for glucose-salt solution) (for compositon see 17.6.2 replacement solution)									•						A
potassium chloride		oral solution					•		•		•					B
glucose (dextrose)	26.2 Parenteral	injectable solution 5% isotonic, 50% hypertonic								•					•	B
glucose with sodium chloride		injectable solution 4% glucose 0.18 sodium chloride (Na+ 30 mmol/1) (Cl- 30 mmol/1)													•	B
potassium chloride		injectable solution					•		•		•					B
sodium bicarbonate		" " 1.4% isonic (Na+ 167 mmol/1) (HCO3- 167 mmol/1)														B
Sodium chloride (cholera fluid)		injectable solution 0.9% isotonic (Na+ 154 mmol/1) (Cl- 154 mmol/1)								•					•	
calcium carbonate gluconate		in 2ml, 5ml, 10ml ampoules								•					•	B
water for injection																
27. Vitamins and minerals																
ascorbic acid		tablet 50mg														B
*ergocalciferol		capsule or tablet 1.25mg (50000 IU)			•	•				•						A
		oral solution .25mg/ml (10000 IU)			•	•	•			•						
*nicotinamide		tablet 50mg														-
pyridoxine		tablet 25mg (hydrochloride)														B
retinol		capsule or tablet 7.5mg (25000 IU), 60mg (20000 IU)	•	•										•		A
riboflavin		oral solution 15mg/ml (5000 IU) tab. 5mg														B
sodium fluoride (8)		tablet 0.5mg (as fluoride)														B
vitamin A & D							•		•				•			A
vit B complex	(Prophylactic NFI therapeutic NFI with Vit C+ folic acid)	tablet + injection)					•			•						A
cyanocobalamin B 12 (Hathi)					•					•			•			B
hydroxocobalamin																
multivitamin																

Voluntary Health Association of India

C-14, Community Centre
Safdarjung Development Area
New Delhi-110016

Telegrams : VOLHEALTH
New Delhi-110016
Telephones : 668071
668072

July 17, 1984.

ESSENTIAL DRUGS

A DEMAND FOR PRIORITIZATION

Prepared for
V H A I members,
Drug Action Networkers
and all those who believe
in the concept
and implementation
of Rational Drug and Health Policy

Background paper
for
Drug Action Network
Core Group Meeting
Wardha

30 - 31st JULY 1984.

Dr. Mira Shiva
Coordinator
Low Cost Drugs
and Rational Therapeutics
V.H.A.I.

D-4/378(c) LCD & RT
VHAI:pt:19.7.'84

ESSENTIAL DRUGS - A DEMAND FOR PRIORITIZATION

- Dr. Mira Shiva, VHAI.

Content Outline

I. Essential Drugs - An Introduction

II. Courageous Efforts - Brief Review

Chile
Srilanka
Pakistan
Mozambique
Bangladesh
W H O
India

III. Our Efforts in the area of essential drugs

IV. The Selection of essential drugs and the essential drug programme - W H O Recommendations.

V. The Rationale of Essential Drugs or Why do we need an Essential Drug List?

A. Existing low priority to essential drugs needed for the priority health needs and the deteriorating trends in output.

B. DPCO The Drug Price Control Order and its negative impact on Production of Essential and life saving drugs i.e. Category I and II drugs.

C. Poor performance of multinationals in production of essential drugs.

D. Dilution of FERA companies - an invitation to more formulations.

E. The need for rational use of scarce resources. Controlling Cost by:

1. preventing wastage of scarce foreign exchange by not importing excess inessentials.

2. ensuring preventive health measures before promoting inessential drugs.

3. ensuring placing essential drugs before inessential drugs

4. increasing production of essential drugs, decreasing drug costs through economy of scale.

5. ensuring bulk purchase of selected essential drugs and thus cutting costs.

....2/

F. Subsidizing costs of essential drugs

G. Need for influencing market demand and thus the drug production pattern in favour of essential drugs

H. Need to decrease drug misuse and overuse

I. Need for efforts in preventing Iatrogenesis

J. Need for ensuring unbiased drug information for health personnel and consumers.

K. Need for ensuring better quality control

L. Need for ensuring generic prescribing

VI. Graded Essential Drug List

I. ESSENTIAL DRUGS

INTRODUCTION

The concept of essential drugs is the focal point of the drugs issue and of the rational drug policy.

Our focussing on essential drugs does not mean that by ensuring production and supply of essential drugs, the health care status of our people will dramatically improve. We are focussing on it to highlight the fact that majority of our people are not merely deprived of health care facilities, but whatever they are given by way of health care does not necessarily have their interest in mind. The kind of health care facilities, medical technologies and drugs being promoted under the garb of "scientificity" and "modern advances" and as "latest break through" usually serve the interest of the "medical industry" i.e. the drug industry and the medical establishment. Some of these modern myths and superstitions have to be demolished. Eg. Myth I - medicine is a noble profession brimming with selflessness, putting patients interest and welfare, above self interest. Myth II - The drug industry produces 'pills for every ill' and is fighting an unselfish battle against death and disease. If it wasn't for them, lots of us would be sick and suffering if not dead. Myth III - India is a welfare state, signatory of the Alma Ata Charter giving priority to Primary Health Care, and that our health policies are people oriented and are guided by recommendations of Committees like the Bhore Committee, 1946, Mathi Committee 1975. Alternative strategy Health for All "ICMR-ICSSR Report 1981" and even the last year's the National Health Policy Statement all of which emphasize that the health needs of the majority have to take priority over sophisticated, centralised, costly, high technology medical services meant for the minority with the purchasing power.

....3/

The concept of essential drugs, questions the health personnel who are supposed to safeguard the health of the people; it questions why their prescriptions include irrational, inessential, costly combinations and often hazardous drugs. It questions the medical establishment for not demanding bans on bannable drugs, nor attempting to ensure and implement such bans. It focusses the attention on the present day medical services- private and government; the prescription patterns; the gross lack of accountability to the public or to any medical council. The doctors bask in the prestige that comes, with the practice of 'white man's' medicine. It is the public that puts them on a pedestal (not far below the one meant for the Almighty). In reality, they, like the drug manufacturers and their representatives are no better than salesmen; and medical care is debased into a 'commercial service' and it sells, even if the people needing it have to beg, borrow, or steal.

If the prescription patterns have to be based unmodified blindly, unchallenged on the medical text book written by and for the West - then we should also ensure that their controls go with them. There should be registration with the medical council, need to pass board exams after certain years of practice, medical audit and withdrawal of medical license for unethical medical practice. If our state mechanism is meant to ensure anything, it is to ensure total safeguard against those who in the name of medicine, believe in making quick money, and use their medical license, to exploit the people. Not merely are such medical practitioners whose number is fast increasing an insult to medical practice, but they set examples for others, so that medicine has become a "Dhanda" (business) for many. Youngsters bribe, fudge mark sheets, pay lakhs of capitation fees to get admission in medical colleges to join their ranks - while Primary Health Centres lie unstaffed, unequipped and disfunctional. Rarely do the prestigious medical establishments raise a hue and cry over the ever increasing medical swindles; against the decreasing health budget of the 5 year plans; against the drug bans that never come or are never implemented; against health and drug policies that are not in the interest of the people.

Myth II - The drug industry is there not to serve, but safeguard its own interests. The performance of multinationals in decreasing production of essential and life saving drugs, and the double dealing in giving biased drug information; their ensuring the purchase of drug prescriptions for ones company by gratifying doctors with samples, gifts and sponsored medical conferences. With loan licensing, products of many of the big name companies are produced by small scale drug outfits with as much quality control as most other small scale drug companies.

All commercial enterprises serve a purpose, but a few like drug industry start sharing the role of a healer, server, educator, benefactor, having touched the dizzy heights of highly technical mystified science.

Myth III - The third myth of course is that our health policy is geared to fulfil the health needs of the majority.

The health budget has steadily decreased. It may have been broken up under different heads but with increasing population and increased need for health services, health budget should be going up much more rapidly.

.....4/

How has the money been spent? What are the disparities existing? What has been the role of the policy makers? What has happened to the various recommendations mentioned earlier? The perspective should have been set when we attained independence. The direction being pursued now hasn't changed very much from the pre-independence period. The public has had no say in deciding the kind of doctors it wants trained with its money and what kind of health facilities and drugs it needs. Such an intervention by the consumers remained impossible inspite of the numbers because so far they have remained unorganized and fragmented.

Focussing public attention on the issue of essential drugs provides a platform for organizing the consumers for focussing attention on our health care services, on our legislations, policies, education and legal systems.

It is to focus on the role the experts, the committees and policy makers have played in the past (many of whom are known to have been bought and sold). It focusses on the role of consumers and on their demand for participation in decision making as a majority, for the benefit of the majority.

Demand for essential and life saving drugs as a priority is an exercise in demystifying medicine; it is an exercise in public education, an exercise in ensuring that public needs guide and influence decision making. This demand is also an exercise in learning to boycott drug decisions and policies which are thrust down peoples throats against their will and against the interest of the majority.

It is part of a slowly emerging consumer movement, peoples science movement and also peoples health movement. It is an integral part of a larger process and not a piece-meal demand of a minor rectification.

The politics of health at the concrete level can only be based on peoples action. As Fritjof Capra points out in the Schumacher Lectures 'Refusal to take even a single pill is such a political act'. On this political philosophy is based the mobilization for essential and life saving drugs as a priority.

Just as manufacture, sale and prescriptions of hazardous and irrational drugs is a oppressive political act, refusal to become victims of this oppression is a political response.

II. COURAGEOUS EFFORTS - A Brief Review

The concept of essential drugs list is nothing new nor did it have its origins in WHO's Technical Report Series No. 615 (1977) as many believe. Many efforts had been made prior to this. We just mention few.

CHILE:

As far back as 1973, the Chilian Medical Commission comprising of Dr. Salvador Allende had believed in limiting the drugs to those that had demonstrable therapeutic value and thus 'scale down the pharmacopea'. Allende during his short tenure as President quite successfully compelled the medical profession to serve "basic" rather than profitable needs. He proposed to ban drugs not prescribed for clients in North America or Europe.

.....5/

Within one week after the taking over of the military junta on 11th September 1973 the Chilian doctors who participated in this revolutionization of medicine, these outspoken proponents of Chilian medicine based on community action rather than on drug imports and drug consumption were assassinated. Men with much courageous ideas even though they are for the benefit of the people, are seldom appreciated.

SRI LANKA:

In 1971 under the guidance of Soneka Bibile, Sri Lanka had formed the State Pharmaceutical Committee to launch its people oriented new Drug Policy. The number of drugs in the market were slashed down from 2100 to 600 and made available mostly under generic names and obtained by calling international tenders. Within 6 months there were savings of about 40% in relation to expenditure incurred earlier.

It is absolutely essential for those of us involved in drug work, to know how the resistance from multinationals, their governments, with support from Sri Lanka's own medical establishment forced the Sri Lanka government, to give into vested interests and revert some of itsown brave and correct decisions.

PAKISTAN:

Pakistan's attempts at restricting the drug list to essentials, with rejection of unessentials met with similar resistance from the 2 most powerful lobbies in the medical industry 'the drug industry and the medical establishment'.

INDIA:

In 1975, the Hathi Committee in India recommended a restricted essential drug list of 116 drugs which were to be sold under their generic names. There was no dramatic opposition to the recommendations. They were just very effectively ignored. So much so that today for interested health and consumer groups no copies of the Hathi Committee recommendations are available, from the health ministry. These recommendations are shrouded in cob-webs. The difference between the Indian experience with essential drugs and that of others is that the demand for them did not emerge from enlightened medical professionals and has till recently remained an official exercise. It was not from people like Dr. Soneka Bibile of Sri Lanka, Dr. Zafrullah Chowdhry and Dr. Nurul Islam of Bangladesh, Dr. Salvador Allende of Chile.

MOZAMBIQUE:

After its liberation from Portuguese rule in 1975 the Mozambique government took some drastic decisions regarding its health and drug policy. Health was nationalized and private practice banned within one month of independence. The number of drugs were decreased from to 430 medicines in 1977. Essential drug list was revised in 1980 and contained only 343 drugs. ONLY THESE DRUGS COULD BE PRESCRIBED.

.....6/

The result of streamlined contracts was that the drug prices of many essential drugs came down to 1/3 of their original prices. The essential drugs became available, to more people in remote areas, not just to the privileged few. This could be done with the drug import costs the same as they were 10 years ago because the selection was more sensible.

W H O:

The WHO Expert Committee on essential drugs in Technical Report Series 615 gave the criteria for selection of essential drugs and a model of such a list. Another report in 1979 was followed by the Technical Report Series 685 which dealt with the 'use of Essential Drugs' and gave the essential drug list for emergency situations and primary health care.

BANGLADESH:

In June 1982 Bangladesh's Military regime under General Ershad, promulgated a Drug Policy based on WHO recommendations. 1742 drugs were banned because of their hazardous and irrational nature. This of course had been preceded by educational campaigns about rational drug use by some of the individuals involved in pushing the National Drug Policy. The January 1982 international conference on Health and Pharmaceutical Policies was one such attempt organized by Gonoshasthya Kendra. Through its monthly magazine"Gonoshasthya Patrika" dealt with this and other issues systematically. Dr. Zafrullah Chowdhury admits that the Hathi Committee and its recommendations hold great inspiration for evolving and for implementation of the Bangladesh drug policy. In Bangladesh the restricted drug list constitutes of 150 drugs. The grading of 150 selected essential drugs has also been done based on location of utilization and level of potential users.

I - 12 Essential drugs have been selected for village level health workers.
II - Additional 33 essential drugs for Primary Health Care up to Thana Health complex level.
III - Additional 105 essential drugs for use up to tertiary level.

There is also a list of 76 supplementary drugs for restricted use which after discussion will be compiled to 100.

The heavy pressure being applied to dilute or just scrap this courageous pro people drug policy, which is ironically very much based on the WHO guidelines for Rational Drug use - has come from the multi-national drug lobby and the medical lobby. The loudest voice being from the US based multinationals and from B M A (Bangladesh Medical Association). It is openly stated by the latter that if India can allow unrestricted sales of drugs banned in Bangladesh, the drugs must be safe and wonderful. After all Indian Medical Establishment with all its brains and advanced technology can't be wrong - (any way we allow continued manufacture and sales of drugs banned by our Drug Controller of India and recommended for withdrawal by our expert committees.)

Efforts to gather support for Bangladesh's brave drug policy had been made by us right from the beginning and our efforts continue; since survival of Bangladesh drug policy is crucial for the people of Bangladesh and other third world countries including India.

.....7/

ZIMBABWE:

Zimbabwe's Government has selected 376 essential drugs to be used in the public health system. Government will not make foreign exchange available for importing drugs outside this list.
Why is this concept of essential drugs seen as such a big threat by medical establishment and the drug lobby? The reason is very obvious. It interferes with the drug companies profit making even though in reality it benefits more people.

III. OUR INITIATIVES IN PROMOTING AWARENESS OF ESSENTIAL DRUGS

By the end of 1980, the drug issue, the rational use of drugs and the role of non-drug therapy and of systems of medicine etc. had become an important component of our training programmes; whether it was upgrading of diagnostic and therapeutic skills of middle level health workers, holistic health workshops, community health or health care management training programmes.

By January 1980 a clearly defined strategy of drug work was drawn up. This was later presented to VHAI's general body for ensuring organizational support. This work strategy figures in the special issue of Health for the Millions - April-June 1981 and indicates the various levels at which it was felt that intervention was required. (Right from village hospital to health personnel and their trainers; policy makers, drug companies, multinationals and international drug and health action groups).

In April-June 1981 issue of our bi-monthly we informed our VHAI members and HFM readers of the concept of essential drugs and gave the essential drug list meant for Primary Health Care. The list of irrational and hazardous drugs which was at that time recommended for being weeded out, was also disseminated to warn the health personnel and health institutions about them.

By 1981 end a serious attempt to draw up an essential drug list of 50 drugs and recommended management of 10 commonest health problems was made, based on the invited views and opinions of selected academicians, health personnel in the field or hospitals and pharmacologists etc. (There were too many disparities in the responses and effort to compile a very unanimous and coherent result based on these responses was abandoned. It was found that most health personnel were not familiar with the concept of essential drugs and WHO's essential drug list)

In January 1982, the first drugs workshop 'Drugs Issues and Feasible Alternatives' was organized in Pune to bring socially conscious health personnel, consumer group activists for drug action together. The Hathi Committee and WHO essential drug lists were made available to the participants of the first Drug Workshop in Pune as well to the participants of various training workshops and organization Development (OD) seminars etc. conducted by VHAI and disseminated amongst various levels of health and non-health personnel.
A sub group constituted of doctors and pharmacologists met during the course of the workshop to compile a mutually acceptable essential drug list. (The Pune workshop list - in the comparative drug list was an outcome of this effort). See Annexure I.

.....8/

By August 1982 it was fully realized that an essential drug list drawn up by us even as a group would not necessarily be acceptable to health personnel. And if while attempts to influence government authorities went on side by side in the voluntary health sector, the acceptance and implementation of this had to be ensured.

The exercise to draw up a comparative essential drug list was undertaken for 3 reasons:

1. To demonstrate that any rational drug policy formulated had a lot in common, no matter from which country.

2. That it was not a handful of concerned persons but expert committees that had drawn up these lists. The fact that these experts believed in the concept of essential drugs, we felt would have greater convincing and educational value.

3. The rationale in making the comparative drug list available to the individuals in the field and solicit a response from these informed individuals was to give a better guideline as well as to involve them in the evolution of a process.

The comparative essential drug list prepared incorporated the following drug lists:

- WHO
- Hathi Committee
- PGI (Post Graduate Institute list) Dr. V.S. Mathur
- Pune Workshop list
- Sri Lanka list
- Restricted lists used by ECHO UK and Action Medeor (both agencies are involved in bulk purchase of essential drugs for third world countries).

It was obvious that these essential drug lists would provide guidelines for drug selection for larger medical institutions. But for smaller health programmes with which I was mainly involved in the course of my work, there was a need for a graded essential drug list, based on the experience, qualifications of the health personnel

- the availability or non availability of other health facilities specially referrals
- availability of supervision, consultation and on going education
- the gamut of health problems dealt with and the workload
- resources available in terms of finances, manpower, diagnostic facilities, transport etc.

Effort to obtain graded essential drug lists from Bangladesh, Sri Lanka, Mozambique and EMRO have been made.

Dealing with Resistance:

The most vocal argument against the concept of essential drug list by the drug lobby and its supporters is that it is relevant only for the extremely poor countries and not for developed countries nor a country like India with the most developed pharmaceutical industry in the third world. This is far from true since drug lists of many developed countries are highly rationalized and limited. Proliferation of non-essential drugs is no indicator of development.

....9/

In 1982 a request to the Editor MIMS was made to:

1) delete the drugs that were recommended forbeing weeded out by the Drug Consultative Committee

2) indicate clearly the drugs included in WHO essential drug list, so as to give a guideline for the readers to help them in their selection process - by underlining or writing these drugs in capitals or italics.

This evoked besides a personal response, an editorial in MIMS where the relevance of the essential drug list only for the struggling poor countries was emphasised. Dr. Halfdan Mahler, Secretary General WHO was quoted as saying "that a consignment of antimalarials was received in a certain country with as much celebration and gaity as demonstrated at that country's independence". This was an attempt to show that the concept of essential drug list is meant only for extremely poverty stricken and not countries like ours. This is totally untrue. Developed countries have made more serious efforts to restrict drugs.

In UK, the 6500 preparations is considered too many by the National Health Campaigners and Charles Medawar of Social Audit in his latest book 'The Wrong Kind of Medicine'. Norway has about 1900 preparations. The Norwegian authorities have licensed a total of 730 active ingredients. An attempt to have less of irrational and non-sensical drugs is not limited to the third world countries but developed countries themselves. How long in the name of 'free enterprise' and so called 'clinical freedom' will irrational and hazardous drugs continue to be inflicted upon the people specially when they are ill affordable by them at the cost of their actual health care needs being met?

Today the question is not whether to include or delete a particular drug, but for health personnel and people alike to be exposed to and to internalize the concept of essential drugs, so that they can make an informed choice about essential and unessential drugs.

"The benefits of our huge drugs list are essentially to do with trade, not health. The advantages of a restricted drug list include having fewer bad drugs and a reduction in drug induced disease, and better information about drug use and less confusion about which drugs to use". (Charles Medawar 'The Wrong Kind of Medicine' page 15).

Dr. John Yudkin who has long been concerned about third world drug policies says 'the drug companies must not be permitted to become a hazard to health in the underdeveloped world by failing to provide information or by drawing scarce resources, away from more effective projects'.

.....10/

IV. SELECTION OF ESSENTIAL DRUGS AND STEPS FOR IMPLEMENTING AN ESSENTIAL DRUGS PROGRAMME - WHO RECOMMENDATIONS

In order to ensure that an essential drugs programme is adequately instituted at the National level, several steps are advised:

1. Establishment of a list of essential drugs, based on recommendations of a local committee constituted of individuals competent in the fields of medicine, pharmacology, and pharmacy as well as peripheral health workers.

2. The international non-proprietary (generic) names for drugs or pharmaceutical substances should be used whenever possible and prescribers should be used whenever possible and prescribers should be provided with a cross index on nonproprietary and proprietary names.

3. Concise, accurate, and comprehensive drug information should be prepared to accompany the list of essential drugs.

4. Quality, including stability and bio-availability should be assured through testing or regulation.

5. The success of the programme is dependent on efficient administration of supply, storage and distribution at every point from the manufacturer to the end user. Government intervention may be necessary to ensure the availability of some drugs in the formulations listed, and special arrangements may need to be instituted for the storage and distribution of drugs that have a short shelf life or require refrigeration.

6. Efficient management of stocks is necessary. To eliminate waste and to ensure continuity of supplies, a Procurement Policy should be based upon detailed records of turnover. In some instances drug utilization studies may contribute to a better understanding of true requirements.

7. Need for both clinical and pharmaceutical research under local conditions.

Criteria for selection of essential drugs:

> ESSENTIAL DRUGS ARE THOSE THAT SATISFY THE HEALTH CARE NEEDS OF THE MAJORITY OF THE PEOPLE. THEY SHOULD THEREFORE, BE AVAILABLE AT ALL TIMES IN ADEQUATE AMOUNTS AND IN THE APPROPRIATE DOSAGE FORMS.

Only those drugs should be selected for which sound and adequate data on efficacy and safety are available. And from adequate clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.

.....11/

Each selected drug must be available in a form in which adequate quality, including bio-availability can be assured. Its stability under the anticipated conditions of storage and use must be established.

The choice between 2 or more drugs which are similar in all the above respects, should be based on careful evaluation of their relative efficacy, safety, quality, price (of the cost of taking a full course and not merely the unit cost) and availability.

Other criteria to be kept in mind are pharmacokinetic properties and availability of facilities for manufacture or storage.

Formulations should be single ingredient drugs. Fixed dose combinations should be acceptable only when a combination provides a proven advantage over single compounds administered separately in therapeutic effect, safety or compliance.

Selection of Dosage forms:

Tablets are usually less expensive than capsules, but while the cost factor should be taken into account, the selection should also be based on a consideration of pharmacokinetics, bioavailability, stability under ambient climatic conditions, availability of excipients and established local preference.

- A range of dosage strengths is provided from which suitable strengths should be selected on the basis of local availability and need.

- The use of scored tablets is recommended as a simple method of making dosage more flexible.

- There is a need to periodically revise and update the list. But frequent and extensive changes are clearly undesirable since they result in disruption of channels of procurement and distribution and may have implications for the training of health personnel.

Provision of information on essential drugs:

'Concise, accurate and comprehensive information on the use of essential drugs should be available to all prescribers in a format that is appropriate to their responsibilities and levels of training.'

Drug information sheets for the doctors by WHO's Expert Committee on the selection of essential drugs has been compiled in the following format:

1. International Nonproprietary Name(INN) of each active substance, and recommended dosage form.

2. Pharmacological information: brief description of pharmacological effects and mechanism of action.

3. Clinical information:

3.1 Indications: whenever it is thought appropriate, simple diagnostic criteria should be provided.
3.2 Dosage regimen and relevant pharmacokinetic data:

.....12/

3.2.1 Average dosage and range for adults and children
3.2.2 Dosing interval
3.2.3 Average duration of treatment
3.2.4 Special situations, eg. renal, hepatic, cardiac or nutritional insufficiencies which require either upward or downward dosage adjustments.
3.3 Contraindications
3.4 Precautions (reference to pregnancy, lactation etc.)
3.5 Adverse effects (quantitate by category, if possible)
3.6 Drug interactions (to be mentioned only if clinically relevant: drugs used for self-medication should be included)
3.7 Overdosage:
3.7.1 Brief clinical description of symptoms
3.7.2 Non drug treatment and supportive therapy
3.7.3 Specific antidotes

4. Pharmaceutical information.

V. THE RATIONALE OF ESSENTIAL DRUGS

The concept of essential drugs is the backbone of any Rational Drug Policy. The repercussions of acceptance and non-acceptance of an essential drug list are too many. If there is one unanimous demand which has to come from us people it has to be the selection of an essential drugs list based on the health needs of majority, for priority to be given to

- ensuring their production
- ensuring their efficient distribution
- ensuring appropriate stocking of pharmacies with these drugs
- ensuring appropriate drug prescription and practices to be based on these accepted drugs.

Since 46% of the drugs marketed are obtained over the counter without a prescription (according to NIN Drug Utilization study) it is obvious that altered or improved 'prescription practices' alone cannot alter the drug consumption patterns. With the degree of self prescription of drugs, selection of essential over unessential drugs can have a great impact. Specially if this is associated with a total boycott by the consumers and health personnel, of highly irrational and hazardous drugs as was done by Swedish doctors. The boycott led by Dr. Olle Hansson, Paediatric Neurologist in the international campaign against clioquinol, mexaform related drugs was later joined by doctors of Norway, Denmark - totally by over 3000 doctors and veterans. The implementation of essential drugs list needs to be done urgently and the reason why it is so crucial are given below:

A. Existing low priority to essential drugs needed for the priority health needs and the deteriorating trend:

The myth of 'pill for every ill' detracts from the real health issues being dealt appropriately. The majority of drugs manufactured are unessential and not based on the health needs of our people. Of the 1260 crores worth of drugs manufactured in India in 1979-'80, only Rs. 350 crores worth of drugs were essential and life saving drugs, the rest were mainly non-essential drugs.

.....13/

The following figures speak for themselves:

Table

		1978	1980
Category	I	4.5%	3.6%
	II	16.7%	13.2%
	III	67.1%	68.6%
	IV	11.7%	14.6%

Source: FMRAI News
July 1984.

The production of category I drugs i.e. essential and life saving drugs and Category II drugs (essential drugs) is showing a declining trend according to Ministry of Petroleum and Chemicals and Fertilizers.

Production of antimalarial, anti-TB, antifilarial and anti-leprosy drugs have been trailing far behind the estimated demand and while demand has increased the actual production has been falling. In fact, production of the antimalarial Chloroquin, and the anti tuberculosis PAS, INH and thiacetazone fell short of estimated demand by about 84, 50, 44 and 70% respectively in 1979-'80, except for a small increase in INH production for all these drugs decreased further in 1980-'81.

	Estimated demand	Production in tonns MT		Estimated Production	
	1979-80	79-80	80-81	81-82	82-83
Antimalarial					
Chloroquin	250	35.76	34.62	58.96	70.00
Amodiaquin	40	38.49	23.15	26.02	33.00
Antitubercular					
PAS & Salts	600	481.78	405.46	261.97	290.00
INH	200	112.42	129.20	110.40	128.00
Thiacetazone	40	12.55	8.44	13.98	25.00
Streptomycin	300	220.16	227.33	255.45	266.00
Antifilarial					
DEC	30	21.57	18.99	16.43	13.00
Antileprosy					
DDS	28	16.20	21.05	25.61	30.00

Ref: Dr. W.Y. Rano - Why don't our drugs match our diseases - Science Today - October 1982.

....14/

Demand Projection for Bulk drugs for the period 1979-80 to '84-'85

	Base year	Estimated Requirement				
	79-80	80-81	81-82	82-83	83-84	84-85
Antimalarial						
Chloroquin	250	275	300	335	365	400
Amdiaquin	40	46	53	61	70	80
Anti Tubercular						
PAS	600	630	660	700	730	770
INH	200	240	290	360	415	500
Thiacetazone	40	42	44	46	48	50
Streptomycin	300	330	363	400	440	485
Antifilarial						
DEC	30	33	36	40	45	50
Anti leprosy						
DDS	28	32	37	45	50	56

Ref: The Indian Pharmaceutical Industry Problems and Prospects P.L. Narayan, NCAER Study National Council of Applied Economic Research - January 1984.

- ICMR and ICSSR study on Alternative Strategy had indicated the grossly inadequate drug production for TB and leprosy which happen to be our priority health problems. With half of the TB patients of the world in India our production of INH was less than 1/3 of the minimum requirement.

- The Malaria deaths in Rajasthan were not merely due to drug resistence and cerebral malaria, but due to non-availability of chloroquin even at certain government PHCs. The estimated requirement and the actual production are getting further apart and reliance on imports is resulting for drugs that are so routinely needed.

Chloroquin imports in tons

1979-'80		1980 - '81		1981 - '82	
Production	Imports	Production	Imports	Production	Imports
35.2	52.8	34.6	71.8	59	166.3

Ref:* NCAER Report - The Indian Pharmaceutical Industry.

* National Council of Applied Economic Research.

/.....15/

- There are an estimated 60 million iodine deficiency cases of goitre in India. It is known that children of iodine deficient mothers are known to be born as cretins, deaf, mutes and mental subnormality.

  The simple technology of production of iodized salt is known. Merely 50 paise worth of iodized salt can make all the difference between a child being normal and subnormal.

  We still produce only 20% of the iodized salt required.

Required amount of iodized salt is -	7 lakh tons
Amount produced -	2 lakh tons
Amount sent to Nepal -	1 lakh tons
Amount left for utilization for the 60 million goitre cases -	1 lakh tons

When adequate production of an essential low cost item like iodized salt for a National Goitre Programme cannot be assured, what happens to production of the essential drugs for non priority national programmes can very well be imagined.

In Kenya, in a pilot project funded by DANIDA and SIDA, supplies of drug kits containing 39 drugs in 15 rural districts has increased the accessibility of essential medicines for the rural population from 10% to 40%.

B. DPCO and its negative impact on Production of Category I and II drugs:

Under DPCO (Drug Price Control Order) the mark up on Category I drugs is limited to 40% and that on Category II is 60%. Producing category IV drugs because of the high mark up allowed are therefore definitely most profitable.

For the decreasing priority being given to essential and life saving drugs DPCO is therefore blamed. With the decontrol of prices of 75% of the drugs as is being recommended by the drug lobby and its supporters, a further switch to production of more profitable unessential drugs is imminent. If government is serious about ensuring that essential drugs are sold at a reasonable price - this can be done by doing away with taxes.

C. Poor performance of multinationals in production of essential drugs:

The outright, calculated neglect of the priority drug needs of the majority is well known. The following table speaks volumes. (See Annexure II - Production of Essential Drugs by Multinationals and Organised Sector)

D. Dilution of FERA Companies - an invitation to more formulations:

With the dilution of foreign equity shares to 40%, various concessions are being granted to the FERA companies so that bulk to formulations ratio will be increased from 1:5 to 1:10. With the drug production pattern as it is, we can look forward to more formulations and more unessential drugs irrelevant to our peoples health need. Bulk production by foreign sector for 1982-'83 was Rs. 55 crores worth; the formulation turnover according to 1:5 ratio should not have exceeded Rs. 275 crores, however, Rs. 515 crores worth of formulations were produced i.e. more than 1:10 ratio when only 1:5 was allowed.

.....16/

E. Rational use of scarce resources:

i) Wastage of scarce foreign exchange: India with its level of indebtedness to IMF World Bank, IDA etc., can hardly afford to squander its scarce foreign exchange for importing inessential drugs.

ii) Inessential vs basic health needs: Worse still is the enforced wastage of scarce resources of the poor on useless nonsensical drugs, when they can hardly afford adequate food and clothing and bare essentials. When the percentage of people, below or around the poverty line happen to be around 60 - 70% of a country's population - the very production and heavy promotion of costly irrational and hazardous drugs is criminal. A strong public opinion alone can ensure withdrawal of such drugs, with priority being given to essential and life saving drugs.

iii) Inessential vs essential drugs: Often inessential drugs are bought at the cost of specifically needed essential drugs. For the ignorant majority, the difference between the therapeutic value of a costly tonic, vitamin, digestive ensymes, antipyretic and much needed specific drug eg. antiasthmatic, antibiotics etc. all written in the same prescription - does not exist. This was shown by Veena Shatrughana's study of Prescription writing and drug consumption. By ensuring priority availability and prescription of essential drugs, we would be contributing to preventing the wastage.

iv) Economics of scale increased: If essential drugs were given priority in production, through sheer economics of scale, the production cost would decrease for the manufacturer and thus the consumer.

v) Bulk purchase: An essential drug list can ensure bulk purchase of selected essential drugs, which can cut down drug costs.

F. Influencing market demand and thus the Drug Production pattern in favour of essential drugs:

If the concept of essential drug list was widely propagated, accepted by choice or by legislation, this would necessarily influence the prescription pattern and hence the drug demand in the market. This would definitely alter the drug production pattern towards essential drugs.

G. Decrease drug misuse and over use:

This can be done with identification of drugs which are - therapeutically effective, safe, easy to administer, and of appropriate cost preferably single ingredient well tried drugs. The use of drugs which are of doubtful value, costly, irrational and hazardous drugs should be avoided. Majority of the drugs available are combination drugs. This increases costs as these drugs are often in subtherapeutic and irrational dosages. According to Halfden Mahler, 90% of drugs in the developing countries are non essential.

H. Preventing Iatrogenesis (Drugs induced health hazard):

As long as potentially hazardous drugs with very high risk (compared to) benefits ratio are misused and overused, unwarranted high incidence of iatrogenesis is bound to occur.

.....17/

In USA where the drug control and the prescription practices are much better controlled, the incidence of iatrogenesis is very high. One in 5 hospital admissions are known to be due to iatrogenesis. In India we have such a high degree of self prescription, prescription writing by unqualified health personnel and by qualified personnel who are made highly biased by drug representatives. This along with poor drug controls ensures drug misuse, overuse and iatrogenesis. Most cases of iatrogenesis are not diagnosed in India. This of course does not imply that they don't exist.

Most of the combination drugs have 2 or more ingredients. It is known that with consumption of over 6 drugs compared to 2, chances of drug interaction increase by 40% as compared to 5% .

I. Drug Information for health personnel and consumers possible:

With 30,000 drugs in the market it is impossible not to be confused about them. A doctor may be familiar with the drugs he or she uses routinely. Unfortunately he or she cannot be so with the various brands used by others. Their prescriptions are often taken from one doctor to another by critically or chronically sick patients.

Confusion abounds, since majority of the health personnel have no access to pharmaceutical index to figure out what drug has been given. Majority of the drugs in the market, are combination drugs. Lack of familiarity with the contents and their dosages makes matters worse. If prescription practices for the majority of the health problems could be based on essential drugs? Relevant drug information about their relative cost, dosages, indications, contraindications, side effects and toxicity could be made available to health personnel and consumer caution be ensured?

Studies also indicate that it is impossible to remember details of even 100 drugs in routine practice. Ensuring that these prescribed drugs are the ones that people need and not what are most heavily pushed by the drug companies because of their profitability, is our responsibility. Focussing on all aspects of essential drugs and rational drug use in medical education would ensure their better use which would be better for the nation and the patients.

J. Ensuring better quality control:

There are 30,000 formulations in the market. Most of them are combination drugs and one in 5 drugs in the market is substandard. With a lesser number of drugs in the market which are single ingredient drugs quality control can be better streamlined. Making profits by promoting unessential drugs is crazy, but to make inadequate number of essential drugs available, with even these being substandard, is really unacceptable.

K. Ensuring generic prescribing:

Generic prescribing is recommended by WHO itself as it cuts down drug costs.

Pharmacology input during medical education, nomenclature used in medical literature and medical journals is based entirely on generic names.

.....18/

With a restricted essential drug list generic prescribing can definitely be ensured. The pharmaceutical industry and government drug control authorities would have to take greater responsibility to ensure quality control AT ALL LEVELS. Brand name prescribing is no solution for substandard drugs. Brand names do not prevent spurious drugs entering the market as most spurious drugs are imitations of well known brands. Name of the specific drug house can be written if it is felt absolutely necessary. Generic prescribing is possible with single ingredient essential drugs which are quality controlled.

L. Subsidizing costs of essential drugs:

With restricted list of drugs meant for the health needs of the majority, subsidizing is possible by removing sales tax, excise duty and octroi for these. Any loss in the taxes can be compensated by increasing taxes on cigarettes, alcohol and other such anti-health products or more so on luxury items meant for the rich. In conclusion, demanding an essential drug programme is aimed at focussing attention and giving priority to health needs of the majority.

CONCLUSION/SUMMARY

Demanding priority production and distribution for essential drugs is accompanied by demand for a just health care delivery system. We know that a just health care delivery system cannot exist in isolation in a socially unjust system. Demand for essential drugs before unessential drugs is accompanied by demand for employment, fair wages, food, water, sanitation and all that goes to ensure good health. Our fight for essential drugs and health care as a fundamental right of every Indian, specially the deprived sections is a fight against the injustice of the present socio-political system, which in reality accepts this deprivation of health and basic health care as a normal phenomenon.

E-4/378(c) LCD & RT
VHAI:pt:19.7.'84

Annexure III

PRODUCTION OF ESSENTIAL DRUGS BY MULTINATIONALS AND ORGANIZED SECTOR

Name of the firms	INH	PAS	THIACITAZONE	ETHAMBUTOL	RIFAMPICIN	STREPTOMYCIN
Abbott	Nil	Nil	Nil	Nil	Nil	Nil
ACCI	Nil	Nil	Nil	Nil	Nil	Nil
Hoechst	Nil	Nil	Nil	Nil	Nil	Nil
S.K. & F.	Nil	Nil	Nil	Nil	Nil	Nil
Searle	Nil	Nil	Nil	Nil	Nil	Nil
Sandoz	Nil	Nil	Nil	Nil	Nil	Nil
Roche	Nil	Nil	Nil	Nil	Nil	Nil
Parke-Davis	Nil	Nil	Nil	Nil	Nil	Nil
Sarabhai	Yes	Nil	Yes	Yes	Nil	Yes
Beohringer Knoll	Nil	Nil	Nil	Nil	Nil	Nil
Glaxo	Nil	Nil	Nil	Nil	Nil	Yes
E. Merck	Nil	Nil	Nil	Nil	Nil	Nil
Ciba-Giegy	Nil	Nil	Nil	Nil	Nil	Nil
Pfizer	Yes	Yes	Yes	Nil	Nil	Yes
Warner	Yes	Nil	Nil	Nil	Nil	Nil
Burrough Wellcome	Nil	Nil	Nil	Nil	Nil	Nil
German Remedies	Nil	Nil	Nil	Nil	Nil	Nil
Cynamid	Nil	Nil	Nil	Yes	Nil	Nil
Ethnor	Nil	Nil	Nil	Nil	Nil	Nil

... Study on Proventive Disease in India ... prepared for the Drug Workshop in Jaipur, organized by VHAI

For sharing this endeavour, we are grateful to the following for their help and moral support in compiling the Essential Drug List.

- Prof. M M S Anuja, Head Department of Medicine, A I I M S (Temporary Advisor)- The use of Essential Drugs, Technical Report Series 685, WHO.
- Dr V S Mathur, PGI Chandigarh, Editor Drug Bulletin for i) providing the graded EMRO list for which he was a consultant
  ii) for providing the PGI drug formulary
  iii) for being with us at Pune Workshop -January 1982 where Pune Drug List was finalized.
- Dr Qasem of Gonosasthya Kendra, for having kindly complied to our request to send the graded Bangladesh drug list.
- Dr Joel Fernando, Medical School, Sri Lanka for providing the Sri Lanka drug list.
- Friends in Echo and Action Medeor who sent their lists.
- Late Mr John Agacy, Secretary Low Cost Drugs and Rational Therapeutics, who tediously typed the first draft of the Comparative Essential Drug list in alphabetical order.
- Alphonse our Secretary of Low Cost Drugs and Rational Therapeutics for typing this comparative drug list based on WHO format.

85.16.

Voluntary Health Association of India

C-14, Community Centre
Safdarjung Development Area
New Delhi-110016

Telegrams : VOLHEALTH
New Delhi-110016
Telephones : 668071
668072

D-10/340(b)
LOD/25.5.84

Rationality in Banning Fixed Dose Combinations

M C Bindal, R.S Saxena(Mrs), Suman Lata(Mrs) & B P Jaju
Dept of Pharmacy & Pharmacology,
LLRM Medical College, Meerut.

Hathi Committee (1975) appointed by Government of India pointed out that the medicinal needs of the people in India can be met by only 116 drugs. However, over 25,000 drug formulations continue to be sold and prescribed in India. Many of these formulations are unnecessary variations of identical basic drugs sold under different brand names or without any proven therapeutic effect or they are too toxic for human consumption. Unless there is a clear cut proven therapeutic superiority or a fixed dose combination, such combinations not only put financial hardship to poor patients but also expose the patients to the undesirable effects of the unnecessary medicament(s) of such formulations. Dr H Mahler, The Director General of WHO feels that 98 % of the drugs available in the developing world are not essentials hence not required. The Drug Technical Advisory Board (DTAB) of India has recently (1982) recommended the weeding out of the following fixed dose combinations with an uniform cut off date of March 31, 1983.

1. Fixed dose combination of amidopyrine.
2. Fixed dose combinations of vitamins with antiinflammatory agents and tranquilizers.
3. Fixed combinations of atropine with analgesics and antipyretics.
4. Fixed dose combinations of strychinine and caffeine in tonics.
5. Fixed dose combinations of yohimbine strychnine and testosterone and vitamins.
6. Fixed dose combinations of iron with strychnine and arsenic and yohimbine.
7. Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.
8. Fixed dose combinations of ayurvedic, unani drugs with modern drugs.
9. Fixed dose combinations of phenacetin.
10. Fixed dose combinations of antihistaminics with antidiarrhoeals.
11. Fixed dose combinations of penicillins with sulphonamides.
12. Fixed dose combinations of vitamins with analgesics.
13. Fixed dose combinations of tetracycline with vitamins C.
14. Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery.
15. Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for the treatment of asthma.
16. Fixed dose combinations of chloramphenicol except with streptomycin.
17. Fixed dose combinations of ergot except combinations of its alkaloid ergotamine with caffeine.
18. Fixed dose combinations of prophylactic vitamins with anti-TB drugs except combinations of INH with vitamin B_6 .

The rational for the undesirability of the above said fixed dose combinations can be based on the forthcoming arguments and facts.:

COMMUNITY HEALTH CELL
47/1,(First Floor)St. Marks Road

1. Fixed Dose Combinations of Amidopyrine:

Fixed dose combinations of amidopyrine(amidopyrine) are irrational because amidopyrine is an outdated and obsolete drug as it causes bone marrow depression leading to agranulocytosis which may be fatal(Beaver 1965). Even though it has marked antipyretic and analgesic properties, its "over the counter" sale in the United States had been prohibited since 1938(Moodbury 1970). In view of the recent development of newer and safer antipyretic analgesics, it is in public interest to drop out amidopyrine altogether from physicians armamentarium.

2. Fixed Dose Combinations of Vitamins with Antiinflammatory Agents and Tranquilisers:

The addition of vitamins to antiinflammatory agents and tranquillisers in fixed dose combinations does not yield any proven increases in the therapeutic effects of these combinations. In a way they are just like placesbos but certainly enhance the cost of formulations. In most of the patients requiring either antiinflammatory or antipsychotic therapy, vitamin deficiency is not an usual associated feature even in our country where malnutrition is so prevalent. Hence vitamin supplementation with these drugs is both a waste of vitamins as well an unnecessary financial burden for the patients.

3. Fixed Dose Combinations of Atropine with Analgesics and Antipyretics:

Analgesics and antipyretics reduce the raised body temperature to normal(antipyresis).But Atropine is known to cause hyperpyrexia (ie. it may raise the body temperature). Hence such combinations is therapeutically antagonistic and is therefore irrational. Furthermore, even in cases of visceral pain (eg. colics), where atropine may be advised with the idea of its antispasmodic property, simultaneous administration of an antipyretic analgesic, which is ineffective against visceral pain has hardly any therapeutic advantage. All the more such combinations unnecessarily expose the patients to the potential toxicity of antipyretic analgesics.

4. Fixed dose Combinations of Strychnine and Caffeine in Tonics:

Fixed dose combinations of strychnine and caffeine in tonics areundesirable because strychnine (formerly used as an appetiser) is now an obsolete drug and its enthusiastic use in tonics may even induce convulsions particularly in susceptible individuals. Similarly caffeine though, has a mild CNS stimulant effect leading to little temporary mood elevation and relief from fatigue, has no tonic effect on the body. Furthermore caffeine products mild physical dependence and habitual use of this drug in tonics may cause psychological and physical dependence for such formulations.

5. Fixed Combinations of Yohimbine, Strychnine with Testosterone and Vitamins:

Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins are irrational because yohimbine is no longer regarded as therapeutically useful aphrodiasiac in man even when mixed with methyltestosterone(Laurance,1980). Furthermore, yohimbine should not be used therapeutically because of its side effects viz Central excitation, raised blood pressure, increased heart rate. Strychnine is also now an obsolete. Vitamins do not play any therapeutic role(except in deficiency diseases) and simply act as placebo, of course, giving the psychological boost to the patient.

6. Fixed dose Combinations of Iron with Strychnine, Arnica and Yohimbine:

Strychnine, arnica and yohimbine combinations are used as stimulant appetizers. In most of the patients (except women) generally there is no deficiency of iron because iron is adequatly stored in the liver. However, in very specific anaemic cases supplemental iron therapy may be given separately. To add iron in these formulations is irrational and may be just for the purpose of increasing the price of the formulation or to seek patient rights for the formulations.

7. Fixed dose combinations of Sodium Bromide/Chloral Hydrate with other drugs:

Fixed dose combinations of sodium bromid/chloralhydrate with other drugs can now be considered irrational because both these drugs are now obsolete due to their toxic manifestations; Bromides on prolonged administration replace the chloride ions of the body. Because of the slow onset of action, cumulative poisoning, manifesting as conjunctivitis, GIT symptoms, dermatitis and mental disturbances is likely to occur. Further their exeeding slow onset of action and low potency make these bromides unreliable hypnotics.

Chloral hydrate, being an irritant of the mucous membranes, causes gastritis leading to a variety of GIT symptoms eg.nausea vomitting flatulence and epigastric distress. Chloral hydrate can even cause hepatic and or renal damage! In view of the recent and more safer hypnotics there is now no justification of prescribing chloral hydrate to patients.

8. Fixed dose combinations of Ayurvedic and Unani drugs with Modern drugs:

The modern (Allopathic) drugs are well, standardised and their standardization methods are official. In case of ayurvedic and unani drugs, official standardization methods are not available at present. Therefore, it does not argue well to have a combination of ayurvedic and/or unani drugs with modern drugs bevause of the standardization problems of the resulting formulations. In view of the lack of authentic repeatable research data on the efficacy of fixed dose combinations of ayurvedic and unani drugs with modern drugs, there is no justification of such formulations to be sold for use by the general public.

9. Fixed dose combinations of Phenacetin:

Phnacetin is gradually loosing its importance because it causes kidney damage when used in large amounts or for long periods. Hence it has no place in routine analgesic, antipyretic and antiinflammatory therapy. Therefore, fixed dose combinations of phenacetin are outdated and hazardous. Formulations containing aspirin with phenacetin and often with caffeine are promoted with claims that they provide greater analgesic effect and/or cause fewwer side effects than does aspirin alone. In most controlled clinical trials such claims have not been found correct.

10. Fixed dose combination of Antihistaminics with Antidiarrhoeals:

The fixed dose combinations of antihistaminics with antidiarrhoeals is rational, only in certain specific cases where the diarrhoea is due to allergy(like protein allergy). In these specific cases, the antihistaminics may be prescribed separately so that such combinations are not irrationally used in the treatment of all other types of diarrhoea. Routine use of these

combinations is not only a waste of antihistaminic drugs but also it exposes the patients to the undsirable effects of this class of compounds.

11. Fixed dose combinations of Sulphonamides with Penicillins:

Even though sulphonamides and penicillins individually do have important role in the therapy of infections. The combination of penicillin with sulphonamides is undesirable. This is because the antagonism of the antibacterial effect may result when bacteriostatic (Sulphonamides) and bactericidal(Penicillin) agents are given concurrently,(Jawetz and Gunnison, 1953). In addition oral combinations may even induce penicillin sensitivity.

12. Fixed dose combinations of Vitamins and Analgesics:

In the fixed dose combinations of vitamins with analgesics, the vitamins do not play any therapeutically beneficial role and rather act as placebo. Therefore, such combinations are therapeutically irrational. Since such formulations are likely to be misused by the patients and if administered for long periods because of their vitamin contents, such combinations are likely to expose the society to a veriety of undesirable effects of analgesics.

13. Fixed dose combinations of Tetracyclines with Vitamin C:

There is no specific therapeutic indication of giving tetracylines and vitamin C together because tetracyclines [illegible] does not cause any specific vitamin C deficiency. Therefore, this combination is of no therapeutic superiority and may be produced by drug companies just for enhancing the cost of their product. Further, in inffective conditions where tetracyclines are indicated, vitamin C deficiency is not an usual associated feature, such formulations should not be routinely employed.

14. Fixed dose combination of Hydroxyquinolines group of Drugs except preparation which are used for the treatment of Diarrhoea and Dysentery:

Halogenaled hydroxyquinolines are indicated only in intestinal infection like amoebiasis. So the combination of hydroxyquinoline with some other antidiarrhoeal and antidysentery drugs like enzymes for the treatment of dyspepsia is undesirable because hydroxyquinolines may induce Subacute Myelooptic neuropathy(SMON). Due to this toxic manifestation the use on this drug in clinical practice has been abandoned in many advanced countries. The clinical use of these formulations for such simple conditions like dyspepsia exposes these patients to the risk of SMON and hence should not be employed.

15. Fixed dose combinations of Steroids for Internal use except combinations of steroids with other drugs forthe treatment of Asthma:

In view of the acute onset of the benefical effect of steroids in a large number of clinical conditions, their use has tremendously increased in recent years. However, fixed dose combinations of steroids with other drugs are objectionable as it is extremely important to adjust the steroid dose to the minimum that produces the desired effect and the dose of the other drug if altered, not on the patients need for it (other drug) but on his need for steroid. In view of the widespread use of such combinations, the patients are exposed to toxic cumulative effects of these drugs. However, in case

of asthma, since immumological factors play an important role and adrenal steroids cause nonspecific reducation of the response to the antigen antibody reactions, the fixed dose combinations of steroids with other drugs in the treatment of asthma is therapeutically rational and justified.

16. Fixed dosecombinations of Chloramphenicol except with Streptomycin:

Chloramphenicol is a drug of choice only in the treatment of enteric fever and gastroenteritis. Its combination with streptomycin in the treatment of gastroenteritis is therapeutically justified because this combination has been found therapeutically superior to either of these drugs alone in the treatment of mixed infections of the gastrointestinal tract. But combination of chloramphenicol with other drugs(like tetracycline) is irrational because both the drugs have almost the same antimicrobial spectrum and also because chloramphenicol is more toxic as it may cause aplastic anaemia.

17. Fixed dose combinations of ergot except combinations of its Alkaloid Ergotamine with Caffeine:

Ergot alkaloid, ergotamine is effective in the treatment of migrains because it is a vasoconstrictor agent and prevents the rhythmic distension of extracranial arteries.

Caffeine may be allowed in combination also because of its vasoconstrictor effect on intracranial vessels. However the combination of ergotamine with other drugs(like paracetamol, prochlorperazine etc) have no therapeutic advantage and hence irrational.

18. Fixed dose combination of Prophylactic vitamins with antitubercular drugs except combinations of I N H with vitamin B_6:

Fixed anti tubercular drug (except INH) are irrational becuase in these combinations, the vitamines have on therapeutic role to play (of course unless there is a vitamins deficiency) and they simply act as placebo and might give some psychological boost to the patient. However, because INH causes vitamin B6 deficiency, its combination with vitamin B6 is rational and therapeutically justified.

Another drug combination which has been recently banned in this country after a much hue and cry from the medical experts is that of Estrogen Progesterone (E P combinations). These combinations were used for test for pregnancy. The use of E P hormonal preparations were banned in U S A by the Food and Drug Administration (FDA) in 1975 because these preparations were found to seriously damage the foetus.

It is often alleged that drug companies levy a heavy burden on the common man by charging more and more through their dubious multiple drug formulations which are their patented products. For example, the real pain killer in most ofthe analgesic tablets is aspirin, the market is flooded with a number of costlier pain killers containing in addition salicylamide, caffeine and quinine sulphate, which have no proven synergistic efficacy. Similarly, amongst anti-cold ointments, only menthol is said to be of any real therapeutic value. Here too, other ingredients of dubious value like camphor, turpentine and thymol are often added in order just to put in market a new formulation and thus increase the price of such a patented formulation.

In our opinion such anti-social problems must be tackeled at all levels. The responsible persons of the society in the medical and health field, like doctors and pharmacists should keep a close watch on the drugs banned inthe developed countries and also on the drugs which on clinical trials have not been found safe and effective. These responsible men should convey all the clinical information on such drugs or their combinations to the appropriate authorities of the Government of India.Though the Drug Technical Advisory Board(DTAB),Drug Consultative Committee(DCC) and Director General of Health Services(DGHS) have been entrusted with this job by the Government of India but other responsible men in the medical field will also have to keep a vigil so that there is no oversight on the part of the official machinery and the harmful and obsolete drugs from developed countries are not dumped in our country any longer. The World Health Organization(WHO) should also play an effective role inthis regard and ensure that only safe and effective drugs are sold to member countries. In addition, the government must adopt the recommendations of WHO on essential generic preparations. In a developing country like ours, the goal must be to ensure availability of essential drugs to patients and health education to all about safe water, sanitation and finally sufficient nutritious food.

However, the major problem lies in the fact that a large number of drug formulations in India have not been adequately evaluated for their safety and this again emphasises the need to exercise strict quality control . This becomes much more significant in the light of the recent statement by the Government in Rajya Sabha that 17.5% of the drug manufactured and sold in the country in the last three years were found to be substandard.

Over all, if employment of such fixed dose combinations aids the busy physician and does not significantly represent a lessoning of his individualized orientation to his patient and are rational from the therapeutic point of view, they are a boon to therapeutics otherwise a curse to the patient and the society.

REFERENCES:

Woodbury, D M (1970) Analgesics-Antipyretics, antiinflammatory agents and inhibitors of uric acid synthesis in The Pharmacological basis of therapeutics by Goodman, L S and Gilman, IV Edition, The MacmIllan Company, London, pp 314-347.

Beaver, W T(1965) Mild analgesics: A review of their clinical Pharmacology. Am J Med Sci 250, 577.604.

Jawetz E and Gunnision J B (1953) Antibiotic synergism and antagonism: an assessment ofthe problem .Pharmacol Rev.5,175-192

Laurance, D R(1980) Clinical Pharmacology, Ed fifth, E L B S Publication, Churchill Livingstons, pp 331, 536,552,617,848

Source: The Eastern Pharmacist-June '83.

Circulated by the Voluntary Health Association of India
for Drug Action Net Workers for information
and necessary action.

Voluntary Health Association of India

D-10/340(c)
LCD.a.20.7.84

C-14, Community Centre
Safdarjung Development Area
New Delhi-110016

Telegrams : VOLHEALTH
New Delhi-110016
Telephones : 668071
668072

HAZARDOUS, BANNED, BANNABLE AND DUMPED DRUGS

(Prepared for Drug Action Core Group meet at Wardha 30-31st July '84 as a Background paper for discussion)

The issue of dumped drugs for past few years has been much in the news. The multinationals involved in manufacture and sales of such drugs have received their dure share of condemnation. Foreign government policies which provided the scope for exports of such hazardous products have been condemned by many of us eg. the Clayton Amendment Act and the U.S. Resolution.

It is well known that sales of medical technologies and drugs is a commercial enterprise, the motivation is profit making and not 'service' or 'welfare work'.

Realizing all this the question arises as to how much as citizens of India, can we expect our drug control authorities to safe guard our interests. The pressure from the drug industry is immense. It is not merely money power but political connections & influence over the medical lobby. Many of the so called medical experts are in their pay roll, many others are conducting 'scientific studies' sponsored by the companies, attending conferences sponsored by the companies, receiving gifts and samples from the companies. This affiliation is not unexpected. Inspite of knowing this our expectations from our drug control authorities is high. After all our pharmaceutical industry is the most developed in the third world, (ie according to UNIDO it belongs to Category 5,- developed enough to be self sufficient).

We have demanded that our imports, production and sales should give priority to essential, life saving drugs over irrational and hazardous drugs. This being along with WHO's guidelines for Essential drugs programme. The drug industry and its supporters allege that concept of essential drugs is only for struggling, least developed third world countries and not for a country like India, with its well developed industry and high and advanced level of medical expertise .However, this same lobby puts India in the category of less developed countries when it comes to the issue of banning drugs and drug control, claiming that considerations of hazards over efficacy are luxuries which we cannot afford!

However, consumers anywhere in the world have a right to expect that irrational hazardous drugs are not issued licences and that licenses of such banned drugs should be withdrawn as soon as possible, bans implemented, and that all drugs in the market are quality controlled. We have 20% substandard drugs ie in 5 will not be effective With increasing number of spurious drugs floating in the market, the problem is beginning to take dangerous proportion.

Since 1980 we've been concerned about this issue of dumped and hazardous drugs. We widely circulated the list of combination drugs recommended for being weeded out and printed it in our special issue of HFM on Drugs April-June 1981. Since then the story of the drug ban has got more and more convoluted and fascinating. Our earlier belief is only reconfirmed that the government is not serious about controlling the sale of

hazardous drugs. The budget allocation for ensuring this, the expertise, technical personnel, quality control labs, qualified drug inspectors, mechanism to keep the health personnel and the public informed about these drugs has remained depressingly inadequate. Inspite of all the hue and cry raised by health and the consumer groups, nothing very much has happened.

The health of the nation seems to be relatively unimportant, as indicated by decreasing health budget. The Central Drug Contrl authorities allege that they have no real powers where implementation is concerned as this depends entirely on the state drug control authorities. They argue that they have inadequate budget and infrastructure.

Expenditure on Health as a percentage of total plan

Programme	FYP I 1951-56	FYP II 1956-61	FYP III 1961-66	FYP IV 1969-74	FYP V 1974-79	FYP VI 1980-85
Health sub-total to plan	3.83	3.04	2.79	2.74	1.73	1.87

One glance at what is happening to the health budget is enough to indicate the priorities health care is receiving in our welfare state.

We have 600 drug inspectors in the country (Hathi Committee has recommended). The required number is one for drug units and chemist shops. Only Maharashtra, Gujarat and Kerala have the stipulated number of drug inspectors and an adequate drug control mechanism.

In this paper we will not touch upon the extent of the problem of substandard and spurious drugs and the name-sake action being taken against those involved in their produce and sales.

Our focus will be on what has happened to the drugs recommended for being weeded out in 1980. In 1980 the Drug Consultative Committee a statutary body consisting of medical experts under Section 7 of the Drugs and Cosmetics Act(Central act 23 of 1940) nominated a subspecial committee to go into the rationality of 34 categories of fixed dose combination drugs. They were to study whether these drugs should be withdrawn or allowed to be manufactured and sold.

The criteria used by the Committee is very sensible and straightforward. A Sub Committee of the Drugs Consultative Committee, comprising state drug controllers, has laid down well thought out and rational yardsticks to determine the desirability of combinations of drugs. As per these norms, combinations of drugs should only be allowed in the following cases:

a) If there is synergistic action
b) Where there is corrective action
c) When two or more drugs are normally prescribed together and taken by the patient simultaneously.
d) When the dosage of each of the drugs need not be individualized.
e) Where a fixed dose combination would ensure better

patient compliance due to convenience of administration.

f) Where two or more drugs, prescribed separately, may lead to non ingestion of one of the drugs, thus adversely affecting the health of the patient.

Conversely, fixed dose combinations of drugs should not be permitted under the following circumstances:

a) Where adverse interactions may occur
b) When one of the combined drugs becomes toxic on prolonged use
c) When abrupt withdrawal of one of the drugs caused withdrawal symptoms
d) If sub therapeutic doses are used in the absence of clinically demonstrable synergism
e) When pharmacokinetic behaviour of the individual agents is grossly different.

The criteria used by Bangladesh for banning 1742 drugs is given in the appendix 1.

We'll just look at what was involved in attempts to ban a few drugs eg. Amidopyrines, High dose E P drugs, Paediatric tetracyclin. Steroid combinations are dealt with later under ambiguity is the name of the game.

The sub committee submitted its report, recommended a ban of 23 combination drugs and giving their reasons for recommending the ban. 16 categories of these drugs were recommended for immediate weeding and 7 of the categories to be weeded over a specified time. Over 500 brand drugs would thus be affected (This list of 23 combinations and the reasons are attached in the appendix). This report was presented to the DCC at a special meeting on 10.10.81 which and later to DTAB and Ministry of Health and Family Welfare accepted it in 1981. The DTAB(Drug Technical Advisory Board) a Statutary body under section 5 of the Drugs and Cosmetics Act Central Act 23 of 1940 recommended banning of 18 fixed dose combination(list attached as appendix 2)

Under section 23 P of the Drugs and Cosmetics act 1940 the Central government has had the powers to issue such directions to the State governments as required to execute the Drug act. Under section 18 of the act the state government has had the power to 'prohibit manufacture,distribution and sale of drugs by a gazette notification.

These drugs were randomly selected from the Pharmaceutical Guide. Out of these 350 brands 44 brands were marketed by foreign sector, 8 by public sector and 298 by private sector. A point to note is that most of these drugs were being produced by private Indian companies and not multinationals. This was to be ' inphased ' discontinuation. According to the authorities"the purpose was to give time limit to firms who may have already purchased the bulk drugs for manufacturing the formulations". What compassion and consideration shown to the drug companies?

AMIDOPYRINE

The Drug Controller of India(DCI) by DO No.1273/77 DC directed the State Drug Controller to ban the fixed dose combination of amidopyrine on effect from 3.2.82. Orders were issued to stop manufacture from 1st July '82 and sale by October 31st '82. This ban was later extended further to 31.3.83.

The DCI through his DO No. 19013/8/81D dated 22.4.82 directed the State Drug Controllers to ban the manufacture of fixed dose combinations from 30.9.82 and their sales from 31.3.83. Sequal to W.C Same panel report government decision to withdraw 350 unnecessary drugs was taken.

When Maharashtra FDA did ban amidopyrines, the multinational most affected managed to get a stay order on the grounds that the drug was allowed to be marketed in other states by their state FDA's. In 1980 33 formulations of amidopyrine produced by 20 so manufactures were in the market. Multinationals and other big drug houses highly trusted by the public such as Suhri Geigy, Sandoz, Suhudgeigy, Unichem, Ethnor, Thems, Indon were involved. Most of these drugs were being sold without adequate warning.

As Praful Bidwai on 19th August 1980 stated in the Financial Times Harmful drugs production still not stopped,"... reluctant to lose their market share, these companies have merely continued to produce and market amidopyrine and are continuing to sell their preparations without even an additional warning about the drugs side effects.

Mukaram Bhagat Centre for Education and Documentation, in 'Aspects of Drug Industry in India' gives the example of Tamilnadu government medical list for government hospitals in which drugs like amidopyrine, phenacetin and analgin are very much included even when they were considered harmful and been disallowed.

PHENACETIN AND HOLOGENATED HYDROXYQUINOLINE:

Ban of fixed dose combinations of phenacetin and hologenated and hydroxyquinoline was to be effective from 1.11.82. The date of the ban of fixed dose combination of amidopyrine, phenacetin and halogenerated hydroxyquinolines was extended to 31.3.83 through DO No. X19013/8/81-D dated 13.8.82.

In 1979 January the Drug Controller of India had issued an order to gradually phase out amidopyrine as always 'phased discontinuation' process was not meant to be implemented as there were no specific DEADLINES.

HIGH DOSE OF E P DRUGS:

Through another DO No. 12-48/79-DC dated 26.6.82 the DCI directed the State Drug Controllers to ban the manufacture of high dose estrogen and progesterone combination from 31.3.83 and their sales from 30.6.83.

M/S Unichem Labs Bombay (OP 2927/82 of writ petition 2928/82), M/S Nicholas Labs Bombay and M/S Organon (now known as Infar (India)Ltd Calcutta filed writ petitions in Bombay and Calcutta high courts against the DCI's instructions to ban these drugs, their contention that Central government has no powers to ban the drugs. The high court of Bombay and

Calcutta have granted stay orders and these products continue to be available in the market.

Even though section 10A and 26A of the amedned Drug and Cosmetics Act (April '82) empower the Central Government to prohibit import, manufacture and sale of any drugs considered harmful/toxic or irrational etc. Since the matter regarding high dose E P drugs was in the court, these drugs have NOT been included in the gazette notification of the DCI issued on 23.7.83 banning 22 fixed dose combinations.

What is absolutely objectionable is the fact that(this is inspite of the act of the Drug Controller of India's earlier instruction dated 26.6.82 banning the production and sales of high dose E P drugs from 31.3.83 and 30.6.83) M/S Organon (INDIA) Ltd have managed to obtain extention of licences to manufacture these products for another 2 years.

A sample of high dose E P drugs from Calcutta with manufacturing date 31.12.83 indicates that the ban is not merely being flaunted by Organon but by other drug companies manufacturing these products.

The misuse of these drugs for hormonal pregnancy tests and for attempting to induce abortions continues massively.

PAEDIATRIC TETRACYCLIN

Manufacture of Paediatric tetracyclin drops was to be banned from 1.5.82, no date was then given for marketing. Paediatric tetracyclin have since been banned on paper. They are still available, OTC, without warning.

Paediatric tetracyclin ban too does not figure in the gazette notification of July 23rd 1983.

On April '82 the Drugs and Cosmetics Act was amended whereby the Central Government and the Central Drug Control Authorities were given specific powers to 'ban the import, manufacture and sale of drugs in public interest'.(This was mentioned in the Drug Action Network Newsletter October '83).

Section 3(b)(i) was substituted and section 10A and 26A were inserted in the act. This came into effect from 1.2.83. This means that had our Central Drug Control authorities wanted it, gazette notifications banning the manufacture and sale of these drugs could have been undertaken immediately under the powers invested in it under section 26A of the act exercised.

The implications of this delay have been that certain drug companies have challenged the drug Controller of India's authority to ban these drugs. Some of them have even got stay order against specific bans, making these bans ineffectual and the whole drug control authority of our nation a laughing stock. The drug control authorities see their role as mainly advisory and hence don't feel particularly perturbed. Actually to come to think of it no one in the Health Ministry at Centre or State level seems to be particularly perturbed.

Allowing this extended time period, during which imports manufacture and sales have continued amounts to 'arbitoriness and discrimination' under article 14 of Constitution of India.

according to Vincent Panikulangara since these drugs would be dumped in the market, substitutes withheld. With our efficiency of drug control mechanism, products in the chemists shops will continue to be sold and never withdrawn.

According to Section 26A of the Drugs and Cosmetics Act 1940

> "Without prejudice to any other provisions contained in this chapter, if the central government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then that government may, by notification in official gazette prohibit the manufacture, sale or distribution of such drug or Cosmetic".

Under section 10A of Drugs and Cosmetics Act of 1940 also there is a mandate that following a gazette notification imports of injurious drugs can be banned.

> Article 47 of the Constitution of India lays down that
> "The State shall regard the raising of the level of nutrition and standard of living of its people and the improvement of public health as among its primary duties and in particular the state shall endeavour to bring about prohibition of the consumption except for medical purposes of intoxicating drinks and of drugs which are injurious to health".

Under section 53 P the DCI directed the State Drug Controllers to ban the 20 fixed-dose combinations. The State Drug Controllers under section 18 of the act could exercise their power and prohibit their manufacture and sales by issuing a gazette notification. According to Vincent Panikulangara, the State Drug Control authorities are guilty of not exercising their power and taking responsibility. They have thus violated section 18 and 33 of the Drugs and Cosmetics Act and violated the fundamental right of the public citizens to health and life under section 21 of the Constitution of India. Article 14 of the Constitution is also violated by their having acted in a arbitrary and discriminatory manner contrary to public interest, in favour of the Drug companies.

Kerala High Court Judge Mr Potti's judgement on Vincent Panikulangara's writ petition speaks for itself.

> "As between the lives of the citizens of this country on the one hand and loss that may result to the manufacturers and traders by the immediate ban on the manufacture and sales on the other, the government had chosen to view the latter as of more concern". It is the duty of the state to protect its citizens from injury and harm especially

when the injury is not inevitable".

- Acting Chief Justice P Subramanian Potti and Justice Paripuran Kerala High Court, in their directive to the Union of India to release the list of brand names of banned drugs.

In October 1982 M/S Nicholas(India)Ltd Bombay filed a writ petition in Bombay High Court against the decision to ban the fixed dose combination of aspirin and vitamin C. The Bombay high court after the hearing of the respondent ruled that State Drug Control authorities has no power under Section 18 of the Drugs and Cosmetics Act to stop the manufacture and sale of these products.(The high court ruled that it would be open to the respondents as and when the law has been enacted to pass any fresh order as it is considered necessary in accordance with the law after following procedures prescribed by the government).

Subsequent to the Drug Amendment Act coming into force on 1.2.83 the manufacturers have again gone to court challenging the central government and sections 26A and 10A of on grounds of "LACK OF OBJECTIVE CRITERION for such ban".(A special handout on Rationale of the ban is available with us).

The Commissionor of FDA Maharashtra State(which is supposed to be having the best drug control mechanism) had informed the DCI that in the light of the ruling given by the Bombay High Court "it would not be possible for him to take any action to stop the manufacture and sale of any of the fixed dose combinations in question".(Letter dated 9 June 1984 by Drug Controller of India to us).

It was probably the above as well as Vincent's writ petition against the state and central drug control authorities for not having used their power that forced DCI to issue the gazette notification. A point to note is that drugs banned earlier and at different types make the brand banned list. E P drugs are not included in the gazette notification.

The ambiguidty of the wording of the gazette notification hit us early, when we attempted to compile the banned brand list. It was not clear whether for eg. in Category 4 include
- any drug containing yohimbine or strychnine would be banned (as neither of the two were considered to have therapeutic value and infact could lead to serious side effects as stated even by the DCC).
- or the ban was applicable to drugs containing both yohimbine and strychnine.
- or to yohimbine and strychnine with testesterone or vitamins
- or ONLY to drugs which contained all 4 ie. yohimbine, strychnine, testesterone and vitamins.

Another doubt was regarding criteria 12 ie. whether it could effectively deal with steroid and antihistamines combination which could be indicated for allergy as well as asthma. First of all DCC had recommended a ban of all steroid combinations. Making this exception would obviously encourage misuse. After all doesn't the microscopic print in the medical literature for high dose E P drugs now-a-days say only secondary amenorrhea and isn't it true that it is mostly used for pregnancy testing and attempting abortion, changing the indication

on paper of a hazardous drug won't alter its use. Similarly allowing steroid combination for asthma won't prevent their misused for other conditions.

The DCC had recommended banning of all fixed dose steroid combination, DTAB decided to prohibit manufacture of fixed dose combination of bronchodilators, antihistaminics and tranquillizers with corticosteroids as early as October 4, 1980.

Dr B Shankaranand, the then DGHS, chairing a meeting had said "The current medical practice in all the developed countries is to give corticosteroids separately and fixed dose combinations of corticosteroids with other drugs are being discourraged".

Prof. Harkishan, Singh of the Department of Pharmaceutical Sciences Punjab University stated that there existed "published evidence to show that cortico steroids taken in small doses over longer periods are more harmful than if taken in larger doses over shorter time".

The Drug Consultative Committee comprising of all state Drug Controllers entrusted the responsibility of evaluating 34 categories of fixed dose combination, on basis of their rationality to a sub-committee. The sub committee comprising of some distinguished medical experts recommended a ban on steroid combinations. The Committee warned against compulsory intake of steroid because the "fixed dose combinations of steroids for internal use can produce serious side effects viz fluid and electrolyte disturbances, hyperglyceria glycosuria, increased suscesptibility to infection including TB, peptic ulcers, osteoporosis, steroid myopathy, cushings syndrome and Hersutism, combination with bronchodilators etc.".

On December 31, 1981, the Drug Technical Advisory Board constituting of exactly the same members reversed its own earlier decision. It felt that there was a need for getting wider medical opinion and further details and allowed the sales of these products.

Dr Gulati MIMS Editor in his editorial MIMS India Vol.2 No.3 February 1982 writing about the "somersault on steroids" says "they must have had very extraordinary reason to
a) reverse their own earlier decision
b) ignore the advise of DCC
c) consider the opinion of the whole battery of eminent and distinguished medical specialists from research institutions as inadequate so as to ask further details and wider medical opinion".

It would be interesting to find out how and why this change in their stand on fixed dose combinations of steroids took place. We would very enthusiastically have undertaken this exercise, had obtaining information such as this, been a less tedious, less time energy consuming and less frustrating affair.

The Kerala High Court judgement, in response to Vincent Panikulangara's writ petition OP 8439/1982 had directed the Central and State Drug control authorities "to publish the list of trade/brand names and the names of the manufacturers of these drugs. This was in 1982. Repeated requests for the same have been made to the Central Drug Controllers office. Some of the Drug Action networkers have been requested to do the same at the State level.

Excuses were made that the drugs have been licenced and registered with State health authorities and the centre allegedly has no clue about the various formulations and brands involved. The drug control mechanism is so inefficient that even to obtain just the list of, these products has taken more than one year. To ensure their ban or 'quality control' would definitely take a century.

It should be noted that the drug ban will be applicable for lesser drugs than what we had anticipated. Inspite of the presence of irrational and hazardous ingredients only those drugs will be banned that contain all the ingredients mentioned in the various categories eg. under category 5 -only those drugs containing all the following ie. yohimbine + strychnine + Testesterone + Vitamins will be affected.

According to Dr Das Gupta, Asst.Drug Controller the banned brand list will be ready in about 3 months. We had prepared our own black lists of banned or bannable drugs as far back as 1982 which have been circulated amongst the health care institutions in the voluntary sector and drug action networkers. These black lists have been for

1) Clioquinols, hydroxyquinolines ie. mexaform and Co
2) Amidonyrines - abalgen Ergopyrine
3) Paediatric tetracyclin
4) Diphenexylate - lomotil etc.
5) Anabolic steroids
6) Penicillin and streptomycin) In DCC recommendations
7) Chloramphenicol and streptomycin
8) High dose E P drugs
9) Antiinflammatory agents and steroids etc.

(Background papers based on the above underlined drugs had been prepared and are available).

2-3 attempts at compiling the banned brand list based on drug banned by the gazette notification have been made. Three things have prevented us from widely circulating them.

i) Our expectations from our drug control authorities to make them available at least after the Kerala High Court judgement and Supreme Court writ petition.
ii) The difficulty in obtaining the drug list of formulations from the State Drug Control authorities.
iii) The process of reformulation of various drugs taking place with our not having any information as to
   a) which drugs were being formulated and sold as reformulating?
   b) Which drugs were being reformulated but their banned formulations under the same BRAND existed were sold unscrupulously in the market?
   c) Which were the hazardous banned drugs still being manufactured and sold as such?

Our health and drug control authorities get extremely upset when we mention the achievements of Bangladesh in their attempts towards a Rational Drug Policy. Inforced to mention Bangaldesh again. It should be noted that after the issuing of the Promulgation banning 1742 drugs in June 1982 the time period given to the drug companies of 3, or 6 or 9 months was given to withdraw these products from the market, to destroy these products even their export to other countries was strictly prohibited. We on the other hand have failed to implement a recommended ban by our own government committees and banned by our own drug controller. The drugs banned were more few hundred, not over a 1000. The time period given was for the

drug companies to complete the manufacture of their formulations and sell off their stocks. The stocks surprisingly like Medusa's head never seem to finish off.

Nepal, Pakistan, Malaysia, Sri Lanka and Bangladesh feel that clioquinol (hydroxyquinoline) formulations have no significant therapeutic value and can have major side effects. They have decided to ban these drugs. Ciba Geigy makers of mexaform have announced their plans to withdraw the drug from international market. We continue to allow them to be sold and promoted under more than 90 brands (including those produced by our public sector.)

The Drug campaigners from Bangladesh, Sri Lanka have complained about the outrageous smuggling in of these banned products from India. Our continuing to allow the manufacture and sales of these hazardous and irrational products is not merely hazardous to the health of our people, it also creates problems for our littler neighbours who are attempting to rationalize their drug policies, in the interest of their people.

If our government authorities cannot make all that goes with ensuring good health, available to its 700 million people it has no business to allow irrational and hazardous drugs to be inflicted upon them.

We will compile our own banned brand list and while the game playing goes on between the health, drug control authorities of centre and state, and the drug industry and the high courts we will ensure that all these drugs are BOYCOTTED by health personnel as well as consumers.

The DCI had in one of his meetings last year pointed out that unhygienic conditions in the public hospitals, lack of clean water, sanitation quackery and unethical practices by medical personnel were greater problems than continuing sales of few hazardous drugs.

We want to make it clear that the issue here is not merely of banning a few hazardous and irrational drugs but it is to focus on what is going on in the name of 'health care'. It is to high light that when causes of ill health lie elsewhere in primarily dealing with them alone will there come about a significant change in the health status and quality of life of our people? There are no effective pills against poverty and the diseases of poverty. To deny people their right to health care is bad enough, but to let loose 'garbage and trash in the name of medical care is is inexcusable, inflaunting and totally unacceptable.

Dr Mira Shiva
Coordinator
Low Cost Drugs & Rational Therapeutics.

copy

85.19.

D-9/330(b)
LCD/a/16.7.84

Graded Essential Drug List

Explanatory Note:

These are the guidelines to help Community health programmes and health institutions draw up their own essential drug list.

This is a compilation of various drug lists and it emphasises the concept of Essential drugs. For those believing in and for those involved in alternative health care, the concept of Essential drugs is an integral part of health work.

The format used for this compiled list is based on WHO's Essential drugs list , Technical Report Series 685. An outline of it is given. It should be noted that certain drugs are repeated as they are used more than one disease entity.

The various drug lists as they appear in the compiled form are as follows:

EMRO(Eastern Mediteranean Regional Office)- WHO

List A - for 8th class passed
List B - for that are class 10 passed and have had training

Bangladesh drug list:

Category I - for village level workers
Category II - for Primary Health Care up to Thana complex level

CMC - Christian Medical Council list - Contact No.63, August 1981, "Getting Essential Drugs to the People"- Stuart Kingma.

Locost:- Low cost standard therapeutics a collective voluntary enterprise for rational therapeutics
C/O Amrl, G P O Box No.7, Vadodara 390001.

PU:- Essential drug list drawn up by sub-group dealing with this at VHAI's Pune Workshop "The Drugs Issues - seeking feasible alternatives".

PGI:- Formulary of Post Graduate Institute of Medical Education and Research.

SL:- Sri Lanka graded Drug list included here is list of drugs recommended for doctors incharge of Peripheral health centre.

G:- Gambia restricted drug list based on their national formulary.

Echo An English NGO supply equipment and drugs to Charity Hospitals overseas.

AM:- Action Medecr. Our humble recommendations
A) for trained village health worker level
B) for trained Paramedic or middle level workers
C) for doctors involved in primary health care

Those drugs included in the Hathi Committee have been underlined. This drug list is meant to be a guideline to help health care institutions in the voluntary health sector to select their own essential drug list. It is up to us to show it to the government and our medical colleagues who believe in commercialisation of medical care that good health care does not necessarily depend upon the length and variety of the drugs used.

COMMUNITY HEALTH CELL
47/1, First Floor, St. Marks Road
BANGALORE 560 001

It is extremely difficult to go against thecurrent created by the market forces. It is a true test of our conviction and our capability to convince others.

NOTE: * - Alternative substitute from the same therapeutic group can be selected based on comparative cost and availability of equivalent products. eg. Hydrochlorothiazide: any other thiazide type diuretic currently in broad clinical use.

Numbers in the Paren thesis following the drug names indicate:

1) Drugs subject to international control under the Single Convention on Narcotic Drugs(1961) and the Convention on Psychotropic substances(1971)
2) Specific expertise, diagnostic precision or special equipment required for proper use
3) Greater potency
4) In renal insufficiency, contraindicated or dosage adjustments necessary.
5) To improve compliance
6) Spedial pharmacokinetic properties for purpose
7) Adverse effects diminish benefit/risk ratio
8) Limited indications or narrow spectrum of activity
9) For epidural anaesthesia

Letters in the parentheses following the drug names indicated the reasons for the inclusion of compelementary drugs

A. When drugs in the main list cannot be made available
B. When drugs in the main list are known to be ineffective or inappropriate for a given individual
C. For use in rare disorders or in exceptional circumstances.

The criteria of selection of essential drugs, Steps to be taken to implement such a programme. Provision of information on essential drugs as recommended by WHO have been dealt with earlier. In the text of the paper the format of the drug list is as follows:

Revised model list of Essential Drugs - a WHO Expert Committee Report - Technical Report Series 685

1.	anaesthetics	1.1 general anaesthetics and oxygen
		1.2 Local anaesthetics
2.	Analgesics, antipyretics, nonsteroidal antiinflammatory drugs and drugs used to treat Gout.	
		2.1 non - opioids
		2.2 Opioid analgesics and antagonists
3.	Antiallergics	
4.	Antidotes and other substances used in poisonings	
		4.1 general
		4.2 specific
5.	Antiepileptics	
6.	Antiinfective drugs	6.1 anthelmintic drugs
		6.2 antiamoebic drugs
		6.3 antibacterial drugs
		6.3.1 penicillins
		6.3.2 other antibacterial drugs
		6.3.3 antileprosy drugs
		6.3.4 antituberculosis drugs
		6.4 antifilarial drugs
		6.5 antifungal drugs
		6.6 antileishmaniasis drugs
		6.7 antimalarial drugs
		6.8 antischistosomal drugs
		6.9 antitrypanosomal drugs.

7. Antimigraine drugs
8. Antineoplastic and immunosuppressive drugs
9. Antiparkinsonism drugs
10. Blood, drugs affecting the
    - 10.1 antianaemia drugs
    - 10.2 anticoagulants and antagonists
11. Blood products and blood substitutes
    - 11.1 plasma substitute
    - 11.2 plasma fractions for specific uses.
    - 11.3 plasma substitute.
12. Cardiovascular drugs
    - 12.1 antianginal drugs
    - 12.1 antiarrhythmic drugs
    - 12.3 antihypertensive drugs
    - 12.4 cardiac glycosides
    - 12.5 drugs used in shock or anaphylaxis.
13. Dermatological drugs
    - 13.1 antifungal drugs
    - 13.2 antiinfective drugs
    - 13.3 antiinflammatory and antipruritic drugs
    - 13.4 astringent drugs
    - 13.5 keratoplastic and keratolytic drugs.
    - 13.6 scabicides and pediculicides
14. Diagnostic agents
    - 14.1 opthalmic drugs
    - 14.2 radiocontrast media
15. Disinfectants
16. Diuretics
17. Gastrointestinal drugs
    - 17.1 anacids and other antiulcer drugs
    - 17.2 antiemetic drugs
    - 17.3 antihaemorrhoidal drugs
    - 17.4 antispasmodic drugs
    - 17.5 cathartic drugs
    - 17.6 diarrhoea, drugs used in
    - 17.6.1 antidiarrhoeal (symptomatic
    - 17.6.2 replacement solution. drugs.
18. Hormones
    - 18.1 adrenal hormones and synthetic substitutes
    - 18.2 androgens.
    - 18.3 estrogens
    - 18.4 insulins and other antidiabetic agents
    - 18.5 oral contraceptives.
    - 18.6 ovulation inducers
    - 18.7 progestogens
    - 18.8 thyroid hormones and antithyroid
19. Immunologicals
    - 19.1 Sera and immunoglobulins
    - 19.2 vaccines
    - 19.2.1 for universal immunization
    - 19.2.2 for specific groups or individuals.
20. Muscle relaxants (peripherally acting) and cholinesterase inhibitors.
21. Ophthalmological preparations.
    - 21.1 antiinfective agents
    - 21.2 antiinflammatory agents
    - 21.3 local anaesthetics
    - 21.4 miotics
    - 21.5 mydriatics
    - 21.6 systemic preparations
22. Oxytocics
23. Peritoneal dialysis solution
24. Psychotherapeutic drugs
25. Respiratory tract, drugs acting on the
    - 25.1 antiasthmatic drugs
    - 25.2 antitussives
26. Solutions correcting water electrolyte and acid-base disturbances.
    - 26.1 oral
    - 26.2 parenteral
27. Vitamins and minerals.

SJMC MNAMS(GP) Handout
Part I

85-20

PRESCRIBING DRUGS

Questions to be answered before writing a prescription :

1. Is this drug really necessary ?
2. Exactly what is to be accomplished by the drug therapy ?
3. Do I have the requisite experience and knowledge about this drug ?
4. Have I weighed the potential toxic effects of the drug against the benefit which is expected ?
5. Have I checked for possible allergic risks, idiosyncratic tendencies, and the patient's drug diet which might interact with the new agent ?
6. Have I selected the best agent available for this particular purpose ?
7. What is the best route of administration and form of the drug ?
8. What dose regimen will be most appropriate for the pruposes of this therapy ?
9. For what period of time, days, weeks, months, will it be advisable to continue this therapy ?
10. What precautions shall I follow to ensure safe continuation of this therapy (appearance of signs and symptoms, blood counts, prothrombin time, etc.) ?
11. Is the patient reliable for this type of therapy ? Will he have proper supervision from his attendants ?
12. Have I given the necessary instructions to the patient or to the responsible relative ?

While these factors in drug therapy appear obvious, it is also evident that some physicians routinely neglect them. Toxic reactions to drugs are not completely avoidable, but they can be kept to the irreducible minimum by exertion of care and precautions. The development of an automatic reflex of checking the above points would ensure the proper degree of conservatism necessary to use drugs safely. So important are these points in modern drug therapy that some advanced clinics and hospitals have trained clinical pharmacists to advise and check and if necessary correct the physician's prescribed regimen.

Now what about the G.P.

The practicing physician receives a lot of advertising material from drug companies. Many physicians confide that they consign this material unread to the waste container. Nevertheless, the fact that this expensive advertising method is continued means that it must be effective. On the other hand, it is only fair to state that this is one of the few means that drug companies have to communicate directly with the physician. Much of the material is informative. Some of it is extremely valuable. It should be understood that drug companies are required to send packaging inserts (the slip of directions and precautions with each unit package) to each physician before a new medicine becomes generally marketed. In many instances this will be the only opportunity a physician will have to see this valuable information. He should not

...2

only carefully read these packaging slips but also keep them on file. They are a better review of a drug than any other source short of a scientific article or text. They contain information about the exact chemical structure of the drug, its pharmacology, its clinical use, contraindications and toxicities, and recommended dosage schedules. Often they give references to sicientific and clinical literature.

In many instances, drug companies will also write to each physician informing him of a recently discovered toxicity or precaution in the use of their products. This may be in advance of published information or governmental warning. Therefore, the physician who does not read the drug company literature is negligent and is denying himself the benefit of priviletd communications. It does not takemany moments to scan through and distinguish between the valuable and the exaggerated claim.

The many drug samples which also arrive in the mail serve the purpose of acquainting the physician with the actual appearance of a particular product. They are, of course, an excellent inducement for the physician to try them on himself, his family, or patients. For the most part, the physician should refrain from succumbing to this inducement. After examination of the actual product, it should be disposed of with certainty, not simply dropped in the waste container. Many a case of poisoning has occurred because the victim learned that the garbage can in back of the physician's house was a ready source of medication. Also, some unprincipled persons make a practice of collecting physicians samples for black-market sale.

The second common source of information is the detail man. Some large companies employ as many as 400 or 500 of these gentlemen. They are generally pharmacists or college graduates who are quite personable and have a flair for conversation. They are assigned territories with the task of regular visits to physicians, clinics, and hospitals to indoctrinate the profession with their drug products. For the most part, they have received some instruction about drugs in the home office, given by the scientific and medical staff of the company. A few have medical backgrounds of an incomplete nature. Thus, it should be understood that their sole function is to describe their product and it purported virtues and advantages over existing products. They are in no position to instruct the physician in what to prescribe and how to treat disease. The physician who learns his pharmacology and therapeutics from a detail man has descended to the level of quackery and should be retired. By contrast, many busy and competent physicians go as far as to refuse to see a detail man. This is undoubtedly to puritan a view. Most detail men are upright and conscientious persons and they do have information to offer. Perhaps the best doctrin to follow is "let the buyer beware". Neverprescribe a new product until you have yourself checked reliable sources of information and are sure you are acquainted with all the facts and background of the drug. The detail man's plug may legitimately be cut short by simply requesting a packaging slip. It is often amusing to compare advertising claims with the cold information of the critically reviewed packaging insert.

— Dept of Pharmacology
St Johns Medical College

PHARMACOTHERAPY VIS A VIS PLACEBOS

V. ISWARIAH. BA., MB., F. R. C. P.
Professor Emeritus, St. John's Medical College, Bangalore.

Scientists who assemble in conferences periodically have often to digest a mass of factual details garmered from the corners of institutional laboratories far and near, that well nigh their heads will be blood with the bludgeoning of heavy data. These lines therefore are not intended to rummage the depths of the 'scientific mind' but rather to be a salve to the grey matter for a little recreating thinking.

The word 'Placebo' is of Latin origin with an eccliastical and medical significance. Eccliastically, it refers to the introductory response to vespers to the dead. In medicine the word 'Placebo' or 'I shall please' has come to signify a drug having no really curative power other than psychological.

Antiquity and Scope of Placebos

Placebos date back to beyond Hippocrates and they were known as such. The Pharos of Egypt were treated by rare medicinal agents like bile of corcodile from the Nile, milk of tiger, fat of viper, horns of unicooss (a mythological animal) gallstones of wild boar, the rarity of these agents subserving the placebo element. The enormous success of homeopathy in the 18th century where drugs were prepared spectacularly and given in great dilution that they could not possibly have exerted any pharmacological action, is another example of placebo.

But why go to history? Does not every prescription carry with it the placebo element? A prayer to Jupiter (R_x superscription or Superstition ??) starts the prescription, it is written on an elegant letter head with the doctor's merits and signed by him, it has to be taken to a drug house, that the patient has to pay for it, that it has often a bad taste are not all these placebo elements? The more they pay for it for subject themselves to sacrifice, the more efficient is the treatment and is not there an element that contributes to treatment apart from pharmacotherapy?

Variety of Placebos

Placebos have been classified into two main groups i.e., the True and the False.

The first or the true placebo is a lactose tablet bread pill, caramel mixture, more effective if coloured, mottled or scored and with a riot of taste. The pure placebo relieves the patient and tranquillises the recepient. The doctor intends this. It may be styled psychotherapy practised by a general practitioner with an innocuous agent. One cannot say if the benefit conferred is dependent on the low intelligence of the patient. Perhaps a costly placebo may be needed for the sophisticated rich. The giving of the medicine is a symbol of "I will take care of you". A whole body of knowledge, wisdom and experience is epitomised in the medicament. The medicament also fulfills the patient's need to feel dependent. A bitter or nauseating agent fills the need for punishment which many feel that they need at some time or other. The riot of smells and tastes is very effective in creating an illusion of an efficacious medicine. Valerian and Asafoetida were once popular 'Specifics' for hysteria and hypochondria. Valerian by the way enjoyed a further advantage. Its utility is not likely to be disturbed by information which the patient may obtain from the dispenser. If the pharmacist looks up its action in his old Materia Medica book, he is sure to find a very long list of conditions for which it is recommended without a vestige of reality. No one denies that when a genuine therapeutic agent is used, the element of suggestion is also there; the element of optimism that the physician conveys to the patient is there to reinforce the specific action of the drug. One has here to remember the old observation of Jonathan Swift, "no patient will ever care to be handled or treated by a personality for whom he has no respect or veneration, even if he happened to be an eminent doctor."

The Second or the False placebo or adulterated placebo or bastard placebo is in a different category. If in the true placebo the doctor plays a pardonable hoax or deception with the intent of pleasing the patient or tranquillising him or relieve his symptoms, in the latter or false placebo the doctor gives something that he thinks will help the patient and in so doing relieves his own symptoms, tranquillises his own self, applies the balm of flattering function to his own self, in other words he practises deception on himself. When one uses an agent of questionable pharmacological activity, a new arrival on the market or in amounts that can by no possibility exercise pharmacological action, there is the real danger of deceiving two–the patient and himself. To this category belong many hormonal products, multivitamins, haemato-netvine tonics, polyantibiotic, steroidal umbrellas. The doctor tells the patient with a gusto of conviction that the patient is going to be cured by it, but it deceives the doctor despite the patient improving in a self-limiting ailment.

Range of Placebos

The extent of this type of placebo action has only been recently appreciated. In reviews of New York Hospital Pharmacopeias every 25 years since 1816, amongst a list of 160 drugs, every subsequent review recommended deletion of a third

of the existing list, not because better substitutes were available but the old ones were declared inert. This means that all the cases treated with those discarded ones (if alive) were cured not by pharmacology but by placebo. Who knows the fate of I. P. 1966 in A. D. 2000?

Again, the extent of placebo action has been appreciated by controlled study of new drugs. Till some years ago, we thought we were making a big advance in rational treatment when we began a study of a drug by comparing, say a 100 cases treated with the drug with 100 cases not treated at all. We now realise that we have to assess a new drug by comparing it with a group not treated with any drug and a group treated with a placebo. Dr. Wolff of Cornell University found in his study that sucrose tablet and some innocuous injections had about the same effect in preventing sea-sickness as barbiturates and hyoscine. Seidel and Abraham found that hypodermic injections of saline were just as effective as vaccines in rheumatoid arthritis.

Frantic claims were made not so long ago for antihistaminics as cure for common cold. Controlled study with placebos revealed that cases treated with many of the antihistaminics were no better than controls in the incidence, severity of symptoms or duration of colds. The old adage "Treated cold lasts one week; untreated cold lasts SEVEN DAYS" still stands.

Physicians who indulge in polypharmacy or lengthy prescriptions are actuated by a belief that many medications are on the border line between pharmacology and placebo and there is always the chance of hitting on some effective remedy in a jumble. This is the attitude to which rational pharmacotherapy is opposed, the result deceiving the doctor as the action of medicaments. Baneful drug interactions in polypharmacy are dangerously revealing themselves. In a very extensive study by Morreli H. F. and Kenneth L. (California Medicine 109 : 380, 1968) Dangerous reaction by drug combination in many directions are pointed out. The development of rational therapeutics will continue to lag in this country as long as we encourage the use of preparations with some potent agents in a jumble of several other deceptives. To validate a pure placebo by a useless amount of some potent material is a substandard practice or hypo-scientific procedure. The path of therapeutic advance is strewn with the bones and bottles of those who failed to make a controlled study. The doctor who has best results with a set of drugs in which he believes highly, is the one who is least fitted to evaluate results critically. The author knows a physician who never fails to prescribe Becozyme for any ailment ; the compound has obviously upset his proportions.

Apparatus, Tests, Injections, X-rays as Placebos

Mass not to speak of class has sufficiently progressed 'in civilisation' as to want an 'Injection' in preference to oral medication. Every house surgeon on night duty should have had expereince of injecting 0.5 ml of distilled water to tranquillise a

patient who had had a taste of morphine. To such a kind of a patient, the specific kind of treatment is a conditioned reflex. Dogs that are given morphine frequently in large doses invariably vomit. If this is done regularlay for 2 to 3 weeks and then sterile saline substituted, the dogs will also vomit. The needle and the injection, set off the pharmacological response to morphine.

Lay dabblers in medicine who exemplify the old adage "Little knowledge is dangerous; drink deep or taste not the Pierian spring' have great faith in biochemical tests, repeated blood taking preferably simultaneously with urine test, blood pressure apparatus to cause cramps, an elegant typed report—these then are the symbol of 'I will take care of you' or the placebo element in treament.

Dr. Lipkin of Cornell college describes a series of cases of Raynaud's disease treated with mecholyl iontophoresis In a control series, saline was applied instead of mecholyl and sometime did not turn on the current but only clicked the dial. Some improvement was noticed in every case of control and in 6 out of 25 cases, the results were excellent. In one case the patient was so treated three times a week by the nurses without the doctor's knowledge with very satisfactory results. Previously this patient had been unable to go out in the cold weather without suffering spasms. Another patient was unable to work for the first hour after she reached office as the touch of the typewriter key would throw her finger into spasm. She was given saline iontophoresis weekly and a saline intramuscular injection twice weekly with remarkable improvement.

Surgical Placebos

That placebo role is not exclusively in the physician's realm has to be remembered. How many tonsils, appendices, gallbladder, and healthy teeth have been sacrificed to provide placebo treatment. It is said that in America a category of women of the leisured class who carry in their handbags not only cosmetics but also results of several lab tests, who with a relish and gusto talk of their ailment, and who are fond of the company of physicians as they are the only persons with whom one dared to talk continuously of one's self without interruption, contradiction or censure, these are the types that court surgical placebos. Each partial evisceration tranquillises them for a brief period till they allow themselves to be practically eviscerated by some one or more surgeon (D.M. Dunlop). How many elderly spinsters have been frightened to surrender their infructuous uterus on the slightest symptom of menopause, as they knew 'too much' about cancer?.

Placebos and Changing Concepts in Therapeutics

As in sartorial realm so in medicine we are victims of changing consent in treatment. Focal sepsis, intestinal intoxication, allergy, avitaminosis, adapatation syndrome and today perhaps genetically determined disorders, have all had their day. We have had diets for Bright's disease, ketogenic diet for urinary infection, step ladder diet of alarming complexity for diabetes, diet for

hypertension, heart disease (poor sodium) bewildering number of diets for peptic ulcer. Some of these are not only unpleasant to the patient, but often positively detrimental to him as in Sippy's diet that often ended in scurvy and anaemia.

Haematemesis often precluded solid diet for several days ; today pulped meat is presented hardly the blood had darkened the oral region. What a heavy toll did focal sepsis receive ! Langdon Browne recalls an incident of his colleague Prof. Leycock Says he,"..... he an eminent physician when on a ward round drew attention of students to a patient's teeth pointing out to them that such teeth indicated that the patient was of what was then called "Rheumatoid diathesis". Thereupon the patient much to the amusement of the students took out the dentures and handed to the Professor asking him if he would like to look at them near at hand". Tonsils, gallbladder, appendix came in this group, while for some time the colon was deemed the nigger in the woodpilex of health. And how about allergy ? Any undiagnosed disease made the medical hunter go in quest of an allergen in the woods. Story is told of an asthmatic Edinburugh businessman who had only two nights of freedom each month from his affliction, when he journyed to and from London for his monthly meetings. In the train he slept like a child. It occurred to the physician in attendance that the pillows in the sleeping car were stuffed with some composite material and not feathers and that he might be allergic to feathers : his skin test was suggestive. And so every pillow and cushion in his Edinburugh house was ripped open, the feathers removed and the composite material installed. But, the asthma at home was as bad as ever. The physician had later realised that it was there in his nuptial couch but not in the sleeping berth to which he was far more allergic, than to feathers. If we stick to the allergy concept, the wife was the allergen !

Placebo Drugs :

About three decades ago, much doubt was raised in the minds of pharmacologists if the so called expectorants used in cough like Ipecac, Scilla, Ammonia carb, Iodide work by faith or by pharmacology. Ammonium chloride is sometimes prescribed in cough mixture in 5 gr. doses, but when given in 30 gr. doses to make the urine acid, does one ever see patients spending their time coughing up sputum ? Potassium iodide is undoubtedly excreted by the salivary, bronchial, lachrymal and nasal glands. There is no reason to believe however that they will run at their bronchi alone when we wish it and not at the nose and eyes, and if they do we call it iodism. When we administer atropine or belladona, we do so hoping that it will have its action just where we want it to act; if it is to reduce bronchial secretion, we think it won't affect other secretions or the eye. If it is to be given in fairly large doses to reduce spasm, we expect no other action but just antispasmodic action. Pharmacologists have been teaching that emetics in subemetic doses cause expectorant action. Some recent findings seem to suggest that emetics in 'supraemetic doses alone have

expectorant action. If these are established, have not all the expectorants so far had exerted placebo action and not pharmacological one ?

But it has to be said that in rejecting a patient's request for a tonic or declining to offer medication when none is of value, a doctor may fail to make effective use of considerable body of scientific evidence on the placebo effect. A report quoted in an Editorial in B.M.J. (II:437, 1979-23rd May) says that a third of health service prescription falls into the placebo category. But the Editor asks '.....Are they used in a systematic way ? The " Pharmacology " of inert placebos include dose effects, time related effects and even drug dependence'.

Intelligence and Suggestion in Placebo Therapy

As noticed, it is sometimes assumed that the element of suggestion as applied to placebo therapy is present in lower degree of intelligence. Often then there is not much relationship between the state of intelligence and the responsiveness to placebos. Sometimes one comes across a highly sceptical patient in whom even genuine therapeutic agents do not work. Medical men who had to treat other medical men should have encountered difficulties in the use of drugs, which otherwise give no trouble in the case of non-medical patients. On the other hand those who are eager to be told about the details of treatment and be warned about possible side-effects may be the first to complain of side effects even before minimum therapeutic dose had been administered.

Harry Gold gives an instance of his encountering another physician. Says Gold, "I noticed him breathing very heavily when we walked upstairs and when asked replied that for many years he had heart failure with auricular fibrillation and showed me his legs that were almost twice their normal size, He carried a bottle of Tr. Digitalis in his back pocket and took a few drops now and then. When I asked him why he did not take more and that regularly, he said that he was very sensitive to digitalis He had also become somewhat addicted to heroin to control his nocturnal cough and dyspnoea. Here was a very intelligent scientist in advanced heart failure virtually without treatment with the only drug he needed. On condition that I would treat him without his wanting to know the details, I made up a bottle of medicine containing a teaspoonful of Tr. Digitalis with a tablespoon ful of Tr. Valerian. The taste as well as the large quantity per dose threw him off the track completely. He took a daily dose containing about 3-4 ml. During the first few days he carried on almost without a moment of sleep because he was too busy passing urine. He lost about 40 pounds and all symptoms of failure subsided. When he knew that he was receiving few drops of digitalis, it made him so sick to his stomach, but when he was kept in the drark he took more than a teaspoonful. The efficiency of a placebo bears little relation to the intelligence of the patient".

It goes without saying that the selection of patients for placebo therapy is as important as the selection of patients for any other form of therapy.

Some may ask if in an ideal community, educated public, abundant doctors with adequate time and energy and wherewithal, whether it would be necessary for this form of therapeutic device or placebo. Is it the best device if the doctor patient relationship is of the optimum or ideal kind ? One is inclined to answer that when it has lived from the time of the Pharos of Egypt to the Americas of 20th century, placebo or chemical device for psychotherapy will remain for all time.

Conclusion

As we grow old we come to realise that all knowledge is provisional. Controls with drugs reveal wide ramification of the element of placebo in drugs or even non-drug therapy. Actions and results once attributed to many drugs are not there ; but instead something new and perhaps pleasant appears. Havelock Ellis reiterates in his writings how he was like Saul, the son of Kish who went out to seek his father's missing asses but found a kingdom. He had searched for truth but had not found it : instead he found beauty. When we search for truth we often encounter beauty and stop to say "Behold the Truth".

It is more important to look ahead, than backwards
That is why our eyes were placed in front

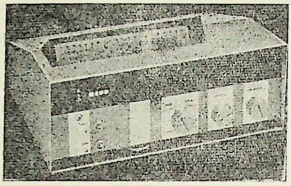
* * *

You cannot escape the responsibility of tomorrow
by evading to-day — Abraham Lincoln

* * *

Words are the voice of the mouth Kind deeds
are the voice of the heart

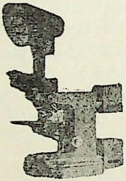
* * *



Kipp and Zonen C C Oximeter

Direct oxygen saturation measurement of blood during heart catheterization. The use of CC Oximeter for the recording of dye dilution curves is an application of utmost importance. The instrument represents a new application of reflex oximetry.

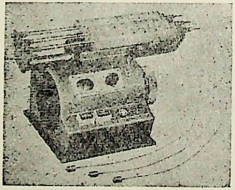
Very short time lag (15–20 seconds) enables the instantaneous observation of the local oxygen saturation



LEITZ Large Field Microscope :

ORTHOPLAN with Projection Attachment.

Trinocular body for wide field eye pieces of 30 mm diameter. The field of view 28 mm dia of the ortho. plan is upto more than twice as that of a conventional microscope.



B. BRAUN

CONTINUOUS INFUSION EQUIPMENT

The apparata have been used since long in Pharmocology and Physiology where it is essential to inject small quntities of liquids at a constant accurately reproducible rate. These instruments have been recognized as essential requirement not only in this field but even more so in human medicine

For further details of these instruments, please write to:
Sole Distributors

THE SCIENTIFIC INSTRUMENT COMPANY LIMITED

Allahabad Bombay Calcutta Madras New Delhi

Head Office: 6, Tej Bahadur Sapru Road
Allahabad.

SICO 1911–1970

Comparative Essential Drug List

Main List	Complementary List	Route of administration dosage forms and strengths	List A Emro	List B	PMC	Low Cost	PU	PG	SL	G	E	AM	A B C	I	II
	1. Anaesthetics														
	1.1 General anaesthetics and Oxygen						•			•					
ether, anaesthetic (2)		inhalation											C		
thiopental (2)		powder for injection, 0.5g, 1.0g (Sodium salt) in ampoule											C		
	1.2 Local anaesthetics														
*Lidocaine		.5% inj, 1,2(hydrochloride) in vial					•		•	•	•		B		•
		inj. 1%, 2% + epinephrine 1:100000 in vial													
		topical forms 2-4 (hydrochloride)													
	2. Analgesics, antipyretics, Nonsteroidal antiinflammatory Drugs and drugs used to treat Gout.														
	2.1 Non-opioids														
acetylsalicylic		tablet 100-500mg, suppository, 50-150mg poed Aspirin	•	•	•	•	•	•	•	•	•	•	A	•	
*ibuprofen		tablet 200mg					•	•							
indometacin		capsule or tablet 25 mg						•				•			
paracetamol		tablet 100-500mg, suppository 100mg + syp	•	•	•	•	•	•	•	•	•	•	A		
	2.2 Opioid analgesics and antagonists														
(Phenylbutazone)/Oxyphenbutazone													A		
morphine (1)		inj 10mg (sulfate or hydrochloride) in 1 ml ampoule					•	•	•	•					
pethidine Hcl. 5ml/ml							•	•	•	•					•
	3. Antiallergics														
*chlorphenamine		tablet 4mg (maleate)					•	•	•	•			A		•
		inj 10mg in 1ml ampoule					•	•	•	•					
epinephrine		inj 1mg (as hydrochloride in 1ml ampoule					•	•	•	•	•		A		

Main List	Complementary List	Route of administration dosage forms and strengths	List A Emro	List B Emro	CMC	Low Cost	PUR	GI	SL	G	E	AM	A B C	I	II
	4. Antidotes and other substances used in poisonings														
	4.1 General														
charcoal, activated		Powder										•	A		
	4.2 specific														
atropine		inj 1mg(sulfate)in 1ml ampoule					•	•			•	•	A		•
diazepam		inj 5mg/ml in 2ml ampoule				•	•		•		•	•	B		•
	5. Antiepileptics														
phenobarbital(1)		tablet 50mg,100mg,syp 15mg/5ml				•	•	•	•	•	•	•	B		•
		capsule or tablet 25mg,100mg(sodium salt)													
		inj 50mg(sodium salt/ml in 5ml vial					•	•	•	•		•			
phenytoin													C		
inj Paraldehyde(Hathi)													C		
	6. Antiinfective drugs														
	6.1 Anthelmintic drugs														
mebendazole		tablet 100mg	•	•	•	•	•	•	•	•		•	A		
piperazine		tablet 500mg(citrate or adipate)	•	•		•	•	•	•	•	•		A	•	
senna tablet	levamisol)II tablet	elixir, Elexir or syp(as citrate)equivalentI		•					•	•			B		
tetrachlorethylene(Hathi)		to 500mg hydrate/5ml	•						•	•			A		
	6.2 Antiamoebic drugs														
chloroquine		tablet 200mg(as phosphate or sulfate)				•	•	•	•	•	•	•	A	•	
diloxanide		tablet 500mg(furoate)							•				B		
metronidazole		tablet 200-500mg		•	•	•	•	•	•	•	•	•	B		•
	dehyro emetine(B),1,7)	inj 60mg(hydrochloride)in 1ml ampoule					•	•	•						
furazolidine		inj 60mg					•	•					B		
pthalyl sulphathiazole(Hathi)											•		A		

Main list	Complementary List	Route of administration dosage forms and strengths	List A Emro	List B	CMC	Low cost	PU	PG	ISL	G	E	AM	A	I	II
	6.3 Antibacterial drugs														
	6.3.1 Penicillins														
*ampicillin(4)		Capsule or tablet 250mg,500mg (annydrous)I		•	•	•				•	•	•	B	•	
		powder for oral suspension 125mg (annydrous)/5ml													
		powder for inj 500mg(as sodium salt) I in vial							•						
benzathine benzylpenicillin(5)		inj 1.44mg benzylpencillin											B		
fortified benzyl penicillin		procaine benzyl penicillin 30000 u/ml + benzyl pencillin 10000 u/ml											B		
benzylpenicillin		powder for inj 0.6g							•	•			B		
		1million IU) 3.0g(=5millionIU)(as sodium or potassium salt)in vial													
		tablet 250mg(as potassium salt)I													
phenoxymethyl penicillin		powder for oral suspension 250mg (as potassium salt)/5ml				•			•		•		B	•	
procaine benzyl penicillin(7)		powder for inj 1g(=1million IU) 3g(=3 million IU)											B		•
	6. Antiinfective drugs														
	6.3.2 other antibacterial drugs														
*chloramphenicol(7)		capsule 250mg				•	•	•	•	•	•	•	B		
		powder for inj 1g(as sodium succinate) in vial													
erythromycin		capsule ortablet 250mg(as lactobionate)/5ml					•	•	•				B		
		powder for inj 500mg(as lactobionate) in vial													
*gentamycin(4)		inj 10mg,40mg(as sulfate)/ml in 2ml vial					•	•					C		
metronidazole		tablet 200-500mg					•	•	•	•	•	•	B	•	

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emco	List B Emco	CMC	Low Cost	PU	GI	SI	G	E	AM	ABC	I	II
		inj 500mg in 100ml													
		Suppository 500mg, 1g													
*Sulfadimidine(4)	(sulphadiazine)	tablet 500mg, oral suspension 500mg/5ml	.	.	.	.	.	.	.				A		
		inj 1g(sodium salt)in 3ml ampoule													
*sulfamethoxazole+trimethoprim(4)		tablet 100mg+20mg, 400mg+80mg		.		.				.	.	.	B		.
*tetracycline(4)		capsule or tablet 250mg(hydrochloride)			.	.	.	.	.	.	.	.	A		.
	doxycyline(3)(5,6)	capsule or tablet 100mg(as hydrochloride)													
		inj 100mg(as hydrochloride)/5ml in ampoule													
	nitrofurantoin (A,B)(4,7)	tablet 100mg				.	.	.		.	.	.			
Hydroxyquinolines						.		.							
Furazolidine		100mg tablet				.	.	.	.				B		
	6.3.3 Antileprosy drugs														
clofazimine		capsule 100mg									.		C		
dapsone		tablet 50mg,100mg				.	.	.		.	.	.	A		
rifampicin		capsule or tablet 150mg,300mg					.	.			.	.	C		
	6.3.4 Antituberculosis drugs														
ethambutol		tablet 100-500mg(hydrochloride)						.	.		.	.	C		
isoniazid		tablet 100-300mg			.	.	.	.	.				B		
pyrazinamide		tablet 500mg				.	.						C		
rifampicin		capsule or tablet 150mg,300mg				.	.	.			.	.	C		
streptomycin (4)		powder for inj 1g(as sulfate)invial			.	.	.	.	.	.	.	.	B		.
thiacetazone+isoniazid		tablet 50mg+100mg, 150mg+300mg				.	.	..				.	B		.
Thiacetazone						.		.					B		
	6.4 Antifilarial drugs														
diethylcarbamazine		tablet 50mg(citrate)			.	.	.	.	.	.	.		C		
	6.5 Antifungal drugs														
nystatin		tablet 500000 IU					.	.					C		

Main list	Complementary list	Route of administration dosage forms and strengths	List A	List B	EMRO	CMC	Low Cost	PU	PGI	SL	G	B	M	AWaRe A	AWaRe B	AWaRe C	I	II
		6.6 Antileishmaniasis																
sodium stibogluconate		inj 33% equivalent of 10% antimony in 30ml														C		
pentamidine		powder for inj 200mg in vial														C		
		6.7 Antimalarial drugs																
*chloroquine		tablet 150mg(as phosphate or sulfate)	.	.	.				.	.	.					A	.	
		syrup 50mg(as phosphate or sulfate)/5ml																
		tablet 75mg, 150mg(as phosphate or sulfate)																
primaquine		tablet 300mg(as bisulfate or sulfate)								.						B		
quinine		inj 300mg(as dihydrochloride)/ml in 2ml ampoule														B		
	pyrimethamine					.						.	.			B		
	sulfadoxine+pyrimethamine(B)	tablet 500mg+25mg									.							.
		7. Antimigraine drugs																
ergotamine(2,7)		tablet 2mg(as tartrate)														B		
		10. Blood drugs affecting the blood																
		10.1 Antianaemia drugs																
ferrous salt	A	tablet equivalent to 60mg iron (as sulfate or fumarate)	.	.			.	.	.	.	.	.	.			A	.	
		oral solution equivalent to 15mg iron(as sulfate)in 0.6ml																
folic acid(2)		tablet 1mg				.		.	.	.	.	.	.			A		
		inj 1mg(as sodium salt)in 1ml ampoule																
*hydroxocobalamin(2)		inj 1mg in 1ml ampoule							.				.			C		
	*iron dextran(B)(5)	inj equivalent to 50mg iron/ml in 2ml ampoule						.	.	.	.	.						
		12. Cardiovascular drugs																
		12.1 Antianginal drugs																
glyceryl trinitrate		tablet (sublingual)0.5mg								.						C		

Main list	Complementary list	Route of administration dosage forms and strengths	List A	List B	CMC	Low Cost	PU	PG	I	SL	G	E	AM	A/B/C	I	II
*isosorbide dinitrate		tablet(sublingual)5mg														
*propranolol		tablet 10mg,40mg(hydrochloride) inj 1mg(hydrochloride)in 1ml ampoule					•	•						C		•
*verapamil		tablet 40mg,80mg(hydrochloride) inj 2.5mg/ml(hydrochloride)in 2ml ampoule												C		
	12.2 Antiarrhythmic drugs															
*procainamide		tablet 250mg,500mg(hydrochloride) inj 100mg(hydrochloride)/ml in 10ml ampoule														
	12.3 Antihypertensive drugs															
*hydralazine		tablet 50mg(hydrochloride)II					•							C		
*hydrochlorothiazine		tablet 50mg					•							B		
*propranolol		tablet 40mg,80mg(hydrochloride)					•	•						C		
	*reserpine(A)(7)	tablet 0.1mg,0.25mg inj 1mg in 1ml ampoule					•	•		•	•	•				•
	12.4 Cardiac Glycosides															
digoxin(4)		tablet 0.0625 mg,0.25mg oral solution 0.25 mg/ml inj 0.25mg/ml in 1ml ampoule					•			•	•	•				
	12.5 Drugs used in shock or anaphylaxis															
epinephrine		inj 1mg(as hydrochloride)in 1mlampoule					•	•		•	•	•		B		
inj mephenteramine sulphate		15mg/ml														
inj norepenalin(Hathi)		1mg/ml					•	•						C		
	13. Dermatological drugs															
Benzoic	13.1 Antifungal															
acid + salicylicacid				•	•	•								B		
Whitfield ointment(Hathi)							•			•				B		
	13.2 Antiinfective drugs															
neomycin+bacitracin		ointment 5mg neomycin sulfate+500IU bacitracin zinc/g				•		•	•				•			

Main list	Complementary list	Route of administration dosage forms and strengths	List A Emrc	List B	CMC	Low Cost	PPU	PGI	SI	G	E	AM	WHO A B C	I	II
tetracycline ointment															
chloramphenicol															
	13.3 Antiinflammatory and antipruritic drugs														
*betamethazone(3)		ointment or cream 0.1%(as valerate)				•		•	•				B		
*calamine lotion		lotion					•		•				B		
*hydrocortisone		ointment or cream 1%(acetate)					•	•	•	•			B		
	13.5 Keratoplastic and keratolytic agents														
salicylic acid		solution topical 5%							•				B		
	13.6 Scabicides and pediculicides														
benzyl benzoate		lotion 25%	•	•	•	•			•		•		A		•
	14. Diagnostic agents														
tuberculin, purified protien derivative (PPD)		injection					•						B		
fluorescein	14.1 Ophthalmic drugs	eye drops 1%(sodium salt)					•						C		
	15. Disinfectants														
*chlorhexidine		solution 5%(gluconate)for dilution.		•	•				•				B		•
*iodine		solution 2.5%	•	•			•	•	•	•	•	•			
	16. Diuretics														
*furosemide		tablet 40mg inj 10mg/ml in 1ml ampoule				•	•	•	•	•	•	•	B		
*hydrochlorothiazide		tablet 50mg				•	•	•	•			•	B		
	17. Gastrointestinal drugs														
aluminium hydroxide(A)		tablet 500mg oral suspension 320mg/5ml	•	•	•	•		•	•	•		•	A		
magnesium hydroxide		oral suspension equivalent to 550mg magnesium oxide/10ml					•	•	•	•	•		A		
	tab. antacid(Anthi)														
*promethazine(A)	17.2 Antiemetic drugs	tablet 10mg,25mg(hydrochloride)5ml.		•	•	•	•	•	•	•	•		A		
chlorpromazine		elixir or syrup 5mg(hydrochloride) /5ml													

Main list	Complementary list	Route of administration dosage forms and strengths	List A	List B	EMC	Low Cost	PU	PG	SL	G	P	M	EC	I	II
	17.3 Antihaemorrhoidal drugs														
*local anaesthetic, astringent and antiinflammatory drug		ointment or suppository	•	•									D		
Oxyphenonium bromide															
*atropine(Nathi)	17.4 Antispasmodic drugs	tablet 1mg(sulfate)		•				•					C		
		inj 1mg(sulfate in 1ml ampoule					•	•	•		•	•	B		•
	17.6.1 Antidarrhoeal (aymptomatic)drugs														
*codeine(1)		tablet 30m (phosphate)								•			B		
oral rehydration salts(for glucose-salt solution)	17.6.2 Replacement solution														
ipecacuanha	antiflatulent		•	•			•				•		A		
activated charcoal															
gamma benzene hexachloride(1)		solution		•								•	A		
	18. Hormones														
	18.1 Adrenal hormones and synthetic substitutes														
*dexamethasone	Hydrocortisone	tablet 0.5mg,4mg						•				•	C		
		inj 4mg(sodium phosphate)in 1ml ampoule													
*prednisolone		tablet 5mg							•						
*ethinylestradiol	18.3 Estrogens	tablet 0.05mg				•		•	•	•		•	C		•
									•				C		
	18.4 Insulins and other antidabetic agents														
*glibenclamide		tablet 5mg											C		
insulin (m & B)							•								
Tolbutamide		injection					•	•	•	•			C		
	Chlorpropamide						•	•	•	•			C		
	18.5 Oral contraceptives								•						
*ethinyl estradiol *levonorgestrel		tablet 0.03mg+15mg+0.25mg				•						•	C		

Main list	Complementary list	Route of administration dosage forms and strengths.	list A Europ	list B	CMC	Low Cost	PUP	GI	SL	G	E	AM	A	B	C	I	II
		18.8 Thyroid hormones and antithyroid drugs															
levothyroxine		tablet 0.05mg, 0.1mg (sodium salt)							;						C		
potassium iodide		tablet 60mg													C		
*propylthiouracil		tablet 50mg													C		
		19. Immunological															
antivenom sera		19.1 Sera and immunoglobulins															
		inj) all plasma fractions should															
		) comply with WHO requirements															
diptheria antitoxin		inj) for the collection, processing													C		
		) and quality control of human															
		) blood and blood products															
		inj) 10000 IU															
		20000 IU in vial															
tetanus antitoxin		inj 50000 IU in vial													B		
		19.2 Vaccines															
		19.2.1 for universal immunization															
BCG vaccine (dried)		inj) all vaccines should comply with													B		
diphtheria pertusis-tetanus vaccine		inj) the WHO requirements for													B		
diphtheria-tetanus vaccine		inj) biological substances.															
measles vaccine		inj)													B		
poliomyelitis vaccine (live attenuated)		inj/oral solution													B		
tetanus vaccine (WHO, Hathi)		inj													B		
		19.2.2 cholera TABC, small pox															
		21. Ophthalmological preparations															
silver nitrate		21.1 antiinfective agents solution (eye drops) 1%													B		
sulfacetamide		eye ointment 10% (sodium salt)													A		
*tetracycline-chloramphenicol		solution (eye drops) 10% sodium salt															
		eye ointment 1% (hydrochloride)															
		21.2 Antiinflammatory agents															
hydrocortizone																	

Main list	Complementary list	Route of administration dosage forms and strengths.	list A Emrc	list B	CMC	Low cost	PU	PG I	SEG	E	AM	A B C	I	II
21.	21.4 Miotics													
pilocarpine		solution(eye drops)2%,4%(hydrochloride or nitrate)					•	•						
	21.5 Mydriatics													
physiostigmine(Hath.) homatropine(A)		solution(eye drops)2%(hydrobromide)												•
	22. Oxytocics													
*ergometrine		tablet 0.2mg(maleate)		•	•	•		•					•	•
oxytocin		inj 0.2mg(maleate)in 1ml ampoule inj 10 IU in 1ml ampoule					•	•	•	•				•
	24. Psychotherapeutic drugs													
*chlorpromazine		tablet 100mg(hydrochloride)					•	•	•	•	•			•
		syrup 25mg(hydrochloride)/5ml												
		inj 25mg(hydrochloride)ml in 2 ml ampoule												
*diazepam		tablet 5 mg					•		•	•				
	25. Respiratory tract, drugs acting on													
*aminophylline	25.1 antiasthmatic drugs	tablets 200mg		•		•	•	•	•	•	•	B		•
		inj 25mg/ml in 10ml ampoule			•									
epinephrine		inj 1mg(as hydrochloride)in 1ml ampoule										C		
*salbutamol		tablet 4mg(sulfate)			•	•	•	•	•	•				
		oral inhalation(aerosol)0.1mg per dose												
		syrup 2mg(sulfate)/5ml												
adrenalin tartarate maliate in 1000							•	•	•	•	•	C		•
P E T- phenobarb 5mg, ephedrine 10mg, theophyline 125?(Hathi)												B		
noscapine(cough suppressant) ephedrine(A)		tablet 30mg(as hydrochloride)				•			•			B		•

85-18

Main list	Complementary list	Route of administration dosage forms and strengths.	list A Enro	list B	CMC	low cost	PU	GI	SL	G	E	AM	I	II	SC
26. Solutions correcting water, electrolyte and acid-base disturbances															
	26.1 oral														
oral rehydration salts (for glucose-salt solution) (for compositon see 17.6.2 replacement solution)									•						A
potassium chloride		oral solution													
glucose (dextrose)	26.2 Parenteral	injectable solution 5% isotonic, 50% hypertonic					•	•		•					B
glucose with sodium chloride		injectable solution 4% glucose 0.18 sodium chloride (Na+0mmpl/1) (Cl-30 mmol/1)							•					•	B
potassium chloride		injectable solution												•	B
sodium bicarbonate		" " 1.4% isonic (Na+167 mmol/1) (HCO3-167 mmol/1)					•	•		•					B
Sodium chloride (chollera fluid)		injectable solution 0.9% isotonic ((Na*154 mmol/1)(Cl-154 mmol/1)													B
calcium carbonate gluconate		in 2ml, 5ml, 10ml ampoules							•					•	
water for injection									•					•	B
27. Vitamins and minerals															
ascorbic acid		tablet 50mg													
*ergocalciferol		capsule or tablet 1.25mg (50000 IU)			•	•			•						B
		oral solution .25mg/ml (10000 IU)			•	•	•		•						A
*nicotinamide		tablet 50mg													
pyridoxine		tablet 25mg (hydrochloride)													B
retinol		capsule or tablet 7.5mg (25000 IU), 60mg (200000 IU)	•	•											A
riboflavin		oral solution 15mg/ml (5000 IU) tab.5mg											•		B
sodium fluoride (8)		tablet 0.5mg (as fludride)													B
vitamin A & D															A
vit B complex (Prophylactic NFI therapeutic NFI with Vit C+ folic acid tablet + injection)							•	•				•			
cyanocobalamin B 12 (Mathi)									•						A
hydroxocobalamin					•				•			•		•	B
multivitamin									•					•	

Med Services
Nov 84

Learning to use antibiotics wisely.

First guidelines

1. Use an antibiotic that kills bacteria rather than one that just slows them down. This usually gives quicker results, and prevents the infection from becoming resistant to treatment.

2. Use an antibiotic that causes fewer side effects and is less risky. For example, if the person is not allergic, it is safer to use penicillin or ampicillin rather than an antibiotic like erythromycin that can cause poisoning.

3. When possible, use a narrow-range antibiotic that attacks the specific infection rather than one that attacks many kinds of bacteria. Broad-range antibiotics cause more problems--especially diarrhea and thrush--because they attack good bacteria along with the bad. The good bacteria prevent the growth of harmful things like moniliasis (funguns that can cause diarrhea, thrush, etc.)

4. Use a broad-range antibiotic only when no other will work, or when several kinds of bacteria may be causing the infection (as with infections of the gut, peritonitis, appendicitis, some urinary infections. etc.)

Additional guidelines for further learning

5. Use antibiotics only for bacterial infections. Do not use them for viral infections, because antibiotics do nothing against viruses (common cold, measles, chicken pox etc.)

6. Be careful never to give more than the recommended dose of a toxic (poisonous) antibiotic. However, it is usually not dangerous to give higher doses of an antibiotic that is not poisonous (penicillin or ampicillin). For example, it is all right to use penicillin for months or even years after it has expired, and to increase the dose to allow for any loss of strength. (But tetracycline becomes more poisonous when old. It should never be used beyond the expiration date or in more than the recommended dose.)

7. Do not use an antibiotic that slows down bacteria together with an antibiotic that kills them. The combination is often less effective than one alone. (Once the bacteria are captured or slowed, they stay hidden where the other antibiotics cannot kill them.) For example, never use tetracycline in combination with chloramphenicol.

8. Whenever possible, avoid using a toxic medicine for a person with diarrhoea or dehydration. A dehydrated person's body cannot get rid of poisons as quickly in the urine. Even normal doses of a toxic medicine may build up and poison the person. (Sulfas are especially riskly for treating diarrhea. Unless the person is making a lot of urine, sulfa can form crystals in the kidneys and cause damage.)

9. Do not use toxic medicines during pregnancy--especially during the first three months. Some medicines can cause severe birth defects.

10. Use a medicine the family can afford. When choosing between medicines, always consider the relative cost, and weigh this with other advantages and disadvantages.

--Helping Health Workers Learn

David Werner and Bill Bower

Prescribing Drugs

DR-2 copy

Questions to ask yourself before writing a prescription?

1. **Need** — Is this drug really necessary?
Is it being given to make the patient feel that something is being done?

2. **Aim** — What aim is to be achieved by this drug?
What disorder of function is to be corrected?
What symptoms have to be relieved?

3. **Knowledge** — What is the approved or generic name?
What class does it belong to?
What are its characteristics?
Do I have the requisite experience or knowledge to use it?
Have I weighed the potential toxic effects against the expected benefit?

4. **Route and Dosage** — By what route, in what dose and at what intervals is the drug to be given and why?
In what forms does the drug come?

5. **Alternatives** — Have I selected the best agent available for this particular purpose?
What other remedies might have been chosen?
How do these compare in efficacy, safety, cost?

6. **Duration** — For what period of time, days, weeks or months will it be advisable to continue therapy?
When and how could a decision be made to stop?

7. **Observations** — What observations can be made to judge whether the aim has been achieved?
When should they be made and by whom?
What laboratory investigation, if any, would help in this assessment?

8. **Elimination** — How is the drug eliminated?
Will the patients illness change the usual pattern of distribution, effects or elimination of the drug?

9. **Unwanted effects** — What are the side effects or toxic effects of the drug?
Are they acceptable?
How frequent are they?
How can they be modified/managed?

10. **Precautions** — Have I checked for the following
a) possible allergic risks
b) possible idiosyncratic reactions
c) patients drug diet which may interfere

with the drug
what precautions can I take to ensure continuation of therapy

11. Contraindications – Are there any conditions in which this drug is contraindicated?
Are these 'absolute' or 'relative'
– Are there any drugs which should be avoided when the patient takes this treatment? Which and why?

12. Patient's point of view
What does the patient believe about the drug?
What has he been told about it?
And what has he remembered?
Does he need additional information?

13. Patient reliability
Does his relative need additional inform.?
Is the patient reliable for this type of therapy
Will he need/get proper supervision by relatives or attendants

14. Cost.
Is the drug the cheapest drug of that type.
If not could a cheaper drug do the job as well.

15.

15. Finally is there anything else I need to know about this drug???

Adapted From

i) A. Henxheimer. The Lancet II 1186-1187, 27th Nov. 1976
ii) Formulary and Therapeutic guide – Kenyi Holy Family Hosp.
iii) Prescribing drugs – MNAMS Handout, Dept of Pharmacology, St Johns Medical college.

DR-2
F.No.73.

PRESCRIBING DRUGS

Questions to ask yourself before writing a prescription.

1. Need : Is this drug really necessary ?
   : Is it being given to make the patient feel that something is being done ?
2. Aim : What aim is to be achieved by this drug ?
   What disorder of function is to be corrected ?
   What symptom/s have to be relieved ?
3. Knowledge : What is the approved or generic name ?
   What class does it belong to ?
   What are its characteristics ?
   Do I have the requisite experience or knowledge to use ir ?
   Have I weighed the potential toxic effects against the benefit ?
4. Route and Dosage : By what route, in what dose and at what intervals is the drug to be given and why ? In what form/s does the drug come ?
5. Alternatives : Have I selected the best agent available for this particular purpose ?
   What other remedies might have been chosen ?
   How do these compare in effecacy, safety, cost ?
6. Duration : For what period of time, days weeks or months will it be advisableto continue therapy ?
   When and how could a decision be made to stop ?
7. Observations : What observations can be made to judge whether the aim has been achieved ?
   When should they be made and by whom ?
   What laboratory investigation if any would help in this assessment ?
8. Elimination : How is the drug eliminated ?
   Will the patients illness change the usual pattern of distribution, effects or elimination of the drug ?
9. Unwanted effects : What are the side effects or toxic effects of the drug ?
   Are they acceptable ?
   How frequent are they ?
   How can they be modified/managed ?
10. : Have I checked for the following :
   a. Possible allergic risks
   b. Possible idiosyncratic reactions
   c. Patients drug diet which may interfere with the drug
   What precautions can I take to ensure continuation of therapy.

11. Contraindications : Are there any conditions in which this drug is contraindicated ?
Are these 'absolute' or 'relative' ?
Are there any drugs which should be avoided when the patient takes this treatment ?
Which and why ?

12. Patient point of view: What does the patient believe about the drug ?
What has he been told about it ?
And what has he remembered ?
Does he need additional information ?

13. Patient reliability : Does his relative need additional information ?
Is the patient reliable for this thpe of Therapy ?
Will he need/get proper supervision by relatives or attendants ?

14. Cost ; Is the drug the cheapest drug of that type ?
If not could a cheaper drug do the job as well ?

15. Finally is there anything else I need to know about this drug ?

Adapted from :

i. A Herxheimer : The Lancet II 1186-1187, 27th Nov 1976

ii. Formulary and Therapeutic guide-Kurji Holy Family Hospital

iii. Prescribing drugs - MNAMS Handout, Dept of Pharmacology, St.John's Medical College, Bangalore.

* * * * * * * *

DR 2

GENERAL LAWS

Medical practioners must know and thoroughly understand the basic provisions in law that provide them protection.

Relevant provisions in the Indian Penal Code are detailed in the following.

(Section : 52,80,88,89,90,9293,269)

The Doctrine of Good Faith

- act done for the benefit of a person with due competence, care and caution.

Deficiency in medical service

- failure to follow due norms.

Free and informed consent

- Consent without coercion or inducement and after full information to the patient.

Negligence - its essential ingredients

- act done without due care and caution.

Negligence - legal requirements to prove negligence

- Duty to care
- Deficiency in service
- Damage
- Direct correlation between deficiency and damage.

GOOD FAITH

IPC-52. Nothing is said to be done or believed in "good faith" which is done or believed without due care and attention.

The term rashly implies an indifference to obvious consequences to the safety of others.

ACT NOT INTENDED TO CAUSE DEATH, DONE BY CONSENT IN GOOD FAITH FOR PERSON'S BENEFIT

PC. 88. Nothing, which is not intended to cause death, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, or be known by the doer to be likely to cause, to any person for whose **benefit** it is done in **good faith,** and who has given a **consent,** whether express or implied, to suffer that harm, or to take the risk of that harm.

Explanation - Mere pecuniary benefit is not benefit within the meaning of sections 88,89, and 92.

THE FOUR Ds

1. Duty to care (Duty to care arises only when a doctor accepts or agrees to treat a patient. The acceptance or the agreement can be express or implied, against payment or free)

2. Dereliction of that duty or deficiency

3. Damage to the patient

4. Direct correlation between the deficiency and damage (The damage must be a direct result of the deficiency alleged)

LIABILITY

A. Personal

B. for act of subordinate, agent or employee

C. of hospital

- Respondent Superior "let the master answer".
- The captain of the ship doctrine
- Vicarious (substitute) liability or Tortuous Liability

DEFENCE AGAINST NEGLIGENCE

1. **Denial Defence** Actual denial of negligence having taken place.
2. **Affirmative defence** by providing new factual information to show that the plaintiff's condition has a cause other than the doctor's negligence.
3. **Delegation of duty** to a subordinate
4. **Contributory negligence** by the patient.
5. **Assumption of risk** by the patient.
6. Emergency of the situation.
7. **Release of tort feasor.**
8. **Res judicata**
9. **Statutes of limitation**
10. **Immunity** to charitable and government institutions.

Onus of proof

- Generally the onus to prove negligence is of the complainant. However, later it may be shifted to the defendant as the complainant does to posses the necessary details to prove his allegations, the defendant then is required to prove the absence of negligence.

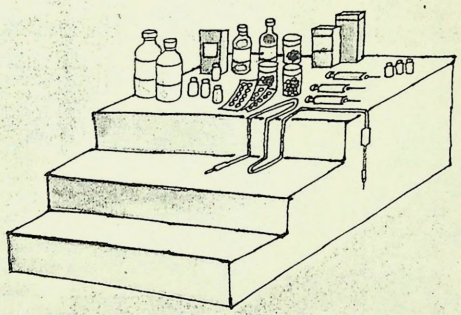
Exception

Res Ipsa Loquitur. "the thing speaks for itself"
"Common sense dictated that the accident could happen only if someone - a doctor or a nurse - was negligent."
" The doctor had direct control over the apparent cause of that injury but failed".

"Gross negligence".

DR-2

Out of Reach!



Jayadev Babu

Spiralling drug prices, and less than ethical trade practices by pharmaceutical companies, endanger the wide eyed Indian consumer's physical and financial health.

BY JANAKI VENKATARAMAN

Been to your corner drug store lately? One of my friends did, and he's never been the same again. "Do you know what I had to pay for the antibiotics my medical specialist prescribed me?" he asked dazedly and, without waiting for an answer, went on, "For just four capsules I paid Rs 107! And I have to take eight in all. Rs 214 for one course of antibiotics -- I am going to be wiped out!" he moaned.

"That must be a third generation antibiotic," I murmured sympathetically.

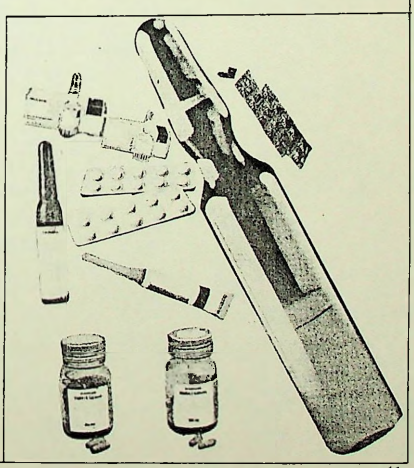
"Why the devil is my doctor prescribing me third generation drugs? I was happy with my first generation Rs 3-a-capsule treatment," the man wailed, adding, "The pharmacist tells me that if I had got the antibiotic last year, I would have paid only Rs 90.25. At this rate, I imagine we'll have to choose to fall ill only when the drug prices are just right. And that's not all. The doc prescribed me a course of Vitamin C which costs around Rs 15 per sheet now. He also prescribed a 'vitaliser' because I told him I was feeling none too perky — that course set me back by Rs 50. I have spent Rs 300 on just one visit to the drug store — this is apart from my doc's fees, which he has hiked recently. You know what I think? If the disease doesn't kill you, your medical bill definitely will."

"That's an observation as old as the hills," I told him unkindly and the conversation ended right there.

My friend, of course, was not the only one to complain about the rising drug prices. Over the last six months, despite the fact that the Union government has been dithering over the new drug policy (which is likely to take a great many drugs off the price control list) the prices of many medicines (barring paracetamols and a few such very basic drugs) have been rising steadily and, according to most consumers, alarmingly. There has been an increase of a minimum of Rs 2 per ten capsules or tablets of even basic vitamins. While drug manufacturers point out, not without truth, that drug prices are still the cheapest in the world in India, there is really no point in talking about open market prices in pharmaceuticals here as long as the per capita income and buying power of the average Indian remain what they are today. As it is, only 25 percent of Indians are said to be able to afford allopathic medicines on a regular basis, and these are concentrated in the urban areas. The vast majority of rural Indians manage on home remedies, cheap and spurious allopathic drugs, or no drugs at all.

There is a very strange situation prevailing in the Indian pharmaceutical industry today. While India has perhaps the largest concentration of drug manufacturers in any country in the world — some 4000 regular manufacturers, apart from countless small units and loan licensees (who use the facilities of a registered pharmaceutical unit on a lease basis) who do not come under any form of stringent drug quality or price control. There is still a shortage of many essential drugs which Indians require. Every country has its own pharmaceutical needs and the governmental drug control authorities are expected to make sure that these are available to the ordinary citizen without failure in supply, in good quality and at reasonably affordable prices. Consider the drugs that are used to treat a few diseases that Indians seem prone to. Half the world's tuberculosis patients live in India, one third of the world's leprosy patients are Indian; 1.5 million Indian children die of preventable and easily treatable diarrhoea; 40,000 children become blind annually for lack of Vitamin A. Epidemic breakouts of typhoid, jaundice and cholera are common, and yet each time the epidemic breaks out, it is found that there is a shortage of supply of the medicines meant to treat these diseases.

Take just two instances of our lopsided pharmaceutical development. A study by the All India Drug Action Network shows that at least 10 million Indians suffer from TB, 2.5 millions of these are infectious and 5 lakhs die from the disease every year. The BCG vaccine has been found to be largely ineffective in preventing the disease, so the answer to the question of controlling the disease clearly lies in treating it, early and effectively. Yet the traditional drugs used for fighting the disease are in perennial short supply — India produces only one third of its requirement of anti TB drugs. The latest and most effective drugs for fighting the disease are too pricey to be dispensed free to patients under the national TB control programme. It is not that Indian pharmaceutical concerns do not have the capacity to meet these needs — it has been found that their



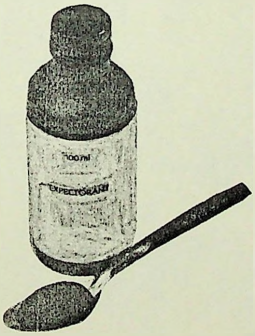
capacity is very under utilised in the production of traditional anti-TB drugs like Streptomycin. At the same time Streptomycin is being manufactured in hazardous combinations with other drugs to be indiscriminately used in treating fevers, other infections, even diarrhoea. Injection ampoules of Streptomycin in combination with penicillin are found in plenty. It has been pointed out time and again that such irrational use of Streptomycin (where it is totally unwarranted) can lead to patients resisting the drug when it is used on them for treating TB.

Take the case of an even more basic drug — Vitamin A. Deficiency in this vitamin is causing blindness in thousands of Indian children, it also leads to higher infant mortality, a greater incidence of diarrhoea and measles among little children. The long term and real solution is for all Indian children to be given a nutritious, balanced diet which contains adequate quantities of foods rich in Vitamin A. All round inflation is, however, making this more difficult for families to provide. The only viable alternative is to supplement the children's diet with Vitamin A in drug form. Yet the production of Vitamin A has not only not increased in the country, it has actually *decreased*. At the same time, while the vitamin is becoming increasingly scarce for children it is being added to cattle and poultry feed and edible oil — this does not really benefit the children who suffer from Vitamin A deficiency, as their families are hardly likely to be able to afford vitamin enriched cooking oil.

The above are just two instances of our lopsided pharmaceutical production. It is so lopsided as to appear mad. Yet, as everyone knows, there is always some reason and method behind every madness. The reason is the drug price control order of the government. And the method is to circumvent it by cutting down on the production of drugs controlled by it and increasing the production of new formulations/variations, which are *not* covered by the drug price control.

Very frequently essential medicines vanish from the shelves of the pharmacists as manufacturers create an artificial short supply and eventually manage to hike up the price of the concerned drug just a little. "Time and again my patients complain that one or another of the drugs I prescribe for them are not available even after they have searched in four or five shops," says Dr S Jagadheesan, a GP. "Keeping drugs in short supply is obviously just a marketing strategy," he says.

"The *real* problem is the government's totally unrealistic price control policy," says Jayanth Asher of Asher Pharmaceuticals, a Madras based drug concern. He merely echoes the sentiments of drug manufacturers all over India. "Since the government brought in the drug price control order in the early 1970s, the prices of almost all inputs in the pharmaceutical industry — raw materials, packaging material, transportation, electricity charges, everything — have gone up. Yet we were made to artificially hold down the line on our selling price. At one point doing this became non-viable. Many small units began to fall sick. As for the bigger companies and multinationals, they began to diversify."



The Indian market is now flooded with inessential and spurious formulations and tonics which are useless at best and hazardous at worst, due to drug manufacturers trying to escape the grip of the drug price control order.

Many multinationals did this by branching off into the production of so called health foods like high protein beverages, and also into the manufacture of pesticides and other chemicals. Both they and the bigger Indian companies did one other thing to escape the stranglehold of the drug price control order — they began concocting new formulations of old drugs, and also inessential drugs and tonics, which they pushed for all they were worth by suitably 'persuading' doctors. As all indigenously manufactured new formulations are exempt from the DPC order for a few years after their launch, the drug companies began making a killing on these products. Consequently the Indian market is now flooded with drug formulations and inessential health tonics and tablets which are useless at best and hazardous at their worst.

As far as one can see the drug companies have displayed no compunction about pushing these wasteful and expensive products to a wide eyed and largely ignorant public through the medium they trust most — the medical practitioner.

As R Srinivasan, Secretary, Pharmaceutical Distributors Association, puts it, in a little trade journal he edits, "We have to admit the fact that ethical promotion, the values that were prevailing about 10 to 15 years ago, have virtually disappeared... Manufacturers have to survive in the present competitive market. The name of the manufacturers or their reputation, are no longer the factors that influence the medical profession..." So what does?

Well, as both pharmaceutical manufacturers and several doctors we met agreed, doctors are definitely being persuaded to prescribe new formulations by drug company representatives, with costly gifts, extravagant launch parties, and attractive 'commissions' in the form of airconditioners, refrigerators and the like, if they prescribe a desirable amount of the drug concerned. Many drug manufacturers are said to sponsor contests and schemes to encourage doctors to push their brands, as if they were selling cosmetics. Even the public sector IDPL is said to have recently offered a deluxe Maruti car to doctors in a contest to promote awareness of one of its brands. Further, almost all medical seminars, study tours abroad for medical teams etc, seem to be sponsored by one

drug company or the other. In such an atmosphere, it seems difficult to imagine a doctor prescribing a drug totally impartially. Many are not averse even to pushing inessential but expensive formulations on their unsuspecting patients, even though they know that the formulation is not likely to help them in any significant way. One senior member of the Drug Manufacturers Association candidly admitted that many of the expensive haemotonic syrups prescribed by doctors for 'improving the general health' of their patients, are nothing but blood collected from slaughter houses (the cattle, although they are supposed to be tested by vets who have to certify that their meat is safe for consumption, hardly ever are), to which anti-coagulants, preservatives, alcohol, sugar and Vitamin B12 are added. "It's bottled and sold as *the* thing for anaemia and a host of other deficiencies. In fact, the Drug Regulatory Body has said quite clearly that such syrups have no therapeutic value, but they have not been banned, all the same. Worse, as the blood is not treated for any bacteria it may contain, there is no guarantee that it may not spread some infections from cattle to humans," he said, adding, "What is the point of pushing such a product on the unwary customer except the profit of the manufacturing company?"

But then, all this is only to be expected in a country in which hazardous drugs, banned in very many countries in the rest of the world, are still sold freely. In a rather frightening booklet the Voluntary Health Association of India warns that no official list of drugs, banned by the Drug Controller of India, has so far been publicised, so that the general public or even medical practitioners are totally unaware of them. Except for the pamphlets which the drug companies themselves provide along with the drugs and promotional literature, which they publish, there's hardly any unbiased information about drugs available for the consumer to go by.

Consider some of the drugs which have been banned worldwide because of their observed hazardous effects on patients, but are still sold in India, one way or the other. In 1971, after evidence from Japan, USA, Canada, France, India and a host of other countries piled up to prove that Clioquinol, the drug used to treat diarrhoea (and popularly marketed as Mexaform and Enteroviofoim by a multinational drug company) had very serious side effects, including damage of the central nervous system and blindness, the drug was banned worldwide. It took more than another ten years for the government of India to ban the drug in this country. But, despite the ban in 1982, Clioquinol continues to be sold here. Here's how. A little after the ban, another government gazette notification excluded all preparations for treating diarrhoea from the ban and those intended for external use (Clioquinol is safe as an external medicine). Therefore countless people continued to take the drug long after it was banned elsewhere. The sad truth is that most forms of common diarrhoea, for which it is used, are easily treated by the oral rehydration therapy, a pinch of salt and a scoop of sugar in a tumblerful of boiled water is enough to bring common forms of diarrhoea under control!

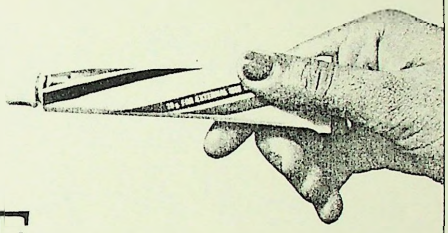
Similarly the over-the-counter pain killer, Analgin, has been banned in many countries around the world, as it can cause a blood disease which could be fatal. For pain and inflammation, for which it is usually recommended, ordinary Aspirin would be just as effective and far less dangerous. But Analgin is sold commonly in various forms in India.

Oxyphenbutazone, prescribed for various muscular pains, aches and sprains, is another drug which was withdrawn from the world market, by the very company which first manufactured it, because of its serious side effects, leading to fatalities, but is marketed in India to this day. More often than one likes to remember, the question of why a drug banned elsewhere in the world was being sold in India, when raised in Parliament, has been answered with bland ignorance from the health minister concerned ("Banned? Is that so? No side effects have been reported from anywhere in *our* country," is the standard response). One doctor with whom we discussed this issue came up with an amazing explanation. "Not every drug banned in Western countries needs to be banned here," he said. "What harms them may not harm us, as we are racially different from them."

"How come the hazardous drugs are always banned in the developed countries but marketed in the developing nations?

That has nothing to do with race!"

"But don't you see? The Western nations are also the developed nations and the Asian and African countries just happen to be developing," countered the doctor. He did fall silent, however, when it was pointed out to him that many of



Ethics seem to have vanished from pharmaceutical salesmanship. Doctors are often said to be 'persuaded' with lavish gifts to push products, which are irrational, often useless, but always expensive, on their unsuspecting patients.

the banned drugs sold in India still, have been strictly banned in Bangladesh (racially akin to us) which has, suprisingly, a very enlightened and strict drug policy.

Voluntary agencies have been fighting a losing battle against inessential, hazardous and irrational drugs. The last mentioned are usually combination drugs in which one of the components is either entirely useless for treating the condition of the patient or, sometimes, dangerous. Tonics and diet substitute crowd the chemists' shelves whereas a sensible diet would help patients more. Food substitutes like glucose drinks are sold at high rates whereas these nutrients can be easily got from a good diet and sunlight. Combinations of pain killers with sedatives, which are extremely habit forming and could easily be fatal when taken in excess, are sold across the counter. Many pain killers are combined with vitamins and a higher price charged for this, while there is no rationale for combining the two. The best way to sell and buy essential drugs is in their individual form, marketed under their generic names. The profusion of brand names merely confuses doctors and patients alike.

The extent to which spurious drugs abound in the market is hardly ever exposed in urban areas. "Go to Nainiappa Naicken street in George Town," one doctor advised me. "There are wholesale dealers of common drugs there who could sell you the tablets at a fraction of the cost compared to those from reputed companies. But no one can vouch for the quality or efficacy of those drugs."

But who buys and uses these drugs?

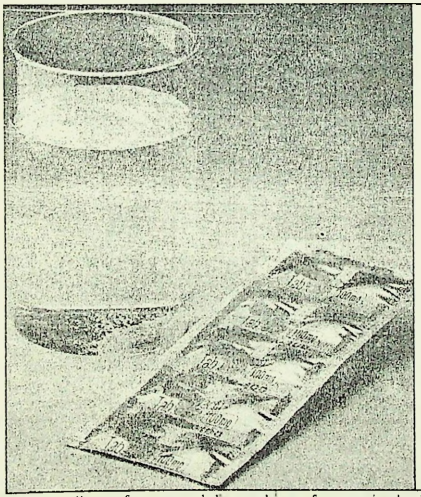
"Cross Madras city limits and the dispensaries stock all manners of drugs from small time manufacturers. In Madras itself, doctors who dispense their own prescriptions stock them. These are doctors who usually charge around Rs 5 per patient and try to keep their drug costs within that limit. As you go deeper south, many of the multinational and major Indian drug companies often do not feature in the local drug shops, which stock only the medicines produced by small pharmaceutical units in the region. Such units do not come under the drug price control order (but their prices are naturally limited by competition) and often they are hardly ever subject to rigorous quality control," said our informant.

The pharmaceutical industry alone cannot, of course, be blamed for the sorry state of affairs. The fact remains that government drug controlling bodies are lax, often ignorant and have a tendency to interact too closely with the pharmaceutical companies.

As for the other side of the story, drug manufacturers complain about being excluded from all economic benefits by the government. "The present economic liberalisation should apply to the pharmaceutical industry too," they say. "While this could make the costs of drugs spiral upwards for a while, there is no question that market competition will bring down the price."

One wishes this were true. But we all know that the price of any commodity, once it goes up, never comes down, atleast not substantially. And if India were to agree to the Dunkel Proposal for Drug Patents (how long it can resist that, one doesn't really know) that whopping cost will definitely be passed on to the consumer. The only good thing about removing price curbs on the pharmaceutical industry is that it might encourage the mass production, and therefore easy availability, of essential drugs. But that in itself might mean nothing if the consumer cannot afford to buy them.

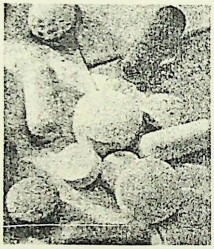
"If liberalisation doesn't take place and drugs are not removed from the grip of price control, you can be sure that in the next few years, the pharmaceutical industry will be unable to produce essential drugs and then the country will have to import them — the cost will be much more," warned a pharmaceutical manufacturer. "What we are now facing is an unbearable burden. The cost of



Ten million Indians suffer from tuberculosis, atleast 5 lakh die annually from the disease. 40,000 Indian children go blind every year from Vitamin A deficiency. Yet there is perennial short supply of both anti-TB drugs and Vitamin A, not because the Indian drug industry does not have the capacity to produce them, but because it is not profitable for it to do so.

every input has gone up, we are taxed at the raw material level and at the product level and then we pay sales tax. The industry will simply crumble at this rate."

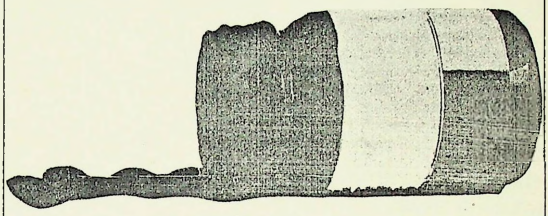
Will it, really? Critics of the drug industry point out that even as things are, it's in a very profitable shape. S Pushpavanam, consumer activist and secretary of the Consumer Protection Council, Tiruchi, points out that even under the mark up set up by the DPCO, 1979, a wide profit margin was given to drug manufacturers. This was further increased in 1987. Now the industry is demanding a 100% to 120% mark up. "None of the pharmaceutical companies have suffered a loss in the last decade. None of them have gone sick... the investing public are enjoying the boom in the price of their shares," he points out.



"Did you know that some oft prescribed haemotonic syrups are nothing but the blood of cattle collected from unhygienic slaughter houses (and untreated for bacteria) to which preservatives and Vitamin B 12 have been added? Such tonics are sold even after the Drug Regulatory Body has certified that they have no therapeutic value."

Sane Medicine

Tips on what to look for when buying drugs.



Pharmaceuticals, and medicine in general, have always been shrouded in mystery for the common man. Besides, the patient is always anxious not to question his doctor about the line of treatment or medicines prescribed by him, for fear of causing offence. In other words most of us, when prescribed something by a doctor, accept it without question. Perhaps it would be better to have a little more awareness of what exactly we are consuming by way of drugs, enquire about their side effects and learn to read the fine print on the tablet foils. The Voluntary Health Association of India offers a few tips to consumers about how to get the best out of drugs without letting them cause us bodily or financial harm.

* When your doctor prescribes a drug do ask him about its side effects, especially if you have health problems which could be aggravated by the intake of such drugs. Ask him for how long you should take the drug and then follow his instructions implicitly. Ask him also about the diet and other precautions you should take while you are on the drug.

* Do not buy irrational or hazardous drugs — a well balanced diet is far better for your health than expensive diet supplements or tonics. If vitamins have to be taken they should be taken for a specific deficiency, not at random.

* Try to get information about banned drugs from the state drug controller's office — do not use them.

* If you find banned drugs being sold, buy a supply, get a bill from the chemist and submit both to the state Drug Controller, the Drug Controller of India and the All India Drug Action Network (AIDAN).

* Encourage use of home remedies for minor ailments.

* Encourage a clean environment which can prevent many diseases.

* Encourage your local doctors to prescribe only essential, single, appropriate drugs — avoid taking fixed combinations of drugs unless specifically asked to do so by your doctor.

* Study the contents of popular, over-the-counter painkillers etc, and find out if they contain hazardous chemicals. Do not buy them if they do.

* Do not allow strong anti-diarrhoeal drugs to be given, especially to children, without trying oral rehydration therapy first. It often stops all ordinary forms of diarrhoea.

* If given a very long prescription, find out which are the essential drugs and which are merely tonics. A lot of food can be bought for the price of those tonics, which usually have little value. Many patients in India have only enough money to buy the essential drugs. If pressurised to buy the tonics as well they might buy only a short supply of the essential drugs, which will not help them get well at all.

* Drugs without printed information about them in their packages should be reported to the state Drug Controller.

■

Some doctors place the blame for the consumer having to pay more for his medicines squarely at his own door. Dr Sumanth Raman points out, "The patient always seems to want instant relief and even though all he might need is a paracetamol tablet, he doesn't feel satisfied until he is given something much stronger. The doctor is forced to oblige, otherwise the patient merely moves on to the next doctor who can put him back on his feet faster! Also, patients seem to believe that the more they spend on the treatment, the more effective it is likely to be. When one brand of the same medicine is cheaper, both doctors and patients automatically assume that it has sacrificed quality — small wonder then, that drug prices are shooting up!"

It is the same get-well-fast syndrome of the patients that is responsible for doctors prescribing them the latest third generation antibiotics. These, apart from being phenomenally expensive (owing to the research and development efforts that have gone into them) are not really necessary in many cases. They are, in-fact, dangerous, in the sense that by indiscriminate use, the patient might easily develop a resistance to them and later, when he really needs them, they might not work for him. As far as expense goes, however, newly developed drugs *do* become less expensive a few years after their introduction. There are two reasons for this — one is that they are not covered by the drug price control order for a few years after their introduction, so drug companies hike up the price of these drugs to the maximum during this time. The other is that the price of a newly introduced drug stays high until competition from other drug companies bring it down. One doctor showed us identical strips of a recently introduced antibiotic. The strip from an earlier batch cost Rs 175 for ten, while the price of the later batch was Rs 115 for ten — obviously between the two batches, the competition had come up with the same drug, at a lower price! Even at Rs 115, the drug was obviously being sold at a profit, so consider the profit margin of the earlier batches! Small wonder, then, that consumer activists point out that "the profit margin in the pharmaceutical industry can be as high as between 100 percent to 400 percent!"

What may then be done to ensure easy availability of essential drugs at reasonable prices? The first solution that comes to mind is that the government take up the manufacture of essential drugs and flood the market with them. But this is easier said than done. Almost all the public sector drug industries, including the giant, IDPL, face heavy losses and the threat of closure owing to sheer inefficiency, corruption and unrealistic overheads.

Very many drugs, banned elsewhere in the world because they are hazardous to human health, continue to be sold freely in India. Even when a drug is banned, the government gazette couches the ban in such ambiguous language that drug manufacturers easily find loop-holes in it to continue manufacture and sale of the banned drug.

The story of IDPL sounds, in fact, horrific. "Its losses are ten times its capital, pilferage of drugs (and replacement with spurious capsules or tablets) is rife, the labour are heavily unionised and inefficient — it's simply becoming non-viable," said one doctor in the know. "It certainly hasn't built up any confidence in the consumer regarding the government's ability to keep up a steady supply of essential drugs."

Over the years, atleast two committees have been set up by the government to bring in a newer and more rational drug policy — the Haathi Committee of 1975 and the Kelkar Committee. Both have made a number of recommendations, not one of which has been implemented. In fact, it is said that Bangladesh, when it formulated its drug policy took suggestions from the Haathi Committee report!

India has a teeming drug manufacturing industry, with almost Rs 4,800 crore worth of formulations. With the government slowly liberalising the economy, these formulations are expected to touch the Rs 16,000 crore mark within a year or so. Whatever its profitability, almost no pharmaceutical concern engages in original research and development. R & D wings being engaged merely in duplicating (sometimes as early as within six months) formulations discovered abroad. As no patent cost is paid at the moment, in the case of Indian drug companies, this amounts to cheap copying. As a result drugs are, when all is said and done, far more affordable in India than elsewhere in the world. But for how much longer? Caught between the swiftly spiralling prices of drugs on the one hand and the rising costs of hospitalisation on the other, and pressurised into buying diet supplements and inessential and hazardous medicines from all sides, the Indian consumer is likely to be exploited to the full — as long as he doesn't put his foot down and develop an awareness about his health needs. Otherwise, as a wag once put it, 'You spend the first half of your life spending your health to gather wealth and the rest of it spending your wealth to get back your health'! The way drug prices are skyrocketing now that should perhaps read, 'Spending your wealth, even as you earn it, on recovering your health.'

With reports from:
Sudha G Tilak
Indira Krishnan
Elizabeth Cherian

CLARIFICATION: In the article *Steroids at play on sports fields*, on May 22, 1995, in the sixth para it should have read as: "These drugs are used with a hope to overcome the phobia"; and "In fact, amphetamine takers almost always 'think' they are performing better than they actually do."

ECONOMIC AND POLITICAL WEEKLY

Irrational Prescription

THE government's contortions on the drug policy would have been amusing if it were not for the fact that they crucially affect the current and future health status of all sections of the population. However, the recent spurt of ministerial blether on the 'forthcoming' drug policy, increasingly irresolute and uninformative, appears to indicate that a decidedly pro-industry policy is all packaged and ready, awaiting a politically appropriate moment.

The policy has been a long time in the making because the government finds itself in something of a bind. It cannot openly succumb to the pressures of the politically influential pharmaceutical industry in the face of the persistent challenge, nationally and internationally, from the consumer movement to introduce a semblance of rationality in the 'therapeutic jungle', proliferating in India. And yet, the logic of its initiatives on the economic front is pushing the government towards a more liberal environment with fewer controls on pharmaceutical products. All this has meant that over the last year or so, discussions on the drug policy have focused on such issues as the size of the price control basket, mechanisms for determining prices, decontrol, export benefits, etc. The entire debate on the quality of essential drugs and the rationality, efficacy or the necessity of the thousands of products which strew the drug market has been mislaid.

According to reports the new 'drug policy' will recommend that the price control basket shrink further to include as few as 30 drugs from its present 143 under two categories. And this spread is to be determined not by such criteria as the country's requirement, the efficacy of the drug, etc, but by such factors as the turnover limit. This is hardly surprising given that the government has never attempted to assess requirements of drugs on the basis of actual need, nor perhaps developed the expertise needed to conduct such an exercise. Requirements are estimated, when necessary, generally on the basis of the previous year's sales. This has led to distortions such as the almost perennial shortage of drugs for tuberculosis or vitamin A supplement for the blindness control programme, while a wide range of combination analgesics, combination antibiotics and irrational dosage formulations are widely available making up the Rs 6,000 crore market. Nor is it surprising that the price control basket is to shrink yet again. The industry has painstakingly endeavoured to show how difficult it is for the government to implement price control norms for a large number of drugs, especially given the industry's own propensity for embroiling the authority concerned in long drawn out disputes over price fixation. That the solution lies not in limiting price control but in limiting the number of products in the market, a point repeatedly made by the WHO now being echoed by the World Bank, is unacceptable because it impinges on such sensitive issues as the state's interference with the market.

Another component of the policy is to be the constitution of a national drug control authority (NDA). Such an authority was mooted in the 1986 policy, but the manner in which it is taking shape now is perturbing. Its main task appears to be to facilitate price fixation, and the ministries of industry and chemicals and fertilisers are reportedly in disagreement over who should have authority over such a body. Meanwhile there are reports that the NDA will effectively override the authority of the drug controllers, whose links are with the health ministry, in the states and the centre. This would mean in effect, that the role of the health ministry in evolving the drug policy, already small, will be further curtailed. India, incidentally, is perhaps the only country where the major responsibility for formulating and implementing a policy on the pattern, pricing and availability of drugs does not lie with the health ministry. It is hardly surprising then, that issues such as an essential drugs programme are unheard of in connection with the process of evolving a new drug policy.

Thirdly, the policy reportedly emphasises the need to encourage R and D and proposes several steps towards achieving this end. This clearly is the government's instant response to the drug MNCs reported hesitation in expanding their R and D operations without adequate assurances from the government. But what kind of research will this be? Even if the investments were to be in developing new products, it is pertinent to note that only three out of the ten new drugs developed offer superior therapeutic value. In the absence of controls on the type of products to be introduced in the market, this move will, if it produces anything at all, only add to the profusion of the 'therapeutic jungle'.

Essentially then, the new drug policy, it would appear, will drop all pretence of treating drugs differently from other merchandise. That this can only lead to distortions because the prescribing and use of drugs are influenced by solely commercial promotional methods, especially in countries with little or no continuing education programmes for doctors and no state-sponsored or other alternative therapeutic information, has been widely accepted today. The disastrous state of India's national formulary and the absence of uniform prescription guidelines has, for instance, further aggravated the prevailing confusion in the drug market. A recent prescription audit in one district of Maharashtra of over 3,000 prescriptions from private and public institutions using internationally accepted indicators has shown that over 45 per cent were grossly irrational. More than 55 per cent of the doctors were found to prescribe more than three drugs usually unnecessarily. The realisation that drugs must be treated as an integral component of health care has prompted a growing number of countries, including Bangladesh, Pakistan, Bhutan, Sri Lanka in the neighbourhood, the Andean countries, Nicaragua, Australia and several African, west Asian and European countries to take steps towards introducing an essential drugs programme. Interestingly, the World Health Assembly held in May last has passed a firm resolution on the need for promoting the concept of an essential drugs programme and implementing controls on unethical promotion and marketing of drugs. But this would necessarily mean the availability of a comprehensive graded drug list which would automatically weed out the unnecessary, unethical and of course, hazardous formulations—in other words, a drug policy with an essential drugs programme as its central focus. This, unfortunately, is not what the central government and industry mean by a drug policy.

mfc ms

TOWARDS RATIONAL THERAPEUTICS

Extracts of a letter from a young doctor in a small rural hospital in Madhya Pradesh.

Dear Friend,

.....About drug prescribing practices in our hospital--in the first few months of my work I had ordered many new drugs. Later I realised mainly because of financial conditions of the patients that only important essential drugs and a minimum possible list should be adopted.

Antibiotics

We use commonly Procaine Penicillin and Penidure. They used to use a lot of Streptopen, which I don't. I mainly use procaine penicillin. Then I use a lot of septran when there is double pathology, like respiratory tract infection with urinary tract infection or otitis media. We use tetracyclines very rarely. Injection Terramycin I don't use at all. So also chloromycetin. I never use chloramphenicol. If I doubt enteric fever, I start with septran. Then we have streptomycin only for TB patients. Crystalline penicillin I use only in new borns. At present I feel very confident regarding the usage of antibiotics and I don't use two drug combinations, so I have stopped using chlorostrep.

Diarrhoea

This is usually controlled with rehydration salts and plenty of oral fluids.....Slowly discontinuing lomotil and other drugs.

Cough syrups/Tonics

When I joined there were lots of varieties of cough syrups, cough/cold tablets and also lots of variety of tonics. It took me nearly a year to cut down many brands. We had 11 brands of cough syrup and 10 brands of tonics.

Now we make cough mixture in the hospital for free patients and we have 3 other brands of cough syrup.....

About tonics--it takes a lot of patience to convince patients--they don't need tonics--they can get the same benefit with proper food and milk/eggs. Now-a-days very few people ask for "Thakath ka sissi" and we have only two types of tonics....

I have kept multivite tablets, fersolate and calcium tablets. Not a single brand of costly vitamin capsules or tablets are stocked. They used to use a lot of varieties. Slowly I stopped even B-complex injections...

For TB patients we have pyridoxin. For children we have Vit A & D and multivite drops. Vit C. I hardly use--nor do I use calcium injections except in tetany.

Antacids

We had lots of brands before. Now we use Belladinal and two brands of antacids only.

.....One thing I have succeeded in proving here is that you can run a small hospital and treat patients successfully with only a handful of drugs which are cheap and good quality. Why do we insist on each doctor or specialist having his own petty brand of drugs in our large hospitals and even the medical college hospitals?.....

Yours sincerely,

L.M.

DR - 2

World Health Organization
Organisation mondiale de la Santé

FORTY-SEVENTH WORLD HEALTH ASSEMBLY

Provisional agenda item 19

A47/7
21 March 1994

WHO ethical criteria for medicinal drug promotion

Report by the Director-General

In resolution WHA45.30 the Forty-fifth World Health Assembly urged Member States "to intensify efforts to involve government agencies including drug regulatory authorities, as well as pharmaceutical manufacturers, distributors and the promotion industry, health personnel involved in the prescription, dispensing, supply and distribution of drugs, universities and other teaching institutions, professional associations, patient and consumer groups, and the professional and general media (including publishers and editors of medical journals and related publications), in the implementation of the principles embodied in the WHO ethical criteria on medicinal drug promotion."

The same resolution requested the Director-General:

(1) to request the Council for International Organizations of Medical Sciences (CIOMS) to convene a meeting of interested parties in collaboration with WHO to discuss possible approaches to further advancing the principles embodied in WHO's ethical criteria for medicinal drug promotion;

(2) to consider other approaches and mechanisms in the Member States to improve the implementation of WHO's ethical criteria for medicinal drug promotion;

(3) to report the outcome of the meeting of interested parties and other actions of the Organization relevant to this issue to the Forty-seventh World Health Assembly through the Executive Board.

The report of the resulting consultation (Geneva, 5-7 April 1993), as prepared by the Chairman in agreement with all participants, is attached.

Following consideration of this subject by the Executive Board at its ninety-third session, when it noted the Director-General's report of which this is the updated version, the attention of the Health Assembly is in turn drawn to the progress made and to the recommendations of the CIOMS/WHO consultation (Annex).

RA
19/12/97

CONTENTS

INTRODUCTION

1. The meeting requested in resolution WHA45.30 was jointly organized by WHO and CIOMS, and held in Geneva, 5-7 April 1993. Each of the interested parties, as defined in the resolution, was represented at the consultation.

2. Background papers were prepared by WHO. Further papers describing the results of relevant studies or giving views on key issues were prepared by participants representing, in particular, industry, regulatory and academic bodies and consumers. A report of a preliminary meeting on the complementary issue of the provision and dissemination of "independent" drug information was also brought to the attention of participants. The full proceedings will become available during 1994.

3. The report of the consultation (Annex) reflects the spirit of the debate. It was prepared on the basis of contributions made during the meeting and further comments during the drafting process. It is constructive and forward-looking. It focuses primarily on the application of the criteria in developing countries. It does not dwell on the deficiencies of the past. It sets out a commitment as agreed between the parties and outlines tasks for the future. It also defines an overriding ethical precept: the right to be informed.

FUTURE ACTIVITIES

4. The 19 recommendations of the consultation are broad in scope. They relate to education and communication; the interface between promotion and regulation; the development of national policies; and international collaboration. It appears that all the interested parties accept the validity of the WHO ethical criteria and are prepared to work collaboratively to further their implementation.

5. It was generally appreciated that challenging problems will continue to emerge; that the policies and programmes of the interested parties will also change; and that the ethical criteria themselves will need to be adapted to changing circumstances. It was recognized that if collaborative efforts to promote the use of the criteria are to succeed they must not only be concerted: they must be responsive to change, and they must be given time.

6. There was recognition throughout the consultation that progress will be dependent upon the leadership provided by WHO. It was recognized that the Organization is particularly well-placed to appreciate the needs and circumstances of national drug regulatory authorities as part of national drug policies and to further develop dialogue on how control of advertising can best be integrated into the process of drug registration. It must be achieved without limiting the capacity to meet other vital objectives of the registration process, including the need to assure quality and to prevent trade in substandard, spurious and counterfeit products.

7. WHO is already promoting implementation of the ethical criteria from the regulatory perspective through:

- promulgation of its *Guiding principles for small national drug regulatory authorities*,[1] and preparation of model legislation and model software package for drug registration, which provides a means of controlling drug promotion through the establishment of an approved scientific data sheet;

- development of its Model prescribing information, its system of information exchange on national regulatory decisions, and its contribution to the United Nations Consolidated List of Products

[1] WHO Technical Report Series, No. 790 (1990), Annex 6.

whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments;

- field-testing of recently prepared guidelines for use of the Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, which now contains provision for exchange of drug data sheets and for approved labelling.

8. WHO remains concerned, however, about the paucity of "independent" factual and authoritative information directed to prescribers and to patients and other users of drug products in many countries.

9. WHO is also providing information to Member States on national initiatives to compare labelling of locally-manufactured drug products that are produced for the domestic market and for export to developing countries, respectively.

10. The following statement, issued following the consultation by the International Committee of Medical Journal Editors' meeting in Chicago in August 1993, is encouraging:

> *Most medical journals carry advertising, and advertising generates income for owners of journals, but advertising must not be allowed to influence editorial decisions. Editors must have full responsibility for advertising policy, and readers should be able to distinguish readily between advertising and editorial matter. Juxtaposition of editorial and advertising material on the same product or subject should be avoided wherever possible. Finally, editors should consider for publication all criticisms of advertisements.*

11. Further discussion of these activities and on progress achieved in implementing the recommendations contained in the report of the WHO/CIOMS meeting on the ethical criteria will be contained in the Director-General's progress reports on WHO's revised drug strategy.

MATTERS FOR PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

12. Delegates at the Forty-seventh World Health Assembly are invited to note the progress in advancing the principles and improving the implementation of WHO's ethical criteria for medicinal drug promotion, and attention is drawn in particular to the recommendations contained in the report on the CIOMS/WHO consultation.

ANNEX

CIOMS/WHO CONSULTATION

WHO ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION

Geneva, 5-7 April, 1993

BACKGROUND

The CIOMS/WHO Consultation on WHO's Ethical Criteria for Medicinal Drug Promotion was held in Geneva, 5-7 April, 1993. The meeting was attended by representatives of national drug regulatory agencies, the pharmaceutical industry, health professionals, consumer advocates, editors of scientific journals, and the Secretariats of WHO and CIOMS.

The meeting was held in response to a resolution of the Forty-fifth World Health Assembly in May 1992, that called upon WHO, in collaboration with CIOMS, to convene a meeting of interested parties to discuss possible approaches to advancing the principles embodied in WHO's Ethical Criteria for Medicinal Drug Promotion.

In his opening remarks to the Consultation, the Director-General of WHO, Dr Hiroshi Nakajima, called for the participants to build their contributions on "dialogue" and "consensus". He said that an important opportunity would be lost if the participants insisted on dwelling on the symptoms of the problems posed by drug promotion, rather than on the causes that underlie them. Only if these causes were fully analysed, and appropriate solutions identified, would the outcome of this consultation be of lasting value.

Dr Bryant, Chairman of the Consultation, pointed out the major tasks of the consultation to the participants:

- to examine the problems that surround inappropriate promotional practices as they conflict with the Ethical Criteria for Medicinal Drug Promotion, with special reference to developing countries;
- to consider what further steps are required to more fully understand the nature of those problems, keeping in mind the ways in which the problems vary according to a country's social, economic, commercial and health development;
- to explore what concrete actions might be undertaken to remedy those problems, keeping in mind that short, medium and long-term strategies would be required, both taking into account the limitations of developing countries, and being aware of the particular strengths of those countries;
- to forward to the Director-General a report of the deliberations for his consideration for further action.

PREAMBLE

WHO's Ethical Criteria for Medicinal Drug Promotion are built on health care imperatives that themselves have an ethical base. Equity is the fundamental value underlying the development of public health services, according to which there should be universal coverage and care according to need.

An essential part of such services is that physicians and patients should have knowledge about and access to therapies that are appropriate to their needs. Two further concerns bear on the nature of these services:

- the regulation of medicinal drugs must ensure the quality of drugs and information relating to them;

- the promotion of medicinal drugs must be consistent with their rational use.

The World Health Assembly, in its resolution WHA41.17 (1988) that established the Ethical Criteria, urged Member States "(1) to take account of these ethical criteria in developing their own appropriate measures to ensure that medicinal drug promotion supports the aim of improving health care through the rational use of drugs"; and "(2) to monitor and enforce, where appropriate, the implementation of the measures they have developed."

In 1992, a further resolution was adopted by the Assembly stressing the lack of progress in this area and requesting that further action be taken to implement the Ethical Criteria. The challenge to the Consultation, therefore, was to define impediments to implementation of the Ethical Criteria. Several aspects of this challenge were identified as:

- inappropriate promotion of medicinal drugs;

- limitations in the capacities of developing countries to establish drug regulatory and monitoring systems; and

- inadequate communication of the existence, meaning and purposes of the Ethical Criteria.

A further challenge involved exploring the potential for more constructive interactions among the relevant parties: (1) to support efforts of countries to ensure that medicinal drug promotion does not conflict with the rational use of drugs; and (2) to adopt measures based on the WHO Ethical Criteria as appropriate, and to monitor and enforce such measures.

A critical reference point with respect to the Ethical Criteria is that they should be integral to a comprehensive national drug policy as defined and recommended by WHO:

> "To ensure an adequate supply of safe and effective drugs of good quality, every country should have a national drug policy as an integral part of its health policy. Appropriate legislation and regulations will be needed to help implement such a policy." (*Guidelines for Developing National Drug Policies*, World Health Organization, Geneva)

Such a national drug policy would include provisions to control drug promotion, disseminate reliable independent information, and ensure the quality of available drugs.

Rights to information emerged as an issue of fundamental importance. The participants concurred that an ethical precept inherent in the Ethical Criteria is that patients and prescribers have a right to information about medicinal drugs that is factual and supportable, and that provides specific directions for appropriate drug use and monitoring of therapy. Positive claims for a product must always be balanced by information concerning important side-effects, contraindications, warnings, etc. The information should be provided in such a way as to allow patients to decide whether they wish to receive the therapy. This right to information should be emphasized and preserved.

The right to objective and balanced information is an essential element of national drug (and health) policy, and is ensured through the establishment of a national regulatory capacity, preferably as part of an

RECOMMENDATIONS

Given the critical importance of education and communications about the Ethical Criteria, we recommend:

- that relevant educational materials be developed and disseminated both nationally and internationally by WHO, universities and other interested parties;
- that WHO alert Member States to the importance of this role for universities and other educational institutions and assist them in educational programme development;
- that WHO take a leading role in promoting the provision of therapeutic guidelines for prescribers, including information that is independent and comparative, and includes explanations of the Ethical Criteria;
- that WHO, member state regulatory authorities, the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), the World Federation of Proprietary Medicine Manufacturers (WFPMM), the International Organization of Consumer Unions (IOCU), Health Action International (HAI), and other interested parties explore ways in which clearing house functions relating to WHO's Ethical Criteria and medicinal drug promotion can be established, identifying specific areas in which interested parties can fulfill these functions. WHO, for example, could act as a clearing house for regulatory and legal information.

II. STUDIES IN RELATION TO THE ETHICAL CRITERIA AND DRUG REGULATION AND PROMOTION

While many of the problems associated with inappropriate promotion are well known, the understanding of others would be assisted by further studies. Studies on the implementation and monitoring of the WHO Ethical Criteria for Promotion of Medicinal Drugs would also be beneficial.

5. **Implementation and Monitoring in relation to the Ethical Criteria.** Resolution WHA41.17, calls for Member States to take the Ethical Criteria into account as they develop measures to ensure that medicinal drug promotion supports the rational use of drugs, and to monitor and enforce the measures they have developed. WHO and its Member States have also been concerned about the limited awareness and use of the Ethical Criteria. Thus, at issue are both the monitoring of the quality of promotion, and the monitoring of the implementation of WHO's Ethical Criteria.

6. **Periodic review of the Ethical Criteria.** The Ethical Criteria should be reviewed periodically and modified as appropriate. Such review and modification should be undertaken judiciously, after careful study of the Ethical Criteria and their effectiveness internationally and at country level, and of how changes might impact on related policies of WHO, governments and other interested parties.

7. **Study of the content, flow and use of information relating to medicinal drugs.** There are often dysfunctional relationships between the quality of information related to medicinal drugs and those who would stand to benefit from it. People need accurate, independent and comparative drug information. At times, however, the information is inappropriate, whatever its distribution. At other times, the information is appropriate, but it doesn't reach those who could use it. At still other times, the potential user may not have the capacity to absorb and benefit from the information. These problems suggest the usefulness of a study of the flow, content and uses of drug related information.

8. **Formulate a typology of countries with respect to their current capacities for appropriate drug regulation and control of promotion.** Developing countries vary greatly in their capacities for drug regulation and for controlling drug promotion. The development of a typology that identifies the

integrated drug policy, as proposed in WHO's Guiding Principles for Small National Drug Regulatory Authorities.

Another issue of serious concern in the drug field is the production, promotion and distribution of spurious and counterfeit drugs. The participants urged that WHO continue its work with Member States and other parties to combat this problem as a follow-up to the "Joint IFPMA/WHO Workshop on Counterfeit Drugs", held in Geneva, 1-3 April, 1992.

The spirit and proceedings of the Consultation reflected a common commitment to enhance the positive contributions of medicinal drugs to the well being of people in all countries, with special concern for those of the developing world, and ensuring that this contribution is not impeded by inappropriate drug promotion.

TOPICS RECOMMENDED FOR FURTHER ACTION

I. EDUCATION AND COMMUNICATION

The Ethical Criteria should be widely disseminated, well understood, and function in support of the improvement of health care through the rational use of drugs. Education and communication about the Ethical Criteria are essential.

1. **Materials for the education of health personnel and other appropriate parties.** Educational materials relating to the Rational Use of Drugs and the WHO Ethical Criteria are currently limited in both appropriateness and availability for the varied audiences who need to be reached, including health personnel, the general public, marketing managers, sales representatives and the media.

2. **Roles of universities and other educational institutions in furthering the use and effectiveness of the Ethical Criteria.** Universities are in a critical position to contribute to greater understanding of the Ethical Criteria by health personnel. Thus, promoting an awareness of problems associated with drug promotion, and developing critical appraisal skills concerning pharmaceutical promotion and other sources of information about drugs, should be an integral component of undergraduate and continuing education for health personnel. Universities can also undertake research on relevant issues, such as how well drug promotion complies with WHO's Ethical Criteria.

3. **Guidance for prescribers.** Health personnel with responsibilities for prescribing medicinal drugs often lack up-to-date knowledge of drugs and their rational use. An international collaborative approach can be taken to develop and provide guidance to prescribers, such as assisting in the production of therapeutic guidelines that provide information that is independent and comparative, and includes explanations of the Ethical Criteria and their applications to prescribers and other parties.

4. **Clearinghouse functions for materials relating to WHO's Ethical Criteria and to medicinal drug promotion.** Several kinds of materials could be helpful to countries and organizations working toward more effective approaches to the implementation of WHO's Ethical Criteria for the promotion of medicinal drugs: existing legislation relating to medicinal drug promotion; national and organizational codes relating to ethics and medicinal drug promotion; materials available from drug regulatory agencies; and educational programs that promote the WHO Ethical Criteria and develop critical appraisal skills. Additionally, information concerning regulatory actions taken by national authorities could be of use both to other regulatory authorities and national and international organizations. These materials are often widely dispersed and difficult to access.

characteristics of countries at different stages of this process, as well as the sequence of developmental steps required to increase competence in this field, would provide an analytical method for increasing understanding of these problems.

RECOMMENDATIONS

To promote and carry out studies appropriate to the effective implementation of the Ethical Criteria for the Promotion of Medicinal Drugs we recommend:

- that WHO, in consultation with concerned parties, determines how to proceed with monitoring of the implementation of the Ethical Criteria, continues its work to develop performance indicators in this area, and considers what remedial measures should be taken when there is non-compliance with the content of the Ethical Criteria;
- that WHO, in consultation with interested parties, periodically review the Ethical Criteria;
- that WHO, in consultation with interested parties, explore the possibilities of initiating studies of the content, flow and use of information relating to medicinal drugs;
- that WHO take the lead in developing a typology of the current capacities of countries for appropriate drug regulation and for controlling promotion and in using the typology for studying capacity building in this field.

III. NATIONAL POLICIES AND ACTIONS

Each country must have its own national drug policy, which has the purpose of ensuring an adequate supply of safe and effective drugs of good quality, an integral part of which will be legal and procedural arrangements for ensuring the appropriate uses and promotion of medicinal drugs. These arrangements will involve interactions with other interested parties, including pharmaceutical companies and their associations, distributors, health professionals, consumer groups and universities.

9. Drug regulation, drug quality, drug promotion. The central features of a national drug policy encompass responsible approaches to drug regulation, drug quality, the quality of information, the rational use of drugs, the provision of affordable drugs, and drug promotion. A vital element of national policy and legislation is the capacity to regulate and control drug labelling and drug promotion through a product licensing system. Additional crucial components of national drug policy include: the provision of independent information and education about drugs; the development of critical appraisal skills in health professionals and consumers; monitoring of ethical standards of pharmaceutical promotion, and auditing the quality of medicinal drug use. Thus, the Ethical Criteria become an integral part of such national drug policies.

10. The establishment of national drug policy committees. A national drug policy committee can strengthen capacities for formulating policies, procedures and programmes that will lead to responsible national pharmaceutical programs. Such committees may begin as ad hoc arrangements and devolve specific major responsibilities to legally established bodies. They should involve all interested parties: government, manufacturers, health professionals and consumers. Other structural approaches to the development of drug policies also need to be explored.

11. The establishment and strengthening of national pharmaceutical industry associations. Corporate practices consistent with the Ethical Criteria should be promoted by national pharmaceutical industry associations.

12. **Medical representatives, symposia and other meetings.** The Ethical Criteria lay down explicit guidelines for acceptable training and conduct of medical representatives and for the conduct of symposia and other meetings to ensure that they are educational rather than promotional.

13. **The complementarity of self regulation and national regulation.** Self-regulatory codes with appropriate sanctions rigorously applied can assist in the implementation of the Ethical Criteria. An interactive combination of self-regulation by companies and national regulation by governmental authorities is often a constructive arrangement. One functioning without the other can be sub-optimal. The value of autonomous bodies to set ethical standards, review and/or clear promotional material, and adjudicate complaints is recognized.

RECOMMENDATIONS

In view of the importance of national actions relating to the Ethical Criteria for the Promotion of Medicinal Drugs, we recommend:

- that WHO and all interested parties emphasize the importance of the Ethical Criteria being incorporated in and supported by national drug policies;
- that governments consider the establishment of National Drug Policy Committees;
- that National Industry Associations be set up and that international industry associations help to establish such associations;
- that WHO, in concert with Member States, consumers, IFPMA and other associations representative of pharmaceutical companies, and national medical associations formulate approaches to problems associated with medical representatives and symposia, including further development and adoption of codes of training and conduct of medical representatives and conduct of symposia, in ways that are consistent with the Ethical Criteria.

IV. INTERNATIONAL COLLABORATION

While national level regulations, procedures and other arrangements for promoting the rational use of drugs are essential, critical contributions are needed from the international level. Important questions arise on how international organizations and interested parties can interact in ways that are supportive of national activities in furthering these important efforts.

14. **Roles of WHO.** WHO has a central role in assisting Member States in establishing and strengthening their programmes for ensuring the quality and rational use of drugs. The Ethical Criteria for the Promotion of Medicinal Drugs represents additional potential support for national drug policies. The further development by WHO of performance indicators, monitoring procedures, and educational modules would assist in the implementation of the Ethical Criteria.

15. **Editorial policies.** The peer-reviewed journals have played a pivotal role in ensuring the scientific integrity of materials they publish. Editors of professional journals can contribute further to rational health care not only by publishing good scientific work on medicinal drugs but also by ensuring that all drug advertisements in their journals accord with the WHO Ethical Criteria.

16. **Relationships of international and national associations.** The IFPMA, WFPMM, and bodies representing generic manufacturers, are key partners in the international effort to ensure responsible promotion of medicinal drugs in accordance with the Ethical Criteria.

17. **Codes of international and national associations and local companies.** Codes that govern the promotion of medicinal drugs in ways that are consistent with and supportive of the Ethical Criteria represent an important contribution. Consultation among the involved parties is required to establish, maintain and update such codes so they achieve their intended purposes.

18. **International, national and local consumer groups.** Consumer groups have key roles to play in this field by, inter alia, promoting the existence of the Ethical Criteria, encouraging their use, developing training and educational materials, and doing studies to monitor promotion. International and local consumer groups can be mutually supportive in these efforts taking account of possibilities to collaborate with all concerned parties.

19. **National and international coalitions of concerned parties.** In recent years there has been greater collaboration among the various parties concerned with improving health care through the rational use of drugs. Now the challenge is to further cooperation among these parties so as to strengthen understanding of and compliance with the Ethical Criteria.

RECOMMENDATIONS

Important contributions can be made at the international level to arrangements for the promotion of medicinal drugs and the implementation of the Ethical Criteria. Accordingly we recommend:

- that WHO continue its constructive role in this important field;
- that scientific journals develop advertising guidelines similar to the guidance they provide to authors, to ensure compliance with the Ethical Criteria;
- that the IFPMA and WFPMM and other bodies exert their further efforts and positive influence on the formation and activities of national associations of pharmaceutical companies in their respective areas;
- that the IFPMA, WFPMM, national associations and local companies continue to develop their own codes relating to the promotion of medicinal drugs in ways that are consistent with the Ethical Criteria;
- that international, national and local consumer groups continue the key roles they are playing in working with governments and industry toward constructive actions relating to the Ethical Criteria for the Promotion of Medicinal Drugs, particularly pursuing studies of promotion, monitoring compliance with the Ethical Criteria, and working to create a critical awareness among consumers.
- that WHO, CIOMS and other interested parties, including donor organizations, consider how these national and international interests and resources can be brought into more effective interaction in relation to the Ethical Criteria, including, as one possibility, the convening of regional meetings to consider these issues.

REFLECTIONS ON THE CONSULTATION

The World Health Assembly established the Ethical Criteria for Medicinal Drug Promotion in the expectation that they would strengthen national and international capacities for controlling inappropriate drug promotion and support the rational use of drugs.

However, WHO and relevant parties have been concerned that the Ethical Criteria have not been widely disseminated and implemented, and that their role in controlling inappropriate drug promotion has

been less than had been anticipated. Accordingly, the Assembly requested WHO, in collaboration with CIOMS, to convene a consultation in order to explore further steps that might be taken to advance the principles embodied in the Ethical Criteria.

While the Consultation focused primarily on the problems developing countries have in responding to the Ethical Criteria, the Consultation was also concerned with the ways in which these issues apply to developed countries.

An underlying reality of this field has to do with tensions existing between industry, governmental regulators and consumer advocates on a variety of matters including drug promotion. Such tensions can have positive effects in that all parties have a common commitment to the well-being of the public, though their perspectives and approaches are often different.

One of the challenges to this consultation was to capitalize on the common commitments and substantial strengths of the interested parties and to identify the areas in which agreement and collaboration could proceed.

The consultation was considered by all who attended to have been a success in bringing participants into substantial agreement on a number of issues and actions to be taken. One overriding ethical precept (that of rights to information) and nineteen Recommendations for Further Action form the core of the Report of the Consultation. The Recommendations have a wide range - Education and Communication in Relation to the Ethical Criteria; Studies in Relation to the Ethical Criteria and Drug Regulation and Promotion; National Policies and Actions; and International Collaboration.

This Report has been carefully constructed on the basis of contributions during the Consultation and the further commentary of participants during the drafting and finalizing of this document.

It should be clear, however, that the larger part of the work in this field still lies ahead. The Recommendations of the Consultation set the stage. The Executive Board of WHO and the World Health Assembly can take the policy decisions necessary to carry the Recommendations, modified as they see appropriate, toward implementation, including the important step of encouraging Member States to act in full support of the Recommendations.

It is apparent that the relevant parties - national drug regulators, industry, consumers, health professionals, international organizations, professional and general media - are prepared to work collaboratively toward greater effectiveness in this field. But such collaboration will not follow automatically. Challenging problems will continue to emerge. The Ethical Criteria will not be static, nor will the policies and programmes of the interested parties. Effective collaboration will require concerted attention, persistence in pursuing key issues (such as identification of measures and procedures for monitoring, and related research), and continued openness to concerted action.

These steps and relationships will build on the growing realization that all parties have a common responsibility, built on fundamental ethical principles, for the well being of patients individually, and of the public collectively.

= = =

DR-2

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

A45/13
18 March 1992

FORTY-FIFTH WORLD HEALTH ASSEMBLY

Provisional agenda item 19.2

IMPLEMENTATION OF WHO'S REVISED DRUG STRATEGY

SAFETY AND EFFICACY OF PHARMACEUTICAL PRODUCTS

Progress report by the Director-General

In resolution WHA43.20 the Forty-third World Health Assembly requested the Director-General, *inter alia*, "to report to the Executive Board and the Forty-fifth World Health Assembly on the use of the ethical criteria for drug promotion endorsed by resolution WHA41.17, and on progress made and problems encountered in implementing the revised drug strategy, the report to cover drug supply, prescribing practices, development of human resources, training of relevant health personnel on the rational use of drugs, quality assurance and drug information". In addition, at its meeting in January 1988 the (then Ad Hoc) Committee on Drug Policies of the Executive Board requested a report on the outcome of a review of the WHO International Drug Monitoring Programme and on guidelines for the implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

The present report was reviewed during the eighty-ninth session of the Executive Board by the Committee on Drug Policies. It provides background information relevant to resolutions EB89.R2 (WHO ethical criteria for medicinal drug promotion) and EB89.R3 (WHO Certification Scheme). The Board concurred with the Committee's recommendation that this report should be reproduced in full as a progress report by the Director-General to the Forty-fifth World Health Assembly.

CONTENTS

RH
10/12/92

I. RELATIONSHIPS WITH NATIONAL DRUG REGULATORY AUTHORITIES

CONTENTS

1. INTRODUCTION

1.1 WHO's revised drug strategy devolves from the Conference of Experts on the Rational Use of Drugs (Nairobi 1985), which brought together representatives of governments, pharmaceutical industries, and patients' and consumers' organizations to discuss ways of ensuring the rational use of drugs, in particular through improved knowledge and flow of information, and the role of marketing practices in this respect, especially in developing countries. In 1986 a report on this meeting and the revised drug strategy[1] was presented to the Thirty-ninth World Health Assembly, which endorsed the strategy in resolution WHA39.27.

1.2 Subsequently, the Director-General reported to the Health Assembly on two specific components of the strategy. In 1988 proposals to extend the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[2] and ethical criteria for medicinal drug

[1] Document WHA39/1986/REC/1, p. 93.

[2] Document WHA41/1988/REC/1, p. 53.

Pharmaceutiques (Dakar, February 1991); a symposium on quality management in drug procurement was organized jointly by the West African Pharmaceutical Federation, the International Pharmaceutical Federation and WHO (Accra, February 1991); and an international workshop of authorities on computer-based drug regulation was held with funding from the Italian Government (Windhoek, July 1991).

15. INTERNATIONAL NONPROPRIETARY NAMES

15.1 A call to assign International Nonproprietary Names (INN) to the rapidly increasing array of products produced by recombinant technology indicates the need for seeking extrabudgetary resources to supplement those available to WHO. There are indications, for instance, that some 400 monoclonal antibodies alone are under development. Also in contention is a wide range of other peptide regulatory factors including cytokines (interferons, interleukins, colony-stimulating factors), erythropoietins, plasminogen activators, growth hormones and other growth factors. The WHO Committee on International Nonproprietary Names for Pharmaceutical Substances faces an inevitable linguistic challenge in its attempts to extend the INN nomenclature in a reasonably systematic manner in the face of such demands.

15.2 The challenge is aggravated when manufacturers seek to promote these products using brand names that are derived from INNs or use stems selected from INNs. Since, with few if any exceptions, no two products that are manufactured independently by these methods can be accepted to be totally identical, and may consequently not be clinically interchangeable, there is a consensus among national nomenclature commissions and the WHO Committee that every such product that is independently produced should be assigned a distinctive INN (unless absolute proof of identity with another product is provided). The assignation of trade names is unlikely to hold significant commercial advantage in these circumstances, but WHO undertakes to consult interested national drug regulatory authorities and IFPMA before exercising any initiative in this regard.

15.3 In the meantime, national authorities are invited to reconsider a recommendation made by the WHO Expert Committee on Nonproprietary Names for Pharmaceutical Substances in 1975[1] that the inclusion in brand names of generic stems selected by the Committee should be discouraged and, as far as is practicable, disallowed.

[1] *WHO Technical Report Series*, No. 581, 1975.

II. WHO ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION

Resolution WHA43.20 requests the Director General, *inter alia*, "to report to the Executive Board and the Forty-fifth World Health Assembly on the use of the ethical criteria for drug promotion endorsed by resolution WHA41.17 ....". In this resolution, Member States were urged to take account of these criteria when developing measures to ensure that medicinal drug promotion supported the aim of improving health care through the rational use of drugs. It also appealed to those involved in the prescription, dispensing, supply and distribution of medicinal drugs to use the criteria appropriately, to adopt the measures developed and to enforce the standards thereby proposed.

CONTENTS

1. INTRODUCTION

1.1 The WHO ethical criteria are based on a draft prepared by an international group of experts comprising drug regulatory officials, representatives of pharmaceutical manufacturers, prescribers, consumer advocates, lawyers and medical journalists. They "constitute a frame of reference for proper behaviour in the promotion of medicinal drugs", but "do not constitute legal obligations; rather they set out general principles which could be adapted by governments to national circumstances". Member States are urged "to take them into account in developing measures to ensure that medicinal drug promotion supports the aim of improving health care through the rational use of drugs".[1]

1.2 An appeal is addressed to the public and all interested parties, including pharmaceutical manufacturers, teachers and editors of medical journals to use them as appropriate to their spheres of competence, activity and responsibility. Both governments and nongovernmental organizations are requested to monitor and enforce relevant standards and other measures that they develop.

1.3 Promotion is defined within this context as "all information and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal products". Specifically discussed are all forms of advertisements addressed to physicians, health-related professionals and the general public; the training and responsibilities of medical representatives; the offer of free samples of drugs for promotional purposes either to prescribers or, in the case of non-prescription drugs, to the general public; sponsorship of symposia; post-marketing scientific studies, surveillance and

[1] *Ethical criteria for medicinal drug promotion*. Geneva, World Health Organization, 1988, back-cover text.

dissemination of information; packaging and labelling; information for patients, package inserts and booklets; and promotion of exported drugs.

2. USE OF THE CRITERIA BY GOVERNMENTS

2.1 The responses to an enquiry circulated by WHO to all national drug regulatory authorities in September 1990 show that, in general, those countries with highly evolved drug regulatory mechanisms have already enacted provisions largely comparable in their general intention with the criteria. Several, none the less, have expressed an intention either to include the criteria, or to adapt them for inclusion, in legal instruments. Thus far, the Ministry of Health of Turkey has used them as the basis for updating regulations on promotion of medicinal drug products for human use, and the Media Council of Australia has incorporated them in its Therapeutic Goods Advertising Code which is binding upon virtually all print, radio, television, outdoor and cinema media throughout the country.

2.2 The criteria have also served to draw to the attention of governments various particulars on which there is no consensus among Member States. Some of these differences reflect differing national conditions, but others reflect divergencies on matters of principle. For instance, some countries, but not others, permit - within defined limits - advertising of prescription products directly to the general public. Some permit comparative advertising, others do not. Different national positions also prevail, for example, on the admissibility of short (or "reminder") advertisements, the use of radio and television and other non-print media, and the use of product samples for promotional purposes.

2.3 One fundamental point that is evident from the replies received, and from the review of relevant legislation in the *International Digest of Health Legislation*, is that effective oversight and control of promotion is possible only when a comprehensive national drug licensing system is in place. Control of promotion implies the existence of standards. In so far as these standards control precise promotional claims, they are product-specific and they can be determined only by an approved scientific "data sheet" that is incorporated into the product licence. Countries that have yet to develop a product licensing system are able to promulgate and enforce general provisions intended to control promotional practices, but they lack the means to check claims on a product-specific basis.

2.4 Even those countries with rigorous product licensing requirements face a daunting task in verifying the compliance of all written advertising material with the approved data sheet. Few countries possess regulatory authorities with the human resources to proactively screen all advertising copy. Some have set up autonomous, multidisciplinary committees to assume this screening function and to review or adjudicate on specific complaints about promotional practices. Some have introduced collateral measures that require the product licence holder to refrain from promoting or distributing a new product until a copy of the approved data sheet has been issued to every registered practitioner. Some have resorted to exemplary prosecution of companies and responsible employees for wilful breach of regulations. All depend, however, on a high level of compliance and self-regulation within the industry to enable them to root out inadmissible practices with reasonable efficiency.

3. USE OF THE CRITERIA BY MANUFACTURERS OF PRESCRIPTION DRUGS

3.1 The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) - which has 45 member national associations representing manufacturers of approximately 80%, by value, of the world's prescription medicines - first adopted a Code of Pharmaceutical Marketing Practices in 1981. This sets out "minimum standards" to be adopted by companies wherever their products are marketed. Many national pharmaceutical manufacturers associations have drawn up more detailed codes through which they exercise varying measures of self-discipline. This control is effected by national adjudicating committees which include members who are independent of the industry. Their work is carried out in an essentially reactive manner by hearing complaints from third parties and sometimes from other companies. The sanctions imposed are administrative: publication of the names of offending companies and, in extreme circumstances, exclusion from membership of the national association for stipulated periods of time. None of this has any impact on other companies, often established in countries without highly evolved regulatory authorities, that are not affiliated to IFPMA. Indeed, these may operate without any tangible external control or oversight.

3.2 Complaints concerning activities of multinational companies in countries that possess no national disciplinary body can be transmitted directly to IFPMA, which is responsible for administering its international code. In this case, each complaint is referred for consideration to the member association in the country in which the headquarters of the accused company is based, although the final opinion communicated to the complainant is formulated by an IFPMA committee which incorporates independent assessors. Given the scale on which the industry operates and the intensity of its promotional activities, the number of cases referred to IFPMA is small: a total of 70 complaints, relating to 912 cases, has been filed over the past 10 years and the annual returns demonstrate a falling trend in the number of cases notified over the past four years.

3.3 IFPMA has informed WHO that it considers systematic monitoring of company marketing activities as quite impracticable and that monitoring could therefore be conducted only on a very limited and arbitrary basis. In commenting on the operation of its Code, IFPMA emphasizes that details of complaints processed between 1983 and 1989 have been published in 10 status reports, and states: "... strenuous efforts have been made to make the existence of the Code known as widely as possible and also to encourage use of the complaints procedure. Although the text of the Code has remained unchanged since its original definition, explanatory material has been added, most recently in January 1989, and many thousands of copies in three-language versions have been distributed throughout the world both within and outside the industry. Additionally the Code has featured in several numbers of the [IFPMA] periodical 'Health Horizons', most recently in May 1989. This publication has a circulation of about 10 000, mainly within the developing world". IFPMA also notes that, in several instances, complaints have challenged the justification of the product, rather than the manner in which it is promoted. The Code reflects the view that, provided the product has been duly authorized for marketing by a competent regulatory authority, it is not for IFPMA to question the judgement of that authority.

3.4 IFPMA has never formally adopted the WHO ethical criteria for medicinal drug promotion. However, it has stated: "... the criteria have been examined closely in comparison with the [IFPMA] Code, which had already been in existence for seven years when they were defined. The conclusion was reached that, in so far as they related to the prescription medicine sector of the industry, there was full congruence between the two, even though certain provisions elaborated in some detail in one document were covered in a more general requirement of the other and vice versa. Since the IFPMA Code is an obligation on its members, the formal adoption of the wording of certain recommendations of the criteria in the Code text would result in conflict between existing regulations in some countries and the requirements of the Code". It sees, in this connection, an important distinction between the binding nature of its Code and the broader advisory purview of the WHO ethical criteria which constitute "an appeal to concerned parties for adoption to the extent considered appropriate to their field of competence". Notwithstanding this distinction, IFPMA contends that "the two documents are fully consonant one with the other and that the industry represented by IFPMA is responding in a practical and effective way to the appeals of the World Health Assembly".

4. USE OF THE CRITERIA BY MANUFACTURERS OF NON-PRESCRIPTION DRUGS

4.1 The World Federation of Proprietary Medicine Manufacturers (WFPMM) comprises 50 member national associations representing manufacturers of medicinal products that are identified by and sold under a trade mark, trade name, brand or other trade symbol, and that are sold or offered for sale to the general public mainly for use in self-medication. It has developed a statement of policy on advertising to the public, and it issues guidelines for voluntary codes of advertising practice which take into consideration the WHO ethical criteria.

4.2 WFPMM does not, itself, promulgate a code on the grounds that "varying conditions ... relating to distribution differences, advanced or less advanced state health services, differing climatic conditions affecting the prevalence of particular minor ailments, legislative differences, etc., will call for differences in the content of such Codes". It believes that "a combination of national laws, voluntary industry codes on a national level, and responsible individual company action are effective in maintaining high standards of advertising among the various nations - taking into account the vital matter of local conditions". It also considers, having regard to lack of pharmacy retail outlets in many areas, even within some developed countries, that "it would be quite improper and not in the public interest to attempt to harmonize retail distribution controls on an international basis".

4.3 In commenting on the WHO ethical criteria, WFPMM considers that, in several particulars, the recommendations do not distinguish clearly between prescription and non-prescription medicines, or between "patients" and "consumers". The requirements of the latter for information, it is pointed out, differ in that patients are under the supervision of a prescriber, while consumers take their own decisions on self-care. It also believes that advertisements of non-prescription products - particularly having regard to the wide range of media employed - cannot be used effectively to convey detailed basic information on medicines; they can only create awareness of a product, and indicate its approved uses. Advertisements, it contends, are not the place to indicate the limitations on the use of a non-prescription medicine other than to specify the category of people who should use it. In a statement of policy on consumer information it identifies labelling as the vehicle for conveying precise and detailed information to the consumer, both at the time the product is purchased and when it is used. However, the statement provides no insight on the extent to which products are actually selected by purchasers on the basis of their labelling rather than on impulse or recollection of a superficial advertising claim.

5. USE OF THE CRITERIA BY TEACHERS AND OTHER HEALTH PROFESSIONALS

5.1 In adopting the criteria, the Forty-first World Health Assembly, by resolution WHA41.17, urged Member States to take them into account in developing measures to ensure that medicinal drug promotion supports the aim of improving health care through the rational use of drugs. None the less, since advertising is inherently promotional in character, there is a need for complementary objective, independent information that is directed both to the health professions and to the public at large. Within the medical establishment, the challenge lies primarily with clinical pharmacologists to promote the changes of attitude implicit in the rational use of drugs; but internists, specialist clinicians and pharmacists each have a vital contribution to offer.

5.2 Doctors will always stalwartly defend their professional freedom to prescribe as their judgement dictates. However, enough has been learned from the introduction of institutional formularies, antibiotics policies and therapeutics committees in recent years to show that peer review of prescribing practices, when undertaken with competence and sensitivity to the need for consultation and feedback of information, can be not only tolerated but welcomed by the profession at large.

5.3 The delivery of medical services is engulfed by an unprecedented cost crisis. The divide between what is possible and what is practicable has passed the stage at which it might be bridged simply by increased charges on patients and public funds. Inevitably, the options are most limited where the need is greatest, but everywhere it is becoming necessary to set priorities and to ensure that they are respected. In varying degree, governments have become directly engaged in cost saving - most notably by promoting generic prescribing, by excluding specific products from reimbursement schemes, by issuing advice to doctors on good prescribing practices and, in some instances, by imposing limits on their drug budgets. Critics argue that prescribing regulation may lead to false economies that neither save money in health care provision overall nor maintain standards of patient care, and that may well neglect the improved quality of life that drug treatments can offer. These differing viewpoints will be resolved only when the generality of prescribers is persuaded, by training or otherwise, routinely to consider costs when weighing the relative advantages and shortcomings of treatment options.

5.4 To this end, WHO is collaborating with the International Union of Pharmacology to depict clinical pharmacology as a specialty of relevance to the socioeconomic aspects of health care. Two exploratory projects have been initiated with this objective in view. One is directed to collating and reviewing information on the teaching of therapeutics in medical schools around the world. The other seeks to compare and to evaluate approaches to the treatment of commonly occurring diseases in a wide variety of medical settings. Preliminary discussions have also been held with a view to updating, within this perspective, the WHO report on clinical pharmacology: scope, organization and training, which was issued in 1970.[1]

5.5 Within WHO, many programme activities are currently directed to rationalization of therapeutic management, particularly in relation to infectious and transmissible diseases. The biennial updating of the WHO Model List of Essential Drugs and the production of the complementary *Model Prescribing Information* series has become a highly coordinated activity, involving not only many technical programmes but also their

[1] *WHO Technical Report Series*, No. 446, 1970.

expert advisory panels. *WHO Drug Information*, now in its fifth year as a subscription periodical, is firmly established as a journal that reflects WHO policies and activities from both the socioeconomic and the technical standpoints in relation to drug use. In future, a higher profile will also be accorded to the pharmaceuticals section of the United Nations *Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments*. With the agreement of the United Nations secretariat this will be produced on an annual basis, initially in English, as a service to national drug regulatory authorities.

6. THE ISSUES

6.1 The basic issues to be confronted are not new, although they constantly acquire new dimensions. Some problems, given good will by all concerned parties, are open to solution. Progress with regard to the others will be dependent upon the availability of necessary human and material resources.

6.2 Health Action International, a public interest group represented in 60 countries, that actively promotes a more rational use of drugs, has recently produced a valuable annotated bibliography to illustrate the panoply of problems that developing countries, in particular, face in their efforts to achieve rational and economic drug use.[1] It cites, *inter alia*, three targets for urgent action that have direct relevance to the WHO ethical criteria: more objective information on the rational use of drugs; more direct access by consumers to such information; and stricter controls on advertising. The directness of the appeal belies the complexity of the issues.

6.3 Many independent publications, directed to personnel at every level within the health care system, are currently available on the properties and uses of medicinal products. Virtually all, however, are produced commercially with a view to maximizing sales, and they are concerned with medicine as it is practised in highly developed countries. Even among these, very few, as yet, discuss cost-effectiveness or other socioeconomic aspects of drug use.

6.4 WHO is perhaps alone in the extent to which it caters, in its printed outputs, for the needs of developing countries. It faces two perennial problems, however: its outputs are restricted to the working languages of the Organization, and lack of exchangeable currency in the target countries frustrates effective penetration into their markets. The distribution of free copies of its publications is necessarily limited and, even at reduced prices, booklets intended primarily for use in developing countries, such as the volume dealing with drugs for parasitic disease in the *WHO Model Prescribing Information* series, are unlikely to generate sales of more than a few thousand copies. Reprinting of material locally by arrangement, either in the original or in the national language, is welcomed. In selected cases, this has dramatically increased the number of printed copies, but in general it does no more than partially solve the underlying difficulty.

6.5 It is encouraging, none the less, that many countries are using material generated within WHO in the compilation of their own national drug formularies. However, doctors also need regularly to update information on the contemporary therapeutic issues that are discussed in the quarterly bulletin *WHO Drug Information*. Two other approaches, one at each end of the technology spectrum, offer promise in alleviating this difficulty. One relies upon local initiatives by doctors and pharmacists, usually in university departments of medicine or pharmacology, to produce independent drug bulletins that are circulated to networks of subscribing doctors. Given encouragement and modest financial support in local currency from official sources, some such initiatives are already exerting a demonstrable influence on local prescribing patterns. The second approach looks to the future. Technology in data transmission has now developed to the extent that it will become cost-effective and practicable within the next few years for virtually all countries to receive information from WHO on diskette not only for reading but - by arrangement with WHO - for low-cost local printing and reproduction. A preliminary inquiry among national drug regulatory authorities has shown that a large majority are already able to handle - and would indeed welcome - information in this form.

6.6 At the present time, however, it is apparent that the resources of pharmaceutical companies to produce information regarding the use of their products surpass those of governments and the health-related professions. Ostensibly, highly evolved regulatory authorities already possess the statutory powers and

---

[1] Hardon, A. et al., eds. *The provision and use of drugs in developing countries*. Amsterdam, Health Action International, 1991.

regulations to exercise the controls required over advertising and other forms of promotion of products. However, the situation that confronts regulators is never static. Pharmaceutical companies have developed in recent years into major sponsors of postgraduate medical education and scientific debate, and their advertising revenues sustain the production of all but the most prestigious medical journals. Much of this activity brings undisputed benefits. This gain could not now be cast aside without gross disruption. None the less, sponsorship of education and research inevitably provides a vehicle for bias and an opportunity for veiled promotion. The problem now in developed countries is not simply the imbalance in the availability of objective information and promotional material but the difficulty of distinguishing the one from the other.

6.7 Specific industry-sponsored approaches currently under scrutiny by the United States Food and Drug Administration[1] include press releases and press conferences; company or privately-funded journals, journal articles, letters and reports and special supplements to journals; lecture tours by scientists or experts that promote one company's product or disparage a competitor's; company-financed scientific and educational seminars, symposia, conferences, programmes and meetings; celebrity endorsements of products; advertisements that feature questionable, unsubstantiated, or selected research particularly if it is funded by the company; and distribution of videos and computer disks of promotional material disguised as news and educational information.

6.8 Two key areas of research that are particularly vulnerable to the bias of sponsorship are post-marketing studies and cost-effectiveness analyses of newly approved products. Post-marketing studies are intended to provide information on the performance of new drugs under conditions of routine use, but opportunity exists to build a promotional dimension into the design. Cost-effectiveness studies are of value to health planners concerned with the delivery of health care. They are also helpful to pharmaceutical companies, which sponsor much research of this type, both for promotional purposes and for strategic planning. Formal evidence of ambiguity in the objectives of such studies is wanting, but it has been claimed from the vantage-point of experience that "review of manuscripts before publication is usual, attempts to fund only positive studies are the rule, and incentives for investigators to make favourable assumptions are ever present".[2]

6.9 In countries where market potential is low, this type of sponsorship bias holds little attraction. But advertising inevitably assumes importance to a local manager who is otherwise unable to maintain sales sufficient to ensure a secure profit margin. Where regulatory oversight is limited, this is too often reflected in journal advertisements containing vague, unqualified claims as well as technical details that are sometimes cast in a typeface too small to be legible. The consequences of this can be profound. Where microbiological facilities are not available, concern about hypothetical antibiotic resistance can be exploited in such advertisements to provide a justification to propose reserve antibiotics for indiscriminate routine use. In a recent extreme case, promotion of potentially dangerous drugs for infantile diarrhoea in developing countries was curbed by some internationally based companies only when evidence associating one of these products with fatal paralytic ileus was publicized internationally. Some of these shortcomings constitute manifest breeches not only of codes but, in some cases, of regulations and statutes.

6.10 With such lapses in mind, the President of IFPMA issued an open letter to the leadership of the world pharmaceutical industry in July 1991 stating, *inter alia*:

> For the future, it is clearly imperative that, in the public interest as well as the long-term interests of our industry, all possible steps are taken to maintain scrupulous respect for the principles of the Code. As an international industry we claim with justification to observe internationally consistent standards and we must be seen to do so, whether it be for product quality, marketing practices or any other aspect of our business. When different norms between countries have to be observed the differences must be seen to be for valid reasons and companies should be prepared to give convincing and vigorous responses to any challenges in this regard.

---

[1] Kessler, D.A. Drug promotion and scientific exchange: the role of the clinical investigator. *New England Journal of Medicine*, 325: 201-203 (1991).

[2] Hillman, A., Eisenberg, J., Pauly, M. et al. Avoiding bias in the conduct and reporting of cost-effectiveness research sponsored by pharmaceutical companies. *New England Journal of Medicine*, 324: 1362-1365 (1991).

I would urge you to ensure that your staff members are continually reminded of the need to follow well-defined guidelines for marketing activities and to maintain consistent operating standards in all countries. Furthermore, observance of these standards should be required of your licencees and agents as a condition of the relationship.

6.11 From the governmental perspective, consideration is bound to turn to the need for stricter controls. Supplementary legislation will be of value only to the extent that it can be effectively enforced. Evidence of frailty in enforcement capability is evident in relation not only to substandard advertising, but to a disquieting prevalence of counterfeit, spurious and substandard products on many national markets. Effective enforcement becomes possible only where there is a credible drug inspectorate complemented by an efficient drug licensing system. Prosecutions cannot be brought to bear in many instances under typical national drug laws until the legitimate market has been defined through formal licensing of products, manufacturers and wholesalers.

6.12 The administrative requirement of formal licensing can be realized initially by issuing "licences of right" which simply define and provisionally legitimize each medicinal product notified by the responsible person as having been available on the market prior to the day on which licensing requirements were introduced. No assessment is implied in the issuance of a provisional licence. Technical reviews can be undertaken and definitive licences issued subsequently at a speed consonant with the resources of the licensing authority. However, provisional licensing confers two immediate advantages: unlicensed products are identifiable, *de facto*, as illegal; and the licences of products that are adjudged, on specific criteria, to be unsafe or inefficacious can immediately be either withdrawn or modified by administrative action. Since the product licence includes a description of the approved indications for the product together with information on contraindications, precautions and adverse effects, it also provides an immediate control both of product labelling and of advertising claims.

6.13 The administrative exercise involved in setting up such a licensing scheme is not necessarily labour intensive even if traditional filing methods are used; but if data entry and retrieval are computerized, the compilation and subsequent use of the system for enforcement purposes is greatly facilitated. A readily adaptable software package which - with sufficient harmonization of licence applications - could readily allow controlled automated entry of licence details into the data base, is currently being developed by WHO with funds received from the governments of Germany and Italy. The intention is to offer it, free of charge and copyright, to every interested national drug regulatory authority.

6.14 Even when such licensing systems have become standard administrative tools within regulatory authorities, effective pre-screening of all proposed advertising copy will be beyond the capability of small regulatory authorities. An exemplary level of self-discipline will still be required from manufacturers and other product licence holders if expected standards are to be met, and their representative national associations will still need to exercise meaningful oversight in their implementation.

6.15 Self-discipline and self-regulation are prerogatives that create an expectation for accountability of action and a willingness to subject norms and standards, whether actual or enjoined, to debate. IFPMA accepts this thesis and has reacted favourably to a proposal that a forum to enable these issues to be debated by interested parties should be created within the Council for International Organizations of Medical Sciences (CIOMS) - an international organization established jointly by WHO and UNESCO in 1949 that serves the scientific interests of the international biomedical community in general and has a long tradition of involvement in bioethical matters.

THE POLITICS OF HEALTH SECTOR REFORM IN DEVELOPING COUNTRIES: THREE CASES OF PHARMACEUTICAL POLICY

By

Michael R. Reich
Harvard School of Public Health
665 Huntington Avenue
Boston, MA 02115

Prepared for the Conference on
Health Sector Reform in Developing Countries: Issues for the 1990's
New England Center, Durham, NH
10-13 September 1993

RN
10/9/97

THE POLITICS OF HEALTH SECTOR REFORM IN DEVELOPING COUNTRIES: THREE CASES OF PHARMACEUTICAL POLICY

By Michael R. Reich

INTRODUCTION

Policy reform is a profoundly political process. Politics affects the origins, the formulation, and the implementation of public policy, especially when significant changes are involved. For the health sector as well, policy reform requires political skill, as President and Hillary Clinton have discovered (Figure 1) (Peterson, 1993). Yet these political dimensions are seldom analyzed systematically for health sector reform in developing countries. The tendency, especially in public health, is to portray policy reform as a technocratic or economic process. Both economists and health policy analysts tend to provide detailed prescriptions on what should be done, but without clear instructions on how to do it and without good explanations of why things go wrong. A similar pattern has been observed for economic policy-making. As noted by Robert H. Bates, "Politics is rarely placed at the center of economic research" (1991:272). Decision makers in most instances are left to rely on their intuition in managing the politics of reform.

The *1993 World Development Report* (WDR), on "investing for health," exemplifies the downplay of politics. The report provided seven chapters on what countries should do to improve the allocative efficiency of health expenditures in poor countries, but only five paragraphs on the process of health sector reform, under the heading of "directions and prospects for reform" (1993:164-165). And these paragraphs provided few concrete or specific ideas about how to manage what the report called the "continuous and complex struggle" of health sector reform. A similar pattern exists for the more general efforts to promote structural reform in poor countries. Miles Kahler identified a tendency on the part of external agencies (such as the World Bank and the International Monetary Fund) to avoid an explicit analysis of politics, even for major economic policies, and even when political factors were recognized as critical to success; instead, these agencies engaged in implicit or ad hoc political analysis (Kahler, 1989:157-158).

The 1993 WDR seems to rely on a model of policy reform that assumes right action will naturally follow from rational analysis. In presenting its conclusions, the WDR (1993:15) cautioned, "At first glance, it might appear that adoption of this Report's major recommendations will be easy" (although the report did not suggest why one might believe that the proposed policy changes would be easy to achieve). The report then continued to say that "in reality, change will be difficult, since an array of interest groups may stand to lose -- from suppliers of medical services to rich beneficiaries of public subsidies to protected drug companies." But the report still discussed policy reform according to a simple model of political economy: "Broad reforms in the health sector are possible when there is sufficient political will and when changes to the health sector are designed and implemented by capable planners and managers" (1993:15).

represents a value-laden choice of political philosophy, even when (or especially when) the choice is presented as a technical decision. Three broad value systems, reflecting fundamentally different visions of the good society, are commonly called into play to provide the philosophical foundations for policy reform.

Perhaps the most common value system today for policy reform is the utilitarian perspective. This approach employs a consequentialist calculation and comparison of policies to determine which option will achieve the most results for the least inputs. As Kymlicka observed, consequentialism "seems to provide a straightforward method for resolving moral questions. Finding the morally right answer becomes a matter of measuring changes in human welfare, not of consulting spiritual leaders, or relying on obscure traditions" (1990:11). To carry out this calculation for health sector reform, the WDR adopted the metric of cost-effectiveness, using Disability Adjusted Life Years. While this metric may not be the only standard used by the WDR, it certainly stands head and shoulders above all others. The report is titled "investing in health" and the dominant concern is how to obtain the most "health gain per dollar spent." The WDR's recommendations are driven primarily by cost-effectiveness considerations, and they generally assume that if an action is cost-effective, then it should be done.

A second value system is the communitarian perspective, which emphasizes an empirical social contract (whether explicit or implicit) that exists within some actual community. This philosophical approach can provide a community-based notion of the common good, to justify and guide the redistribution of resources through health sector reform. The international movement toward primary health care can be viewed as a communitarian argument to provide health care resources for rural residents of poor countries. The movement for "community-oriented primary care," which seeks to improve primary care in poor communities, is similarly based on principles of grounding health policy and health services "in communities, for communities, and with communities" (Geiger, 1993:946). A communitarian approach to allocating health resources would not necessarily be concerned about the cost-effectiveness of maximizing health within a particular society; it would instead seek to improve health within a particular segment of the society, as part of a community-based vision of the common good, regardless of whether those actions were the most cost-effective. The emphasis on community participation with the PHC movement also corresponds to a communitarian emphasis on a communal political search for the good life (Kymlicka, 1990:226).

To some extent, the WDR proposed a double metric for health sector reform, seeking to increase efficiency and increase equity at the same time. The report, however, did not make clear whether both must increase in order to be acceptable, or how the relative importance of the two objectives should be weighted in deciding what to do first, or what to do when cost-effectiveness and equity are in conflict. In addition to these conceptual ambiguities, efforts to combine efficiency and equity can be politically hazardous. Joan Nelson warned, "While efficiency and social justice argue for targeting benefits to the poor, political incentives point toward broader targeting that reaches some of the more politically

In short, political analysis by economists tends to underspecify the political conditions under which health reform is likely to succeed. The WDR, for example, did not provide any evidence to support the assertion that "sufficient political will" is a necessary condition for health reform; nor did the report define the concept of political will in a succinct or explicit manner -- a pattern I have criticized elsewhere (Reich, 1993). It might have been helpful, at least for some readers, if the report had included this political concept in the introductory section on "definitions and data notes," along with explanations of such economic concepts as cost-effectiveness, allocative efficiency, and disability-adjusted life year (1993:x-xii). Other economists, in their analyses of health sector reform, have recognized more directly the ways in which the current problems and policies in the health sector are "the outcome of a political process" and concluded that significant policy reform is only likely to occur "if there is a corresponding change in the distribution of political power" (Birdsall and James, 1992:25). But they similarly provided few indications of how power should be redistributed (either the proposed reconfiguration or the preferred process) in order to achieve the desired policy reform.

This paper examines the politics of health sector reform in poor countries in four steps. First, I review some of the main reasons why policy reform is political. Next, I briefly describe three political economic models of the policy reform process. Third, I present three successful cases of pharmaceutical policy reform in developing countries, in order to explore the political conditions under which health sector reform is likely to succeed. Finally, I draw some conclusions about the politics of health sector reform, and indicate practical implications for policy makers and international agencies. The paper argues that for reform to succeed, policy makers must develop methods to understand, analyze, and then manipulate the political conditions in favor of policy reform. The paper suggests that the method of political mapping can help policy-makers in analyzing and managing key aspects of health sector reform.

WHY IS POLICY REFORM POLITICAL?

Policy reform is inevitably political because it seeks to change who gets valued goods in society. Five specific reasons can be proposed to explain the political dimensions of policy reform: 1) reform represents a selection of values that express a particular view of the good society; 2) reform has distinct distributional consequences in the allocation of both benefits and harms; 3) reform promotes competition among groups that seek to influence the distributional consequences; 4) the enactment or non-enactment of reform is often associated with regular political events or with political crises; and 5) reform can have significant consequences for a regime's political stability or longevity. Each of these reasons is briefly explored below, to provide an approach to thinking about policy reform in general, which can then be applied to reform efforts in the health sector.

Values: No single definition of the substance of policy reform is universally accepted in the health sector, or in other sectors either. Indeed, the substance of policy reform

influential middle deciles. Tight targeting of more than compensatory benefits may be a realistic option only for governments that do not need political support" (Nelson, 1989:110). The WDR recognized this point briefly, in a paragraph (1993:165) that suggested a gradual shift in resources rather than sudden changes, in order to maintain the support of middle classes and urban groups. In short, the report briefly recognized the potential dangers of making policy recommendations in a political vacuum. But the report left unexplored the implications of compromising the principles of cost-effectiveness and equity in order to create political feasibility for policy reform.

The third main value system used to guide policy reform is the libertarian perspective. This approach emphasizes the principle of individual liberty, that one is entitled to use one's natural endowments to make whatever deals and choices one can, as long as the action does not infringe on the life and liberty of others. The state's role, in this perspective, is limited to the protection of individuals against unjust appropriation, in what Robert Nozick called the "minimalist state" (1974). This theory is non-consequentialist, based on the belief that liberty alone will produce a moral society, without any efforts by the state to redistribute goods in society. The libertarian approach enshrines the market, with its free exchange of goods and labor, as the key to policy reform.

Libertarian values, and the role of the market, provided the foundation for many policy reform efforts in poor countries in the 1980s, especially for economic policy. (Some market-oriented reforms, however, were more consequentialist and utilitarian in emphasizing the greater effectiveness of the market compared to state intervention). These reforms typically sought to reduce the degree of state intervention in the economy, privatize state-owned industries, improve the efficiency of government services through competitive mechanisms, remove government regulatory structures that promoted rent-seeking behavior and obstructed private enterprise, and limit government expenditures and subsidies. Adjustment programs usually included specific measures on: 1) exchange rate reform (currency devaluation), 2) import liberalization (removal of government controls over imports); 3) abolishment of price controls in the domestic market; and 4) fiscal reform to reduce government subsidies. In the 1980s, a major international debate arose over the health and nutrition consequences of structural adjustment policies, with UNICEF in particular calling for efforts to protect the poor and vulnerable groups in poor countries and to place "the human dimension" at the core of economic policy reforms (Jolly, 1988:101). Partly in response to these criticisms, the international architects of economic reforms moved away from a libertarian position and sought to strengthen the state's capacity to protect social welfare, thereby adopting a more utilitarian view.

The choice of a value system to explain and justify a major policy reform represents a political choice, not only because of the philosophical ambiguities about how to defend one system over another, but also because the choice has real consequences for the distribution of resources among different groups in society.

Distributional consequences: Policy reform can produce predictable patterns of distributional consequences across different social groups; indeed, reform is often intended to produce a particular redistribution. Reform can redirect benefits from urban to rural, or from rich to poor, or from organized to nonorganized, or from one ethnic group to another, depending in part on the philosophical assumptions of the reform. In short, policy reform is political, because it seeks to affect who gets what and, as discussed below, it affects group competition in society over who gets what.

The distributional consequences of policy reform can have a significant impact on the ease of implementation. For example, according to Nelson, "The political difficulty of pro-poor measures increases to the extent that the resource transfer from privileged groups is obvious, long-term, and large (relative to the incomes of these same privileged groups)" (1989:100). Experience with economic reform suggests that targeting the poor encounters significant political obstacles, as noted above. Nelson reported that "the poor usually benefit to the extent that their priority concerns overlap with those of the somewhat better off. If their interests diverge, the poor are not likely to gain much, and they may even lose ground" (Nelson, 1989:99).

On the other hand, policy reform that promises to benefit more powerful groups in society, or that is perceived as regressive in placing additional burdens on the poor, can elicit protest from domestic groups as well as international agencies. The distributional consequences of structural adjustment reforms, in the economic sector, resulted in street protests in some countries (especially when subsidies were abruptly removed from specific commodities) and also produced a campaign from UNICEF to alter the adjustment policies (Jolly, 1988), even though some economists continued to question to strength of the evidence on health and nutritional consequences (Behrman, 1988). And, indeed, the call for "adjustment with a human face" did result in revised efforts by multilateral banks to protect the more vulnerable groups in poor countries from adverse consequences of economic policy reforms. Distributional consequences thus can affect the politics of international agencies, and thereby produce changes in reform strategies.

The tendency for policy reform to have potentially regressive consequences is reinforced by a classic problem of collective action: that concentrated effects on more powerful groups in society tend to have more influence on government decisions than dispersed effects on more powerless groups (Olson). For example, policy makers may be more willing to take the risk of offending the relatively powerless poor, because of dispersed costs, lack of strong social organization, physical distance from the national capital, and low voting turnout, rather than offending the relatively powerful middle class, because of more concentrated costs, availability of strong social organization, physical proximity to the seat of government, and high voting turnout – even when the aggregate costs are likely to be higher for the poor than for the middle class.

A key political question for policy reform is when and how this problem of collective action can be overcome. What are the political conditions under which reform can have

distributional consequences that do not simply reinforce the existing skewed distribution of economic and political power? Two provisional answers are provided by the literature on economic reforms: through political alliances, and compensatory benefits. Nelson reported that in many situations where governments give higher priority to the needs of poor people, "Political salience increases where the poor are actually or potentially allied with groups in a position to threaten the government's security" (Nelson, 1989:97). Second, progressive distributional consequences are more likely to be politically feasible when other groups also receive some benefits, or as noted above, when the interests of the poor overlap with the interests of the more powerful. How much inefficiency is needed, in order to make pro-poor policies politically palatable, will depend on other political circumstances, including the existing patterns of group competition.

Group competition: Policy reform affects the interests of groups in society, including interest groups, bureaucratic agencies, and political parties. Simple-minded pluralism would postulate that different groups will compete to protect their interests, and that the "stronger" group will win out and thereby affect the substance and implementation of the policy adopted. The pluralist predictions do not always work out in practice, however, due to political biases that affect the relative power of groups, the transaction costs of creating new groups, and the dilemmas of collective action associated with the dispersion and concentration of costs and benefits.

Political leaders are particularly concerned about the differential impacts on groups in the government coalition. Every regime has its allies and partners, arranged in various types of coalitions, to provide support for the government and its policies. As John Waterbury wrote, "Coalitions vary from country to country and over time, but at any point in the reform process, some coalition members stand to lose or gain more than others. The crucial challenge for political leadership is to avoid injuring the interests of all coalition members simultaneously" (Waterbury, 1989:39). Similarly, "political leaders must gauge when injuring the interests of specific groups will trigger a disruptive response" (Waterbury, 1989:46). The strength of the governing coalition, and the confidence of leaders in their ability to control different groups in the coalition, affect the willingness of leaders to assume the political risks of reform (Nelson, 1990a:328). Weak and divided governments are most likely to procrastinate about reform, even when confronted with the sticks and carrots wielded by international agencies (330).

For economic policy, Waterbury argues that it is possible and highly desirable to construct the reform agenda in phases in order to spread the burdens of adjustment across coalition members and avoid harming all allies simultaneously (1989:52). The timing of the reform process, as discussed below, thus can affect group competition and regime stability. Waterbury warns that "only under the most dire circumstances" should all elements of economic reform be introduced at once. While a large literature exists on the questions of appropriate sequencing of economic reform policies (cited by Waterbury), little exists for health sector reform.

In managing the reform process, political leaders are advised to use both compensation and obfuscation: "Compensatory payments may help to mitigate the impact of adjustment and to sequence the distribution of pain among coalition members and large segments of the population. Forthright declarations of policy intent, the laying out of timetables, and the public targeting of specific interests may well leave leaders without room to maneuver and lead to the defection and opposition of groups vital to regime maintenance" (Waterbury, 1989:55). Outside agencies that require strict accounting, accountability, and transparency may contribute to undermining the success of policy reform. Political leaders need to control group competition in policy reform through a two-table bargaining game (Putnam, 1988). The bargains reached with external actors, including international agencies and multinational corporations, must be politically acceptable and sustainable in the domestic political game. Putnam (1988:434) described the two-game politics of international negotiations as follows:

> At the national level, domestic groups pursue their interests by pressuring the government to adopt favorable policies, and politicians seek power by constructing coalitions among those groups. At the international level, national governments seek to maximize their own ability to satisfy domestic pressures, while minimizing the adverse consequences of foreign developments. Neither of the two games can be ignored by central decision-makers, so long as their countries remain interdependent, yet sovereign.

Managing the politics of group competition in policy reform requires a good understanding of who is for the reform, who is against it, and who is not mobilized in one direction or the other. A political strategy for policy reform needs to consider the interests or objectives of key stakeholders, and how important those interests are in the group's priorities. The direction of causation between groups and policies, however, may not always be clear. In some cases, a new policy creates an organized interest group out of the beneficiaries -- a pattern observed in both rich and poor countries (Horowitz, 1989:207). In other cases, enactment of a new policy requires an existing interest group that is both well organized and highly mobilized. A policy maker's ability to mobilize quiescent groups and to quell activated groups can affect the political success of policy reform (Edelman, 1971). As Nelson observed, "If benefits of structural changes are often delayed and accrue to individuals and groups who are not politically organized and may not even recognize their potential gains when the policy is launched, prospects for coalitions in support of the reforms are poor" (1990:359). Managing these processes of group competition must include consideration of timing.

Timing: The opportunity to achieve policy reform is often affected by external events. Reform is usually more feasible at the beginning of a regime than at the end of a regime (although some political leaders at the end of their time in power may introduce reforms to prolong their power or reap some last-minute benefits). Major concurrent events (either real or symbolic) can open up political windows for reform, in democratic as well as non-democratic systems. Disasters, both natural and human-created, provide policy

entrepreneurs with an occasion to push for long-desired ideas. An ability to recognize and exploit those transitions that open windows for reform -- before the windows slam shut -- thus can affect whether reform is achieved.

Horowitz argued that timing is an important explanation for when policy change occurs and how it occurs, in both positive and negative senses. "Fortuitous timing -- in the sense of simultaneity of events -- can open up the policy process. But timing is also an important constraint. Events and conditions accidentally synchronized can turn that decision in a direction different from the one it might otherwise have taken" (1989:204). Because of the many constraints that affect policy making in poor countries, Horowitz stated that "a disproportionate number of policies are adopted at exceptional times -- times of crisis, times when there is a strong demand for change, times when unusual events have immobilized obstacles to new policy or drastically changed the composition of decision making bodies. At such times, organized interests are frequently ineffective. Ideas for policy become important forces, and elites have a good deal of freedom to put their ideas into operation" (1989:205).

Moments of regime transition provide an important opportunity for policy reform. These transitions are generally accompanied by a delegitimization of the previous government, which makes it easier to dismantle existing policies and structures, and an increased executive autonomy or legitimacy for new government in the "honeymoon" period, which makes it easier to introduce new policies and structures (Haggard and Kaufman, 1989:75). Keeler showed a similar pattern for major policy reforms in a study of established democratic polities (Britain, France, and the United States), demonstrating that the size of a government's mandate (measured by a mandate index), along with the severity of the crisis confronted, are good predictors of the size of the window for reform and the scope of legislative achievement. Waterbury noted two different electoral strategies of political timing for democratic regimes: pushing through an adjustment package just after receiving a popular mandate in an election; or starting to implement the adjustment package and then calling an election, hoping that beneficiaries will support the government in the election (1989:52-53). Nelson concluded in her review of economic reforms in 13 countries under 19 governments, "It is hardly news that political leaders are reluctant to take austerity measures shortly before elections" (1990:328).

Regime transitions are critical for non-democratic as well as democratic governments, in overcoming the forces opposed to reform. Waterbury wrote, "Only in rare circumstances -- for example, when a new regime comes to power through a coup or the ballot box -- is the leadership likely to be supported by a consensus sufficient to allow it to lay out policy goals and to stick by them without jeopardizing the cohesion of the regime itself" (1989:55). Of course, the importance of timing depends in part on the substance of the reform. Radical changes require careful consideration of timing, while minor incremental changes are not as dependent on timing. Moreover, the nature of the reform may depend on the nature of concurrent events; natural disasters may create opportunities for certain types of reform, but not for others. Efforts to enact sudden changes in policy,

without propitious concurrent events, can challenge the legitimacy of governments, including authoritarian regimes.

Regime stability: Finally, policy reform is political because it can pose significant political risks and can provide significant political benefits for regimes in power (and for opposition groups out of power). In some cases, efforts to enact policy reform can affect the stability and longevity of governments. One prominent example in health is Mrs. Indira Gandhi's aggressive family planning policy in India in 1976-77, which created coercion and chaos, and in 1977 contributed to her resounding electoral defeat (Gwatkin, 1979). Most political leaders have a strong sense of self-interest and a strong instinct of survival; consequently, they are reluctant to carry out reforms that have a high probability of disrupting the government and ending their rule.

Whether policy reform affects regime stability, in turn, is influenced by various factors. The country's broader political economy provides the context within which policy reform occurs and thereby shapes its political consequences for the regime. Relevant factors include the regime type, especially the degree of democracy or state control over society, as reflected in factors that affect public participation, such as literacy, freedom of association and speech, social activism, and income differentials. If a policy reform can be symbolically connected to an ongoing political struggle within a country, then it can become threatening to regime stability. In extraordinary situations, efforts to push through policy reform can contribute to a government's downfall, especially when opposition arises from previously quiescent sectors or from former allies.

Regime transitions to democracy provide opportunities for policy reform, and indeed often require policy reform. But these systemic changes also create vulnerabilities due to the emergence of new political competition (Haggard and Kaufman, 1989). Expanded pluralism can produce a form of policy gridlock, in which decisions are blocked through democratic processes. And in extreme situations, as in some of the new countries of Eastern Europe, political liberalization can unleash ethnic hostilities that obstruct efforts at policy reform and undermine regime stability.

This review of why policy reform is political remains incomplete, but I hope that the main point is persuasive. This point, which is gaining wider acceptance, stresses the importance of a political economic perspective in assessing the prospects for policy reform and in explaining the successes and failures of the reform process (Grindle and Thomas, 1991; Nelson, 1989; Reich, 1993). As Alberto Alesina wrote about economic policy, "In most cases the crucial ingredients of policy reforms are very simple. The real difficulties are political; for instance, how to share the burden of adjustment, how to implement the program without creating social unrest, and so on. Political issues are much more difficult than technical issues of how to design the 'perfect' program, from the point of view of economic theory" (1992:5). Perhaps better political models could persuade skeptics (should they still exist) about the unavoidable importance of politics in the policy reform process.

concept of political will (Reich, 1993a), and sought to give it substantive content and utility. These three mechanisms, I believe, represent three clusters of political conditions under which policy reform can occur.

The *political will model* assumes that decisions by political leaders are both necessary and sufficient for major policy change. This model resembles the benevolent dictator in a Platonic state, similar to the traditional public administration view of how policy is made. The model posits a technocratic approach with a rational actor model of decision-making, and assumes a strong state, good institutional capacity, and adequate political capital. On the other hand, the model tends to ignore the political constraints to policy reform, and can be politically naive. This model is what Alesina (1992) called the "social planner" model, in which rational analysis is used and implemented by politicians to make the "right" choices, to enhance the public interest of society, regardless of the consequences for particular constituencies or for political futures.[1] In this model, decision makers seek to maximize (or at least increase) the public interest. Empirically, this model may operate under certain political circumstances, such as a strong mandate, strong state, narrow coalition, and strong leadership. The model also shows striking similarities to the concept of the developmental state, which is seen as underlying the successes of the East Asian countries (Öniş, 1991). According to this model, policy reform occurs when political leaders exercise their "will" to further the public interest.

The *political factions model* assumes that politicians seek to serve the desires of different groups, including interest groups, bureaucratic agencies, and political parties. This model subsumes the interest group approach to policy making, with its emphasis on the political competition of groups and ideas, and also the bureaucratic politics approach, with its emphasis on how government organizations seek to protect and promote their narrow sectarian interests. In this model, rational analysis serves mainly as a means to promote and serve organizational interests. This model resembles what Alesina called the "partisan" model in the economic literature, in which aggregate policies (such as fiscal and monetary measures) are used to achieve significant redistribution of income and wealth, in order to reward specific constituent groups. In this model, decision makers seek to serve the interests of their constituencies and can redistribute goods to fit with ideological principles. Some versions of the model assume pluralist principles about the free competition of groups to determine policy. According to this model, reform occurs when it corresponds to the preferred distribution of benefits to specific constituent groups of government leaders.

The *political survival model* assumes government officials seek to protect individual interests, as power-holders, whether elected or non-elected, in order to maintain or expand their existing control over resources. This model incorporates many of the principles of the public choice school, arguing that politicians operate on a logic of "opportunistic" politics (Alesina, 1992). In this model, decision makers manipulate fiscal and monetary policies, for example, in order to achieve an expansionary economic period just before elections in hopes of increasing the probability of political survival. Under non-democratic regimes, the logic of opportunistic politics would lead politicians to drain the public purse for personal gain,

POLITICAL MODELS OF POLICY REFORM

For the purposes of this paper, policy reform is defined more in terms of the degree of change rather than the direction of change. I have sought to avoid assessing the contents of policy reforms, and have focused more on the process than the outcome. The concept of policy reform can also be approached through the degree of anticipated difficulty of implementation. Policy reform usually involves a complex package of significant changes, while incremental changes in policy involve fewer and simpler alterations. The distinction made by Peter S. Cleaves (1980) between "less problematic" and "more problematic" changes in policy provides a good description of the characteristics of policy reform (Figure 2). All policy changes that fit on the "more problematic" side may not be reforms, but it seems likely that all reforms would fit on the "more problematic" side.

In searching for good political models of policy making processes in developing countries, one soon discovers that the literature is rather sparse. "Comparative public policy is a young field, even younger than the systematic study of politics in the developing countries of Asia, Africa, and Latin America. The hybrid of these two fields -- comparative public policy in developing countries -- is younger still" (Horowitz, 1989:197). The comparative analysis of health policy processes in developing countries is even more underdeveloped. Many studies exist of health policy from epidemiologic and economic perspectives; but few address the political aspects of health policy in developing countries. The literature on the political economy of policy reform, on the other hand, mostly examines economic policies, especially in the stabilization and trade arenas. Various models are proposed, including political as well as economic variables, and involving different assumptions about how and why policy reform works (or does not) in poor countries.

This section represents a brief foray into the field of comparative health policy in poor countries, to suggest clusters of political conditions when reform is possible. When can political leaders overcome the constraints of group competition and the demands of political survival and introduce significant reforms in policy? In addition, what can leaders do to shape political circumstances to enhance the probability of significant change? Even when analysts try to explain the factors leading to success or failure of reform, they often fail to address the possibilities of changing the balance of power or managing the politics of policy-making processes in order to improve the probability of success. The literature provides little practical advice on how to identify opportunities for change, or how to assess the positive and negative factors that cannot be changed, in order to determine whether success is likely.

I propose three political mechanisms for consideration: political will, political factions, and political survival. These three categories may seem, to some, rather odd choices for policy-making models. They correspond roughly to three models described by Alberto Alesina (1992) in his review of political models of macroeconomic policy and fiscal reform -- but with new names. I have chosen these names to emphasize the political dimensions of reform. In doing so, I have retreated from my previous critique of the

especially if it seemed their time in office might be coming to an end. According to this model, reform occurs when it serves the personal political survival or the personal pecuniary interests of political leaders.

A full elaboration of these models of policy reform is beyond the scope of this paper. It is worth noting, however, that the three models are not necessarily mutually exclusive, and that all three forms of decision-making may coexist in some countries. On the other hand, some nations may be characterized by a particular political model of policy reform, at least for a limited period of time, which would then have distinct consequences for the likelihood of policy reform. (One could, for example, operationalize the three models and assign countries to the specific categories, in order to determine the degree to which the success of reform is explained by these clusters of political conditions. This methodological approach is not adopted here. For this type of analysis, which seeks to explain different choices in economic policy adjustment and implementation, in 13 nations, using fives set of political economic factors, see Nelson, 1990b.)

These three models, as with all models, have both advantages and disadvantages. On the one hand, these models simplify reality into neat packages that do not easily correspond to real world situations. Indeed, models are intended to simplify the real world, in order to test hypotheses, provoke debate, and encourage people to rethink their assumptions. The models thus present ideal types, which rarely exist in such pure form. On the other hand, the models reflect conventional wisdom about how the world works. From this perspective, the models of political will, political factions, and political survival may be useful in articulating common assumptions about policy reform. Nelson, for example, proposed variations on a political will model and a political factions model as "two extreme positions [that] mark the outer bounds of debate" on stabilization and adjustment programs; she also noted that these positions nonetheless arise in international financial circles and in political analyses in efforts to explain failed reforms (1990b:24). Similarly, the three models proposed above may be useful in analyzing the attitudes of both governments and international agencies regarding health sector reform processes.

PHARMACEUTICAL POLICY REFORM

The reform of pharmaceutical policy in poor countries represents one of the most important areas of health sector reform, as well as one of the most contested. Remarkably, pharmaceutical policy represents one of the few areas in the health sector for which both the World Bank and the World Health Organization agree that major restructuring is needed. Their agreement, however, emerges from different value orientations. The WDR, for example, cited the pharmaceutical sector as an important target for reform, with "substantial scope for reduction of waste and inefficiency in government health programs," and "the most promising area for efficiency gains in the short run" (1993:159). The Bank called for improvements in the selection and quantification of drug requirements, the use of essential national drug lists, and competitive purchasing of drugs. The Bank thus stressed the

utilitarian basis for improved pharmaceutical policies, in seeking to achieve maximal utility from limited resources, reflecting its traditional emphasis on the cost-effective use of health sector resources (Hall, 1986). The World Health Organization has called for similar policy reforms, for the past decade, through its Action Program on Essential Drugs. But the WHO has justified its reforms to the pharmaceutical sector on the basis of achieving greater equity, through improved accessibility and affordability of basic drugs to poor people, and with hardly a mention of improved efficiency (Reich, 1987).

Pharmaceutical policy provides a good area to explore health sector reform for several other reasons as well. First, pharmaceutical expenditures in poor countries typically account for between 10 and 30 percent of total recurrent costs of public sector health expenditures, ranking second after salaries (World Bank, 1993:146). In many countries, pharmaceutical purchases account for an even higher proportion of private expenditures. These high expenditures make drugs a high priority issue for policy makers. Second, pharmaceutical policy usually involves both the public and private sectors, as well as domestic and international actors, in various patterns of collaboration, competition, and conflict. It thus serves as a good example for other areas of health sector reform, such as the introduction of user fees and the promotion of private sector activities, which also involve multiple actors in complex patterns of interaction (but are not considered in this paper). Third, discussion of pharmaceutical policy often elicits a debate about basic social values, including the roles of the market and the state, and the relative importance of efficiency and equity.

For these reasons, an analysis of pharmaceutical policy reform promises to hold important lessons that are relevant for other areas of health sector reform (including efforts to reduce government inefficiencies as well as those intended to increase government revenues). On the other hand, pharmaceutical policy reform may not be representative of all types of health sector reform (such as the expansion of primary health care, or the promotion of immunization). To the extent that the patterns of pharmaceutical reform are not representative of other health areas, the analysis below will be limited in its generalizability. I will return to this question in the paper's conclusion.

Three cases were selected for analysis of pharmaceutical policy reform: Sri Lanka, Bangladesh, and the Philippines. These three cases represent major policy reforms, including many of the characteristics shown in Figure 2, and they stand prominently among the successful instances of pharmaceutical reforms of the 1970s and 1980s. The three cases embody key elements of reforms recommended by both the World Bank and the WHO for the pharmaceutical sector, although they also involved more government intervention in market activities than considered desirable by the World Bank. The three cases also generated substantial controversy, at both domestic and international levels, concerning the passage and implementation of the reform packages. Below, I present the substance of pharmaceutical reform in the three countries, and then compare the three experiences, in search of common patterns in the political feasibility of policy reform.

Sri Lanka: Pharmaceutical reform in Sri Lanka followed the landslide election in 1970 of the Sri Lanka Freedom Party (SLFP) and the inauguration of a strong coalition government consisting of the SLFP and two Marxist parties. Mrs. Bandaranaike returned to power (following her previous stint from 1960 to 1965) as the head of a coalition government that, according to one observer, "exhibited greater ideological coherence and sense of purpose than any previous such alliance. It also dominated Parliament more completely and was forcefully reminded that there was a constituency for thorough radicalism by the 1971 Insurgency [by the JVP, a radical Sinhalese party and unemployed rural youths]" (Moore, 1990:349-50). These conditions spawned a transformation of the Sri Lankan economy, with a wave of nationalizations, expansion of the public corporate sector, and enlargement of the state's control of economic activities. Sri Lanka's pharmaceutical sector reforms occurred within this broad shift in government and political economy.

Following the inauguration of the new government, the Prime Minister set up a two-member committee, including a prominent university-based pharmacologist and a member of Parliament, to prepare a report on measures to rationalize the pharmaceutical sector in Sri Lanka. Their report, issued in 1971, provided the basis for pharmaceutical reform (Wickremasinghe and Bibile, 1971). The main recommendations of the report, and their objectives, were as follows (Lall and Bibile, 1978; Jayasuriya and Wijesinghe, 1991):

1. Channel all imports and distribution of final pharmaceutical products and pharmaceutical chemicals through a state trading corporation, in order to reduce the import bill and reduce retail prices.

2. Reduce the number of drugs permitted, replace brand names by generic names, and replace private advertising of drugs with information provided instead by the state, in order to improve health, through the use of drugs with high therapeutic properties and through better prescribing practices.

3. Remove the protection of process and product patents, in order to obtain newer drugs from the least expensive sources.

4. Provide state imported pharmaceutical chemicals to local manufacturers, in order to promote local production, with distribution and promotion carried out by the state.

5. Expand quality control facilities in the Ministry of Health's laboratory, in order to assure high quality of imported and locally produced drugs.

In 1971, the Sri Lankan government established the State Pharmaceutical Corporation (SPC) to implement the reforms of the Wickremasinghe and Bibile report, under the Ministry of Industries and Scientific Affairs, instead of the MOH. The SPC soon began replacing the 134 private importers of pharmaceuticals, and by mid-1973 had become the sole importer. An international tendering system, with quality control requirements, was used to purchase low-cost generic products when available, to seek non-patent observing sources for newer

patented products, and to bargain with transnational sources for patented products that were not available elsewhere. In addition, the government initiated the National Formulary Committee to reform the list of drugs for the private sector, using similar principles as applied to the public sector since 1959. Brand names were almost entirely eliminated, with the total number of drugs reduced from 2100 to 600. Patent protection laws were not amended in Sri Lanka, but purchases from non-patent-observing sources were actively pursued. Overall, implementation was most successful in the areas of import, distribution, drug list reduction, and promotion, with little progress in amendment of patent law, promotion of local production, and improvement of local quality control facilities. The reforms thus contained some libertarian values (using the competitive international market for procurement), some utilitarian values (emphasizing cost-effective purchases of a limited list of generic products, ignoring certain property rights), and some communitarian values (emphasizing redistribution to poorer members of the community in order to support the common good).

Opposition to Sri Lanka's pharmaceutical reform came from both foreign and domestic sources. On 10 May 1973, Joseph Stetler, the President of the U.S. Pharmaceutical Manufacturers Association, wrote an aggressive and threatening letter addressed to Sri Lanka's Prime Minister (Lall and Bibile, 1978:310). The letter vigorously attacked all of the major provisions of the country's pharmaceutical reform and argued that the policy would have counterproductive consequences -- inhibiting the growth of local industry, discouraging high-quality companies from participation in the tenders, encouraging the purchase of low-quality products with poor health consequences, discouraging international companies from participation in the Sri Lankan market by reduced patent protection, reducing the therapeutic efficacy of drugs by relying on generics with problems in bioequivalence, and reducing the information available to pharmacists and physicians due to restrictions on promotion. Stetler backed up the PMA's complaints about the reform with a broader economic threat, stating that "the action calls into question the Government's position with respect to all foreign investment in Sri Lanka."

Within Sri Lanka, opposition to the reform emerged from private medical practitioners and from local representatives of the international pharmaceutical industry (Lall and Bibile, 1978:311). The domestically based opposition focused on criticism of the quality of SPC purchased drugs, alleging that the lower-cost generic products and the products procured from non-patent observing sources were therapeutically ineffective. The medical profession resisted the change from brand to generic names, due to qualms about the quality of generics and to habit of using brand names. In addition, some patients preferred well-known brand name drugs. According to Lall and Bibile (1978:319, 13n), "The SPC managed, by means of the gradual pace of change and some compromise, to avoid an all-out battle with local firms."

These reforms were achieved in the early years of Mrs. Bandaranaike's government, when the coalition was strongly united in its goals. During these years, the United Front government (as it was known) instituted a ceiling on land-holdings and houses, and imposed

severe import restrictions. The pharmaceutical reforms thus fit with the redistributive, socialist, and statist strategies of the regime in power. The substantive elements of the pharmaceutical reform depended on strong support from progressive academic elites, characterized by Professor S. Bibile, who recognized the socialist government as an opportunity to implement long-desired reforms. (Similar academic entries into government efforts at policy reform occurred in other sectors as well.) The threat of the 1971 Insurgency provided a political impetus to reform, by demonstrating the existence of a radical sentiment in rural areas and justifying transformative policies that might coopt the potential for broad-based revolt. The severe economic conditions existing in Sri Lanka in the early 1970s provided an economic rationale for policy reforms that promised to reduce government expenditures while purchasing larger quantities and achieving greater health impacts.

As domestic political circumstances changed in Sri Lanka, pharmaceutical reform slowed down and was partially reversed. In 1975, the most radical party in the coalition, the Lanka Sama Samaj Party (LSSP), quit the government, and the Prime Minister "moved distinctly to the right" (Lall and Bibile, 1978:305), showing less enthusiasm for pharmaceutical reform. The shift in governmental position was accompanied by more vocal criticism of pharmaceutical policy by vested interests, including doctors and local representatives of multinational drug companies, resulting in some concessions by the SPC on the retention of brand name drugs (309). In early 1977, the Sri Lanka Communist Party quit the coalition government, followed by the resignation of the Minister of Industries, in protest of the Prime Minister's "right-wing policies," including the refusal to nationalize multinational drug companies in Sri Lanka (326). In July 1977, after the SLFP government fell, elections were held, resulting in a resounding defeat for the SLFP and no seats in Parliament for the Marxists (the first time since the introduction of universal suffrage) (Moore, 1990:350).

The new government that assumed power in 1977 was based on the United National Party, with over 80 percent of the seats in Parliament. This party won with campaign promises of economic liberalization, market-oriented policies, and pro-Western geopolitics. The UNP regime reversed some crucial elements of Mrs. Bandaranaike's pharmaceutical reform -- as its own reform policy. In particular the State Pharmaceutical Corporation lost its monopoly on imports and distribution outside of state institutions, as the private sector was allowed to reenter the pharmaceutical market. The partial privatization reportedly produced price competition between the SPC and the private sector, contributing to a market-oriented control over drug prices through SPC decisions to import and distribute products that were considered to have excessive profit margins in the private sector (Jayasuriya and Wijesinghe, 1991:22). In general, the UNP government criticized the reported achievements of the previous regime's pharmaceutical policy and sought to improve the policy in areas of quality control, advertising, and efficiency of the SPC. Indeed, rather than a total reversal, the UNP policy retained and extended some important aspects, such as the concept of essential drugs in registration (Weerasuriya, 1993) and the role of the centralized state purchasing in the pharmaceutical system (for public institutions), but had little success in promoting domestic production, reflecting broader problems of economy policy.[2]

Bangladesh[3]: On 24 March 1982, Lieutenant-General and Army Chief of Staff H.M. Ershad overthrew the Bangladesh government and seized power, declaring martial law later that day. To explain his actions, Ershad declared that "economic life has come to a position of collapse, the civil administration has become unable to effectively function, wanton corruption at all levels has become a permissible part of life. . . [the] law and order situation has deteriorated to an alarming state. . . [and there has been] bickering for power among the members of the ruling party" (Bergman, 1991).

Among the new government's top items for reform was pharmaceutical policy. Within about four weeks of taking over, Ershad had convened an eight-member expert committee to transform government policy on drugs, and two weeks later, on 11 May, the committee presented its report. The committee unanimously recommended 16 criteria as guidelines to reorganize the country's pharmaceutical sector. While "keeping in view the health needs of the country," the report stated its overall objective as follows: "Consistent with the declared guidelines of Government to provide basic needs of life to the majority of the people through austerity and to improve the economy of the country, wastage of foreign exchange through the production and/or importation of unnecessary drugs or drugs of marginal value have to be stopped" (*Report of Expert Committee for Drugs*, 1982). The report appended a list of drugs to be removed from the market, based on the committee's evaluation of all the registered and licensed pharmaceutical products manufactured and imported in Bangladesh. The report thus articulated utilitarian values (in maximizing the health benefits of drug purchases) and communitarian values (in seeking to improve the common good), and became the basis of the new national policy.

The Bangladesh Drug (Control) Ordinance of 1982 was issued soon thereafter, on 12 June 1982, as a declaration by Chief Martial Law Administrator Ershad. The policy applied the concept of essential drugs to both the private and public sectors for pharmaceuticals in Bangladesh (an essential drugs list had been used since 1978 for procurement by the government's Central Medical Stores). The policy's basic strategy was to exclude all non-essential drugs from the country, rather than to promote essential drugs in the public sector while allowing the coexistence of a broader private market. The policy created a restricted national formulary of 150 essential drugs and 100 specialist drugs, with 12 at the health post level, 45 for primary health care, and the full list at tertiary hospitals. The act banned about 1,700 drugs from production or sale in three categories: 299 harmful drugs that were to be destroyed within three months; 127 drugs that required reformulation within one year, due to unnecessary, unscientific, or harmful ingredients; and 1,240 drugs that did not conform to the 16 basic principles and had to be withdrawn within 18 months (Government of Bangladesh, 1985). The ordinance also included measures to promote local manufacture and to restrict the operations of foreign firms within Bangladesh. For instance, if products were produced by local firms, multinationals were not allowed to import similar drugs. The policy also imposed restrictions on transfer prices, requiring that they be similar to international competitive prices.

Ershad's rise to power had created favorable political conditions and incentives for pharmaceutical reform. First, the policy embodied a populist strategy of basic needs (reduced prices of essential drugs) to appeal to Bangladesh's rural poor, who continued to be bypassed by development efforts, despite nearly $13 billion of aid funds committed in the country in the first decade after independence in 1971 (Sobhan, 1982:16). Second, the Drug Policy created a political alliance with one sector of local industry and also with a number of prominent left intellectuals, symbolized by Dr. Zafrullah Chowdhury (a key architect of the new drug policy) as a development activist and a freedom fighter. Third, the policy articulated a vision of self-reliance and priority provision of basic national needs and an attitude of proud defiance against the multinationals -- a stance of economic nationalism. Finally, the policy generated international legitimacy through its support by international agencies and nongovernmental development organizations.

The new drug policy received an immediate and hostile response from the pharmaceutical industry. Domestic firms in the Bangladesh pharmaceutical industry association (Bangladesh Aushad Shilpa Samity, or BASS) purchased full-page advertisements in the Bangladesh press to oppose the drug policy. International firms did the same, arguing that the new policy would discourage foreign investors, would result in more harm than good for public health, and would not achieve the goals of increased availability of medicines. Ultimately, the international industry argued, the policy would result in decisions by companies to halt all pharmaceutical production, including that of essential drugs, and to leave Bangladesh. Attacks on the drug policy continued from *The Pulse*, a medical newspaper in Bangladesh, which denounced the policy as "unimaginative, ill-conceived and hasty," releasing "evil forces" in the market, putting additional burdens on the common man, "delaying recovery from diseases," and "prolonging suffering of the patients" (Anon., 1984).

Pressure on Ershad's government came also from foreign governments, which asserted that the policy would discourage private investors from entering or staying in Bangladesh. Ambassadors from the United States, West Germany, the United Kingdom, and the Netherlands individually visited the Health Minister and the Chief Martial Law Administrator to express their displeasure (Chetley, 1990:99-100). In addition, the U.S. ambassador helped to arrange for a visit of experts from the Pharmaceutical Manufacturers Association and from companies in July 1982. Given the importance of foreign aid in Bangladesh, the official complaints could not easily be ignored by the new government.

The Bangladesh Medical Association (BMA) also quickly emerged as a vocal opponent to the new drug policy. The BMA reportedly agreed with the policy's ultimate objectives but not with its formulation process, criticizing the committee's lack of consultation with the BMA (Chetley, 1986). The BMA criticized the methods used to review all drugs on the market in a two-week period and also attacked the involvement of foreigners from NGOs in design of the drug policy. Although one person in Ershad's expert committee on drugs (K.M.A. Humayun Hye) was also a member of the BMA's pharmaceutical subcommittee, and the other subcommittee member was consulted in the formulation process, the General Secretary of the BMA was not officially consulted because of his connections

with a multinational pharmaceutical company (Chowdhury, 1992). Because of these conflicts, the BMA refused to discuss the policy's implementation after its announcement in June 1992.

The World Health Organization and international consumer organizations, on the other hand, praised the drug policy. WHO Director-General Halfdan Mahler visited Dhaka in September 1982 and stated, "I take this opportunity of congratulating our host country on its courage in starting to put its drug house in order along the lines recently endorsed by the World Health Assembly" (Patel, 1983). In 1986, the International Organization of Consumers Unions published a document that commended the drug policy and the government leader who supported it, stating "General Ershad of Bangladesh is one of the few leaders to have acted on this international consensus of health experts" (Tiranti, 1986). Praise came as well from international medical journals, especially *Tropical Doctor* and the *Lancet*.

While the Bangladesh government persisted with the main thrust of its drug policy, some changes were introduced in response to complaints and pressure from industry and foreign governments. Soon after adopting the policy, the government established a Review Committee of six military doctors who submitted their report in August 1982. Although never made public, the report apparently criticized several aspects of the drug policy (Anon., 1984). Subsequently, the government made a number of concessions to industry in formal amendments to the policy, which included: permitting some banned products back on the market, extending the time periods for implementation, introducing an appeals process (Jayasuriya, 1985:13-16), and altering the list of allowed products. With these compromises, the policy survived opposition from the international pharmaceutical industry, the Bangladesh Medical Association, and Western governments.

Ershad achieved several domestic political objectives with his pharmaceutical reform. His goals included populist political objectives (providing lower prices on some common drugs for the poor), economic political objectives (winning support from the domestic pharmaceutical industry), symbolic political objectives (creating the symbol of an external enemy), and broader legitimacy (gaining domestic and international recognition for his innovative policy). The policy's continuity, however, depended on creating an additional constituency for the policy out of previous opponents. As the policy's benefits of increased local production became clear, the policy transformed the local industry's initial opposition into support. By 1986, the Bangladesh pharmaceutical industry association had reversed its initial opposition to the policy and had become a vocal and public supporter of the drug policy.

The fate of Bangladesh's 1982 pharmaceutical reform, however, remains to be determined in the post-Ershad political era. In early December 1990, senior army personnel in Bangladesh forced Ershad to resign, after several months of rising protests against the government. His fall from power resulted from a combination of economic distress, political instability, and increasing interest group mobilization, which persuaded the military to

withdraw its support from Ershad. An important element in the political equation was increasing opposition from the Bangladesh Medical Association, in protest to Ershad's proposed health reform policy that was announced in July 1990. Following parliamentary elections in February 1991, a new government took office and announced that the drug policy would be reviewed and revised, responding to both domestic and international pressures. The nature of the revision, however, remains undecided in 1993.

The political contrasts between the implemented pharmaceutical reform and the failed health reform are striking and instructive (Reich, 1994). The pharmaceutical reform strengthened the international legitimacy of the Ershad regime and withstood international corporate opposition while reversing domestic corporate opposition; the health reform, on the other hand, strengthened domestic opposition to the government and mobilized the physicians association into active protest. The pharmaceutical reform occurred at the start of Ershad's rule, when hopes were strong that he might bring order to Bangladesh and promote development; the health reform attempt, by contrast, occurred eight years into Ershad's government amidst unstable political circumstances, when he was struggling to control a rising tide of protest from various social sectors. The pharmaceutical reform was rapidly enacted and actively implemented for eight years, with important changes in the production, import and sales systems for drugs in Bangladesh (with problems remaining on the demand side, including persistent problems in prescribing patterns, smuggled products, and poor distribution); the health policy, on the other hand, suffered a rapid withdrawal from public debate following Ershad's removal from office. The pharmaceutical reform occurred under highly favorable political circumstances; the health reform confronted highly unfavorable political conditions, with obvious results.

Philippines: In February 1986, the Philippines underwent a dramatic political reversal and renewal, as the "People Power" movement ended the 16-year regime of Ferdinand Marcos in a revolutionary atmosphere and installed a new government under the leadership of Corazon Aquino. In March of that year, Dr. Alfredo Bengzon, a neurosurgeon with a Masters in Business Administration, assumed the helm of the Health Ministry, with a strong commitment to reform the country's health system. In addition, Bengzon was fortunate to have a good political relationship with President Aquino, because of his role (along with others) in helping to persuade her to challenge Marcos in the election (Kintanar and Robles, 1992:33). The mood of revolutionary fervor that accompanied Aquino's assumption of power created fertile conditions for systemic change in many sectors in the Philippines; while some reforms materialized (as in pharmaceutical policy), others remained unfulfilled promises (such as land reform).

According to Bengzon, he arrived at the issue of pharmaceutical reform "by serendipity" (Bengzon, 1991:6). In April 1986, one month after taking over responsibility as Secretary of Health, he "became aware" that pharmaceutical expenditures accounted for 18 to 20 percent of his Department's annual budget. He responded by seeking to improve the cost-effectiveness of procurement, to use the Department's purchasing power to obtain better terms and volume discounts, and thereby expand the government's supply of drugs. In

exploring the existing system, he discovered that the Philippines did not have a national pharmaceutical policy and that decisions on pharmaceutical production, trade, and information were dictated by the groups involved, heavily influenced by their own interests. He concluded, "In effect then, there was no policy or program standing up for the Filipino as patient and consumer" (1991:6). Bengzon resolved to correct this situation, to improve the procurement problems in his agency, and to improve the availability of drugs to the populace. In presenting the policy, he subsequently emphasized the libertarian principle of providing consumers with greater choice.

To prepare a draft national drug policy, Bengzon followed a consultative and iterative process that involved all the interested parties, in both public and private sectors (Figure 3). The Department's top management (the secretary and two undersecretaries) served as the "initiators and task masters" of the process (Kintanar and Robles, 1992:35). They created a task force to provide background information on pharmaceutical issues and to frame the rules and timing of the consultation process. Different social sectors were then requested to review the terms of reference for the policy and submit position papers, leading to the identification of seven key issues. Face-to-face meetings followed with 61 organizations and 99 individuals. The policy was then created during a live-in retreat by the Department's Executive Committee with "appropriate consultants," and was presented to President Aquino for review in early April 1987. She announced the new policy at the end of the month, just over a year after the Department started work on pharmaceutical reform (Bengzon, 1991:6-7).

To provide a solid legal foundation for pharmaceutical reform, the proponents sought specific constitutional and legislative goals. The new Constitution of 1987 gave a strong mandate to cost-effectiveness, equitable distribution, and government regulation of pharmaceuticals. Article 13, Sections 11 and 12, stated, "The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost. . . the State shall establish and maintain an effective food and drug regulatory system." Following the announcement of the new drug policy, the Congress unanimously passed the Philippine Generics Act in September 1988, giving the Department of Health the necessary authority and sanctions to implement key measures of the PNDP. The Generics Law included the following key provisions (Bengzon, 1991:9):

1. The use of generic name in labelling and advertising, prescribing and dispensing.

2. Development of an Essential Drugs List with a core list of 297 drugs and a complementary list of 263 drugs.

3. Information, education, and communication campaigns to various social sectors and to the public at large.

4. Provision for penalty, which ranges from reprimand for the first conviction to fines and suspensions of licence to practice for repeated violations.

5. Contingency authority empowering the Secretary of Health to do the following:

   a. issue rules and regulations to drug manufacturing companies to produce, distribute and make available to the public, medicines in the form of generic drugs, and

   b. import raw materials when there is a shortage, for the use of Filipino owned or controlled drug establishments, to be marketed and sold exclusively under generic nomenclature.

Opposition to pharmaceutical reform crystallized around the Generics Law, emerging from sources both domestic and foreign, especially from US organizations. Kintanar and Robles (1992:42) described the adversaries and their complaints:

> The Philippine Medical Association filed a suit questioning the Generics Law; some multinationals also brought the issue of generic labelling guidelines to court; the president of the Drug Association of the Philippines -- the organization of multinational firms -- called the Essential Drugs List "extremely dangerous"; the head of the American Chamber of Commerce in the Philippines, Gordon Westley, expressed deep concern "over proposals to use government power to closely control, widely prohibit and minutely redirect private activities in the health sector"; two American senators (Allan Cranston and Richard Lugar) warned President Aquino to "look carefully at plans. . . to implement a National Drug Policy because. . . the task of stimulating new US investments may become more difficult"; lastly, the US State Department was supposed to have floated a document saying that "to avoid serious damage to the Philippine reputation as a place to invest, we urge. . . the government of the Philippines to implement the Generics Law in as non-discriminatory and non-compulsory manner as possible."

In addition, a small group in the Philippine Medical Association attacked the Generics Law as a violation of their human rights because of legal sanctions for physicians who disregard regulations on generic prescribing. A small number of newspaper columnists also criticized the Generics Law (1992:51-52).

Supporters of pharmaceutical reform employed various strategies to contain the opposition, including: continued political support from President Aquino; constituency building and alliances with the church, the media, academia, and health professionals; court decisions against the plaintiffs and in favor of the policy; public protests by "people's organizations" and consumer groups against the firms that filed court suits; public demonstrations in support of President Aquino and the Generics Law; and social marketing of the policy through the mass media to the public and health professionals (Kintanar and

Robles, 1992:42-43). The initiators of pharmaceutical reform anticipated opposition and prepared for it, collecting substantive documentation for court challenges and designing political strategies to mobilize domestic and international support. They also implemented the policy in "relatively easier areas" first, in order to produce visible successes, and agreed to some compromises in implementation, in order to receive cooperation from key organizations such as the Philippine Medical Association (1992:48).

Advocates of pharmaceutical reform in the Philippines recognized the importance of political timing, in passing and implementing the reform; they also recognized that new political circumstances could permit a reversal of the policy. The potential for reversal arose after changes in the executive and legislative branches of government, following the election of Fidel Ramos as the new President in May 1992, who appointed a new Secretary of Health, along with the election of a new Congress. The head of the Philippine National Drug Policy Programme, writing with a journalist, concluded in 1992, "Undoubtedly, opponents of the PNDP are awaiting a propitious moment, one that will give them the opportunity to turn back the clock. . . . The problem this spells out is clear: a programme such as the PNDP is not simply something that can be started, no matter how profound that start is, and then left alone to its own devices. It has to be watched, monitored, supported. It also has to press forward to sustain the pace and institutionalize its accomplishments" (Kintanar and Robles, 1992:53). Their conclusion reflects a basic principle, that reform is constructed and sustained through politics, and its corollary, that reform is also dismembered and reversed through politics.

DISCUSSION

The three case studies share a number of conditions that contributed to making policy reform politically feasible. Below I review and compare these conditions, to identify key political variables that affect the feasibility of pharmaceutical reform, and to explore principles that may be generalized to other areas of health sector reform. Figure 4 provides a summary of the political dimensions of pharmaceutical reform in Sri Lanka, Bangladesh, and the Philippines.

It goes without saying, almost, that three case studies do not constitute proof in social science. At best, three cases can provide the basis for a persuasive argument (and three cases are certainly better than one or two). The limitations of this method are well known, and do not merit repetition here. But it may be worth noting ways in which the analysis could be strengthened. The number of cases could be expanded, and statistical methods could be used to analyze correlations between the political conditions in a society and the political feasibility of a reform. Another approach is to include cases where pharmaceutical reform failed, as in Nigeria and Peru, to seek differences between feasibility and failure. A third alternative is to explore other successful cases of health sector reform, outside the pharmaceutical field, to seek commonalities. Due to the limitations of this essay, the

concluding remarks below should be considered exploratory and tentative, for additional research if considered worthwhile.

Values: The three cases all relied on multiple values in justifying and explaining the policy reform. In each case, the reform involved a complicated package of policy measures, which included different philosophical principles. All three cases promised more cost-effective results, invoking utilitarian values, as well as increased attention to the poor and vulnerable groups in society, suggesting communitarian principles. The reform in the Philippines was defended as improving patient choice, a libertarian objective, but it also was criticized for restricting physician choice at the same time. The reform in Sri Lanka relied upon a vigorous use of the international market to obtain the best products at the lowest price. This mixture of principles, often vaguely articulated, appeared in all three cases, and suggests that policy reform probably does not involve a one-to-one correspondence to a single philosophical axiom. Indeed, if reform is based on a single dominant value, which is explicitly stated and rigorously applied, it could have adverse consequences, making the reform more vulnerable and inflexible, and thereby more susceptible to opposition. A striking commonality is that political leaders in all three cases used the realm of values to distinguish the new regime sharply from the old and to appeal to specific constituencies (in these cases, the majority poor in each society).

Distributional consequences: In these three cases of pharmaceutical reform, the new policies were intended to have similar distributional consequences, as shown in Figure 4. Benefits would accrue in the short term to the poorer groups of society, through improved access to lower priced drugs, with additional benefits emerging over time to local manufacturers that could replace imports. Costs, on the other hand, would be borne by multinational corporations that would lose markets or market share for specific products, and also by some patients who preferred or depended on products that were no longer allowed (including, for example, members of the urban elite who used certain brand-name products). Physicians would lose some degree of choice, through restricted lists of essential drugs, and could lose some income through sales of pharmaceutical products, but would gain through greater availability of basic products and improved efficiency in drug management. In all three cases, two groups of cost-bearers for the reform (multinational corporations, and physicians) were better organized than the presumed benefit bearers (poorer populations of the society), and political leaders needed to design strategies to cope with the political aspects of these distributional consequences, as discussed next.

Group Competition: The three cases showed distinctly similar forms of group competition, with different strategies adopted by the political leaders involved. For this particular reform, a predictable pattern of opposition emerged, with similar groups making similar arguments in each case. In all three countries, the national physicians association and various US private organizations (the Pharmaceutical Manufacturers Association or the Chamber of Commerce) became mobilized in opposition to the reform. The governing coalitions, in all three cases, were sufficiently strong to resist the pressures mounted by both internal and external groups, although they adopted different approaches. In Sri Lanka, the

government relied heavily on appeals to national interest and common good, bolstered by powerful inputs of technical expertise from national authorities. In Bangladesh, the policy reform occurred through an unusually rapid change, using the coercive power of government to squash some opposition, revisions in the policy as concessions to meet other complaints, and rewards to local manufacturers to transform their initial opposition into public support for the reform. In the Philippines, group competition was managed through a consensus-building process engineered by advocates in the Ministry of Health, along with efforts to persuade the physicians association to support the reform and to mobilize social pressure against the opposition from presumed beneficiaries of the policy among the general population.

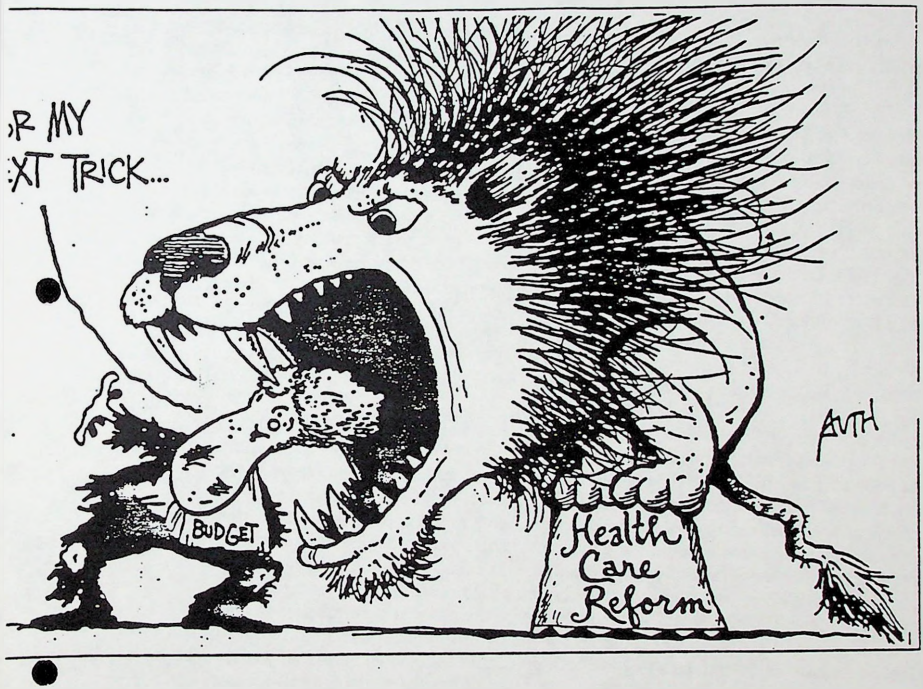
The three cases illustrate the two-table political bargaining described by Putnam (1988), and confirm his point that the domestic political variables often count more than the foreign political variables of MNCs and international banks. Even market domination by foreign firms (at 75-80% of the domestic market) could not obstruct pharmaceutical reform in these three countries. In short, for these cases, the economic structure of the market was less important than political circumstances in determining the feasibility of reform.

Timing: The three cases confirm the general principle that opportunities for major reform have a better chance of success in the early periods of new regimes, in both democratic and non-democratic states. In all three countries, the pharmaceutical reforms occurred in the first years, when political leaders still enjoyed extra political "capital" not yet expended, when coalitions were strong and supportive, when social problems could be blamed on the errors of the previous regime, and when the general public mood still looked optimistically on future prospects. The failure of the health policy in Bangladesh, which was introduced in 1990 after eight years of Ershad's rule, shows how the accumulation of political problems toward the end of a regime can frustrate policy reform. The three cases suggest that the political will model may have some limited applicability at the start of a new regime, but not in a pure sense. Even Ershad, despite his power as a military dictator, needed to negotiate with different groups and provide concessions in order to gain support or non-interference (as suggested by the political factions model). And the political leaders in Sri Lanka and the Philippines similarly became involved in negotiations with different groups to assure the reform's acceptance. The cases suggest that the political factions model is closer to reality, and that the political skill of leaders and the timing of reform critically affect the probability of success.

The three cases also reflect the general principle that policy entrepreneurs seek opportune moments to push their pet ideas (Kingdon, 1984). In Sri Lanka, Dr. Bibile had long sought to achieve a comprehensive pharmaceutical reform, and enthusiastically pursued the chance offered by Mrs. Bandaranaike's government. In Bangladesh, Dr. Zafrullah had attempted to persuade previous governments to enact a pharmaceutical reform, without success, and had a major role in convincing Ershad to launch the reform process. In the Philippines, Dr. Bengzon became the internal initiator of pharmaceutical reform, even though he had not previously advocated this reform, but a number of consumer groups outside the

Figure 1

Politics of Health Sector Reform in the United States



Source: *The News & Observer* (Raleigh, N.C.) 23 August 1993: 10A.

government strongly supported and pushed for the policy change. A similar pattern can be found in the United States, where the Jackson Hole group had plotted and planned for a number of years, with a special commitment from Dr. Enthoven, for an opportunity to get its proposal for "managed competition" on the agenda for health sector reform – and they succeeded with Clinton.

Political stability: In these three cases of pharmaceutical reform, the governments successfully resisted strong opposition from domestic and foreign pressure groups. In short, the political leaders managed the policy reforms in ways that protected the regime's stability. The challenge, however, is not only to protect the regime's stability from being undermined by policy reform, but also to protect the reform's continuity from being undermined by subsequent political change. As I noted above, political processes provide the means to achieve policy reform, but they also provide the means to unravel previous reforms. A policy reform is especially vulnerable to political reversal when it redistributes resources to relatively powerless and unorganized groups in society. A reform can be protected against full reversal if constituencies are created both inside and outside government, as has happened in Sri Lanka since 1977. The degrees of reversal for Bangladesh and the Philippines are still uncertain. A reform can also be protected if the marginal groups can become better organized and develop into an effective constituency for the redistributed system, or if they can ally themselves with more powerful groups in society (Reich, 1991); this is not easy to achieve in pharmaceutical reform, because of the collective action dilemmas, that is, the transaction costs that mitigate against organizing the unorganized.

Implications for health sector reform: Which lessons of pharmaceutical reform are relevant for other substantive areas of health sector reform? While I do not present evidence for the following assertions, I would suggest several broad conclusions that apply to the politics of other health sector reforms. First, the three cases reflect the special role of physicians as an organized interest group in health sector reform. Any effort to reform the health sector must take into account the physicians association, and must design strategies to coopt, neutralize, or mobilize this group. Second, while health is often a relatively low national priority compared to the productive sectors of the economy, the three cases show that it is possible to catapult health sector reform onto the national political agenda. Third, the cases suggest that the political conditions for policy reform can be manipulated by skilled political leaders, to create reforms that are both politically feasible and politically sustainable. A systematic assessment of the opportunities and probabilities for enacting health sector reform can be carried out through political mapping (Reich, 1993), to assist decision makers in managing the politics of policy reform.

Figure 2

Characteristics of Policy Affecting its Implementation

Less Problematic	More Problematic
Simple technical features	Complex technical features
Marginal change from status quo	Comprehensive change from status quo
One-actor target	Multi-actor target
One-goal objective	Multi-goal objective
Clearly stated goals	Ambiguous or unclear goals
Short duration	Long duration

Source: Cleaves, 1980:287.

ENDNOTES

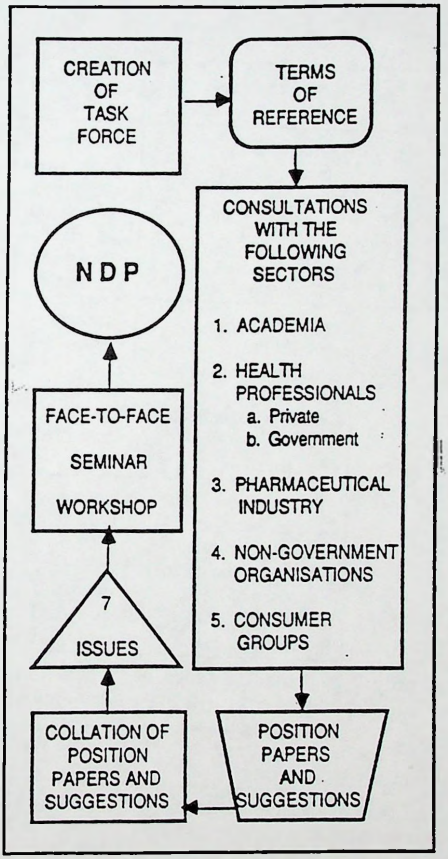
1. As Bates (1991:265) noted, Kenneth Arrow in his book on *Social Choice and Individual Values* long ago dispelled the notion of a state that adopts policies to maximize some social welfare function, unless there is a dictator who can make the appropriate decisions without compromise and despite opposition. And, as Bates emphasized, the world's experience with dictators on both the right and the left shows otherwise. The policies adopted by these governments (and others) "do not represent the preferences of some single actor. They represent the outcome of a political struggle, in which competing interests with rival visions of the social good seek the power to impose policies that are consonant with their preferences upon the collectivity" (1991:265).

2. More generally, the post-1977 economic reforms by the United National Party did not promote exports very effectively, due to a substantial continuation of import controls (Navaratne, 1991), and did not involve a vigorous privatization program, consisting mainly of a slowdown in the creation of new state-owned enterprises, with only two sales completed by mid-1990 (Adam et al., 1992:312-313). An analysis of Sri Lanka's post-1977 economic reforms, and its divergence from a "classic" structural adjustment and stabilization program, however, is a separate story from the main thrust of this paper.

3. This section on the Bangladesh pharmaceutical policy draws on Reich, 1994.

Figure 3

Consultation and Consensus-Building Process
Followed for the Philippines National Drug Policy



Source: Bengzon, 1991:7.

Figure 4
The Politics of
Pharmaceutical Policy Reform in Three Countries

Reform Politics	Sri Lanka	Bangladesh	Philippines
Values	- democratic election, socialist values, redistributive - for common good (C) - use intl market (L) - cost effective (U)	- military coup, populist, anti-corruption - basic needs for common good (C) - reduced usage of unnecessary drugs (U)	- democratic election, people's power revolution, - social equity (C) - efficient procurement (U) - patient choice (L)
Distributional consequences	- pro-poor - anti-MNC - reduced benefits to urban elite - potential benefits to local firms - improved efficiency	- pro-poor - anti-MNC - reduced benefits to urban elite - potential benefits to local firms - improved efficiency	- pro-poor - anti-MNC - reduced benefits to urban elite - potential benefits to local firms - improved efficiency
Group competition	- policy change based on local academics & official report - persuasive power of common good - opposed by med assoc & USPMA	- sudden change with little consultation - coercive power of govt plus concessions - opposed by med assoc & USPMA & local firms	- consensus-building process through MOH, with mobilization of social groups - opposed by med assoc & USPMA
Timing	- post-election, party switch, strong socialist mandate - economic difficulties - start of coalition govt	- post-military coup, as one of first govt actions by Ershad - seeking natl and intl legitimacy	- post-election in democratic revolutionary spirit - near start of Aquino govt
Political Stability	- coalition govt, when govt weakened due to divisions, policy weakened - partial reversal when new govt elected in 1977	- able to withstand strong challenge by MNCs and western govts - head of state involved - concessions offered and opponents coopted	- able to withstand strong challenge by MNCs and western govts - President involved - strong Minister of Health

abbreviations: C = communitarian; L = libertarian; U = utilitarian; MNC = multinational corporation; USPMA = US Pharmaceutical Manufacturers Association

BIBLIOGRAPHY

Adam, Christopher, William Cavendish, and Percy S. Mistry. 1992. *Adjusting Privatization: Case Studies from Developing Countries*. London: James Currey Ltd., pp. 299-322.

Alesina, Alberto. 1992. "Political Models of Macroeconomic Policy and Fiscal Reform," World Bank Policy Research Working Papers, WPS 970, September.

Anon. 1984. "Bangladesh: Government's Drug Policy Assailed Again," *Lancet* 14 January: 97.

Bates, Robert H. 1991. "A Critique by Political Scientists," in Gerald M. Meier, ed., *Politics and Policy Making in Developing Countries: Perspectives on the New Political Economy*. San Francisco: International Center for Economic Growth, pp. 261-272.

Behrman, Jere R. 1988. "The Impact of Economic Adjustment Policies," in David E. Bell and Michael R. Reich, eds., *Health, Nutrition, and Economic Crises: Approaches to Policy in the Third World*. Dover, MA: Auburn House, pp. 103-144.

Bengzon, Alfredo. 1991. "National Drug Policy: International Perspectives," *Australian Prescriber* 14(suppl. 1):6-11.

Bergman, D. 1991. "Bangladesh's Opening for a New Beginning. *Economic and Political Weekly*, 16 February: 382-6.

Birdsall, Nancy, and Estelle James. 1992. "Health, Government and the Poor: The Case for the Private Sector," World Bank Policy Research Working Papers, WPS 938, July.

Chetley, A. 1986. "Bangladesh: New Measures to Improve Provision of Pharmaceuticals," *Lancet* 1 November: 1029-30.

Chetley, A. 1990. *A Healthy Business? World Health and the Pharmaceutical Industry*. London: Zed Books.

Chowdhury, Zafrullah. 1992. Personal Communication.

Cleaves, Peter S. 1980. "Implementation Amidst Scarcity and Apathy: Political Power and Policy Design," in Merilee S. Grindle, *Politics and Policy Implementation in the Third World*, Princeton: Princeton University Press, pp. 281-303.

Edelman, Murray. 1971. *Politics as Symbolic Action: Mass Arousal and Quiescence*. New York: Academic Press.

Geiger, H. Jack. 1993. "Community-Oriented Primary Care: The Legacy of Sidney Kark," *American Journal of Public Health* 83:947-947.

Government of Bangladesh. 1985. "Drug Control and Distribution in Bangladesh," in WHO, *The Rational Use of Drugs*, Report of the Conference of Experts, Nairobi, 25-29 November. Geneva: World Health Organization: 215-222.

Grindle, M. S., and J. W. Thomas. 1991. *Public Choices and Policy Change: The Political Economy of Reform in Developing Countries*. Baltimore: Johns Hopkins University Press.

Gwatkin, D. R. "Political Will and Family Planning: The Implications of India's Emergency Experience," *Population and Development Review* 5:29-60, 1979.

Haggard, Stephan, and Robert R. Kaufman. 1989. "Economic Adjustment in New Democracies," in Joan M. Nelson, ed. *Fragile Coalitions: The Politics of Economic Adjustment*. New Brunswick: Transaction Books, pp. 57-77.

Hall, Karen Lashman. 1986. *Pharmaceuticals in the Third World: An Overview*. Population, Health and Nutrition Department of The World Bank, PHN Technical Note 86-31, November.

Horowitz, Donald L. 1989. "Is There a Third-World Policy Process?" *Policy Sciences* 22: 197-212.

Jayasuriya, D.C. 1985. *The Public Health and Economic Dimensions of the New Drug Policy of Bangladesh*. Washington, D.C.: Pharmaceutical Manufacturers Association.

Jayasuriya, D.C., and F.D.C. Wijesinghe. 1991. *Essential Drugs in Sri Lanka: Regulatory and Economic Aspects*. Nawala, Sri Lanka: Institute of Comparative Health Policy and Law.

Jolly, Richard. 1988. "A UNICEF Perspective on the Effects of Economic Crises and What Can Be Done," in David E. Bell and Michael R. Reich, eds., *Health, Nutrition, and Economic Crises: Approaches to Policy in the Third World*. Dover, MA: Auburn House, pp. 81-102.

Kahler, Miles. 1989. "International Financial Institutions and the Politics of Adjustment," in Joan M. Nelson, ed. *Fragile Coalitions: The Politics of Economic Adjustment*. New Brunswick: Transaction Books, pp. 139-159.

Keeler, John T.S. 1993. "Opening the Window for Reform: Mandates, Crises, and Extraordinary Policy-Making," *Comparative Policy Studies* 25:433-486.

Kingdon, John W. 1984. *Agendas, Alternatives, and Public Policies*. Boston: Little, Brown.

Kintanar, Quintin L., and Alan C. Robles. 1992. "Making Policy: Focus on the Philippines," in Alan Robles, Malou Mangahas, Sheila S. Coronel, and Eric Gamalinda, eds., *Prescription*

for Change: National Drug Policies, Social Transformation and the Media. Manila: Philippine Center for Investigative Journalism, and Stockholm: Dag Hammarskjold Foundation, pp. 32-53.

Kymlicka, Will. 1990. *Contemporary Political Philosophy: An Introduction*. New York: Oxford University Press.

Lall, Sanyaja, and Senaka Bibile. 1978. "The Political Economy of Controlling Transnationals: The Pharmaceutical Industry in Sri Lanka, 1972-1976," *International Journal of Health Services* 8:299-328.

Moore, Mick. 1990. "Economic Liberalization versus Political Pluralism in Sri Lanka? *Modern Asian Studies* 24:341-383.

Navaratne, N.M.C. 1991. "Who Bears the Incidence of Import Protection? Evidence from Sri Lanka," *World Development* 19:1409-1419.

Nelson, Joan M. 1990a. "Conclusions," in Joan M. Nelson, ed., *Economic Crisis and Policy Choice: The Politics of Adjustment in the Third World*. Princeton: Princeton University Press, pp. 321-361.

Nelson, Joan M. 1990b. "Introduction: The Politics of Economic Adjustment in Developing Nations," in Joan M. Nelson, ed., *Economic Crisis and Policy Choice: The Politics of Adjustment in the Third World*. Princeton: Princeton University Press, pp. 3-32.

Nelson, Joan M., ed. 1989. *Fragile Coalitions: The Politics of Economic Adjustment*. New Brunswick: Transaction Books.

Nelson, Joan M. 1989. "The Politics of Pro-Poor Adjustment," in Joan M. Nelson, ed. *Fragile Coalitions: The Politics of Economic Adjustment*. New Brunswick: Transaction Books, pp.95-113.

Nozick, Robert. 1974. *Anarchy, State, and Utopia*. New York: Basic Books.

Olson, Mancur, Jr. 1965. *The Logic of Collective Action: Public Goods and the Theory of Groups*. Cambridge: Harvard University Press.

Öniş, Ziya. 1991. "The Logic of the Developmental State," *Comparative Politics* 24:109-126.

Patel, S.J. 1983. "Editor's Note," *World Development* 11:251-252.

Peterson, Mark A. 1993. "Political Influence in the 1990s: From Iron Triangles to Policy Networks," *Journal of Health Policy, Politics and Law*

Putnam, Robert. 1988. "Diplomacy and Domestic Politics: The Logic of Two-Level Games," *International Organization* 42:427-360.

Reich, Michael R. 1987. "Essential Drugs: Economics and Politics in International Health," *Health Policy* 8:39-57.

Reich, Michael R. 1991. *Toxic Politics: Responding to Chemical Disasters*. Ithaca: Cornell University Press.

Reich, Michael R. 1993a. "The Political Economy of Health Transitions in the Third World," in Lincoln C. Chen, Arthur Kleinman, and Norma Ware, eds., *Health and Social Change: International Perspectives*. Boston: Harvard University Press.

Reich, Michael R. 1993b. *Political Mapping of Health Policy: Draft Guidelines*. Boston: Harvard School of Public Health.

Reich, Michael R. 1994. "Bangladesh Pharmaceutical Policy and Politics," *Health Policy and Planning*, in press.

Report of Expert Committee for Drugs. 1982. Mimeo from N. Islam, Chairman of Committee. Dhaka. 11 May.

Sobhan, R. 1982. *The Crisis of External Dependence: The Political Economy of Foreign Aid to Bangladesh*. London: Zed Press.

Tiranti, D.J. 1986. *Essential Drugs: The Bangladesh Example Four Years On*. Oxford: International Organization of Consumers' Unions, New Internationalist Publications, and War on Want.

Waterbury, John. 1989. "The Political Management of Economic Adjustment and Reform," in Joan M. Nelson, ed. *Fragile Coalitions: The Politics of Economic Adjustment*. New Brunswick: Transaction Books, pp. 39-56.

Weerasuriya, K. 1993. "Essential Drugs and the Registration of Pharmaceuticals: The Sri Lankan Experience," *Bulletin of the World Health Organization* 7:229-235.

Wickremasinghe, S.A., and S. Bibile. 1971. *The Management of Pharmaceuticals in Ceylon*. Colombo: Industrial Development Board of Ceylon.

World Bank. 1993. *World Development Report 1993*. New York: Oxford University Press.

DR - 2.

सत्यमेव जयते

Dr. A. Rama Mohan Rao
State Informatics Officer &
Technical Director

भारत सरकार
GOVERNMENT OF INDIA
सूचना प्रौद्योगिकी मंत्रालय
MINISTRY OF INFORMATION TECHNOLOGY
राष्ट्रीय सूचना - विज्ञान केन्द्र
National Informatics Centre
(कर्नाटक राज्य एकक)
(Karnataka State Unit)
६व ७ वाँ तल, मिनि टावर,
6th & 7th Floor, Mini Tower
डा. अम्बेडकर वीधी, बेंगलोर - ५६० ००१
Dr. Ambedkar Veedhi, Bangalore - 560 001
Phone : 286 3790, 286 3218
Fax : 286 3382
Grams : NICNET
E-mail : root@nicksu.kar.nic.in
Website : http://kar.nic.in

संख्या
No. 7(37)/99-KSU/STO/1233

दिनांक
Dated 03-10-2000

Sir,

As per the request of the Directorate of Health and Family Welfare Services, we have prepared the draft study report for the computerisation of "Drugs Procurement and Distribution System" after having the extensive discussion with the officers of your department. I am enclosing the same for your approval.

NIC is ready to take up immediately the development of the web site to update the drugs stock position of GMS on daily basis so as to know the drugs position of GMS throughout the state on click of mouse. This web site may be temporarily hosted on the NIC server till the GMS comes up with its network.

With regards,

Yours Sincerely,

(A.Rama Mohan Rao)

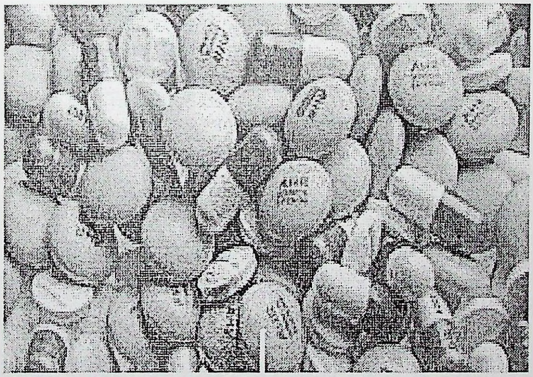
To,

Shri. Sanjay Kaul, I.A.S.
Commissioner
Directorate of Health and Family Welfare Services
Ananda Rao Circle
Bangalore

'UDY REPORT

ON

COMPUTERISATION OF DRUGS PROCUREMENT AND DISTRIBUTION SYSTEM OF DIRECTORATE OF HEALTH AND FAMILY WELFARE SERVICES,BANGALORE



SEPTEMBER,2000

BY

NATIONAL INFORMATICS CENTRE, BANGALORE

COMMITTEE TO STUDY THE PROCUREMENT AND DISTRIBUTION OF DRUGS IN THE HOPSITALS

The Government of Karnataka in the Order number : HFW 145 HPC 99, Bangalore dated 01-01-2000 has constituted a committee to study the procurement and distribution of drugs in the hospitals.

1.	Dr.K.B.Makapur, Director, State Health Institute of Health and Family Welfare Services, Bangalore	Chairman
2.	Shri. Anandrajashekar, Drugs Controller, Bangalore	Member
3.	Shri.K.R.Shrinivas, CAO, KHSDP, Bangalore	Member
4.	Dr. A.Rama Mohan Rao, Technical Director and State Informatics Officer, NIC, Bangalore	Member
5.	Dr.M.B. Karakannavar, Additional Director, KFW, Gulbarga	Member
6.	Dr. Sulochana, KHSDP, Bangalore	Member
7.	Dr.V.R.Satish, Resident Medical Officer, NIMHANS, Bangalore	Member
8.	Shri. Sai Vilvananthan, CAO-cum-FA, DIRHFW, Bangalore	Member
9.	Shri. P.S. Bhagwan, Deputy Director, DIRHFW, Bangalore	Member

The objectives of the committee were to study the existing set-up and functions of the Government Medical stores and present the specific recommendations to the Government of Karnataka in respect to the following.

1. Quantification of drug requirements (including the basis on which the quantities are to be studied.)

2. Procurement and Inventory Monitoring including the records to be kept computerised of inventory control, scheduling of purchasing and minimum and maximum stock limits to be maintained in respect of each drug.
3. Establishment of drug stores at the district/divisional level (including whether the sub stores and distribution centre and present system of centralised procurement should continue or whether the sub-stores should directly procure the drugs from R.C. holders as per the local requirements and settle the bills on the basis of funds released by the Directorate.)
4. Distribution of drugs to the districts (including whether the delivery system/ collection system to be followed and in case of the former , whether such delivery is to be done by the G.M.S. or R.C. holders)
5. Storage requirement with reference to legal or licensing conditions and the estimated cost.
6. Staffing pattern and training requirements (Financial implications should be assessed in case additional staff is proposed.)
7. Stock and issue registers to be maintained in the hospitals / centres/ institutions and how the public is to be kept informed about the drugs availability in the stock.
8. Whether the financial limits to supply of drugs to the various institutions need to be enhanced and if so to suggest the essential financial limits together with the additional requirement of funds.
9. Any other matter incidental to arising from any of the above terms.

In the proceedings of the meeting, the committee requested NIC to prepare a report on Drugs Inventory System in the Government Medical Stores and sub stores.

As per the directions by the committee, NIC has prepared this report covering the objectives of computerisation, proposed computerised system, System requirement, infrastructure requirement, cost estimation, training and manpower requirement .

1.0. INTRODUCTION:

1.0.1. Background

The Government Medical Stores, Bangalore under the Directorate of Health and Family Welfare Services, Bangalore performs the following functions :

- Forecasting the departmental requirements of the drugs/medicines/chemicals based on the average consumption of drugs for past one or two years, balance on hand and the indents.
- Preparation and issue of Purchase Orders to the Primary Manufacturers identified in the Rate Contract Book by the High Power Committee.
- Collecting penalty in case of belated supply of drug items.
- Supplying the drugs purchased from various sources to the indenting Health institutions as per their indents and Budget provision.
- Storing the Drugs items safely in separate stores within the Government Medical Stores.
- Monitoring the movement of drugs
- Monitoring the Stock availability

1.0.2. Drawbacks

The existing system has the following drawbacks.

- In the prevailing manual management system there was no comprehensive information collection and retrieval mechanism available .
- The data is not in ready to use form and hence considerable time and energy is being wasted for compilation processes.
- Laborious procedures in certain tasks like stock availability listing
- Preparation of MIS reports is laborious
- Delay in official communication
- Search and retrieval of information is laborious

1.0.3 The requirements of the health institutions

There is a need to make the system more effective in handling the distribution of drugs related activities by the department. The institutions want the system to should be capable of providing qualitative services. Hence the necessity for

- A transparent system in availability of drugs
- A transparent system of distribution of drugs
- Faster processing of indent/request for drugs
- Projection of the future requirement of drugs in a better way
- Avoiding delay in official communication

1.0.4. Need of the Sub stores

- Institution wise monitoring of utilisation of drugs
- avoiding delay in distribution by bringing the stores near the institutions
- Avoiding delay in official communication
- Projection of the future requirement of drugs in a better way
- Monitoring of drugs being lifted by hospitals/institutions

1.0.5. Need of the Government Medical Stores

- Institution wise monitoring of utilisation of drugs
- Analysis of movement of drugs by scientific methods
- Improvement in procurement and accounting system

1.0.6. The Guidelines

The guidelines set for the new system is as follows

- to bring transparency in distribution of drugs
- to reduce the time for distribution management
- to improve the distribution facilities by using modern techniques

- to establish a wider reach for interaction with public

1.0.7. Objectives

- Automate the issue of drugs to the indentors with necessary validations
- Automate submission of indent details
- Facilitate monitoring the movement of drugs
- Facilitate the checking of drugs availability position at the sub stores
- Generation of statistical reports dynamically
- Keep track of the defaulters who fail to furnish stock details
- Easy and wide access/ restricted access of information related to drugs , medical stores and the suppliers.
- Keep track of the expiring/banned/prohibited/non-standard drugs and raise alerts.
- Analysis of the drugs movement in a scientific method.
- To project the future requirement of the drugs in a scientific way.

1.0.8. Purpose

The purpose of this document is to discuss about an information system for the Government Medical Stores, Bangalore and the proposed sub stores at the district level, which is expected to lead to the development of a Drugs Monitoring and Information System. The requirements discussed have been derived from the discussions between the Officers of the Directorate, Health and Family Welfare Services, Bangalore, Government Medical Stores , Bangalore and NIC. This document attempts to satisfy the functional and administrative requirement of central stores and sub stores in a detailed manner.

1.0.9. Scope

The scope of this document is to outline the necessity of an information system and various modules for GMS, Bangalore and Sub stores. It covers the following modules.

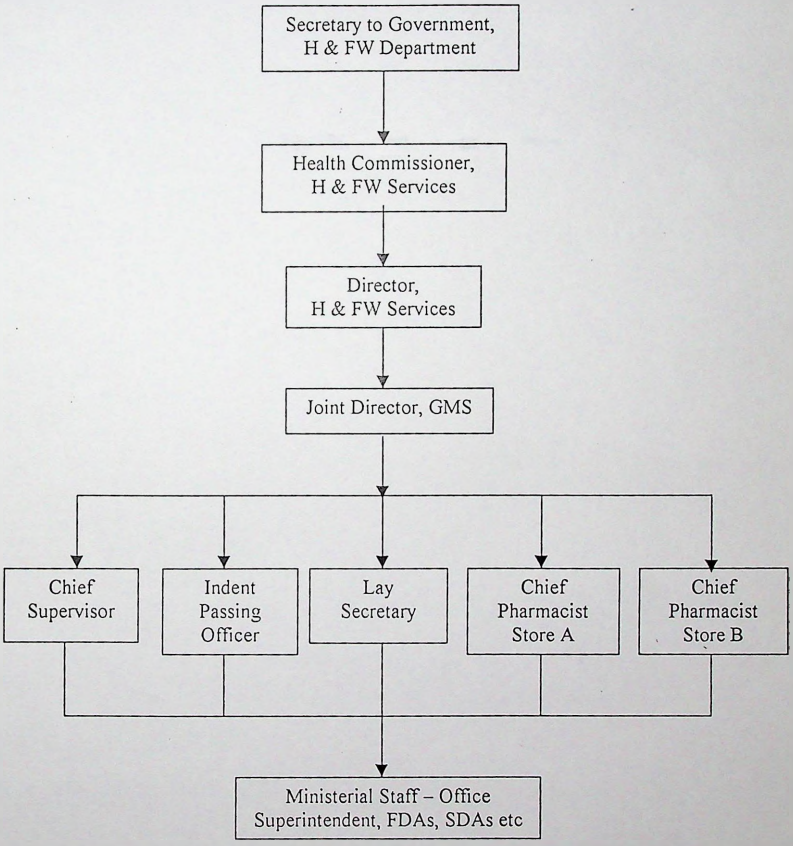
1. State level Drug Inventory System
2. Sub Store level Drug Inventory System
3. System for Purchasing drugs
4. System for monitoring distribution of drugs
5. System for monitoring consumption of drugs at various levels/stores

1.0.10. Abbreviations followed in this document :

DIRHFW	Directorate of health and Family Welfare Services
GMS	Government Medical Stores
MIS	Management Information System
SRS	Software Requirement Specification
NIC	National Informatics Centre
NICSI	National Informatics Centre Services Incorporated
TAC	Technical Advisory Committee
HPC	High Power Committee
LL	Leased Line
VSAT	Very Small Aperture Terminal
RF	Radio Frequency
FAQ	Frequently Asked Questions
DHO	District Health Officer

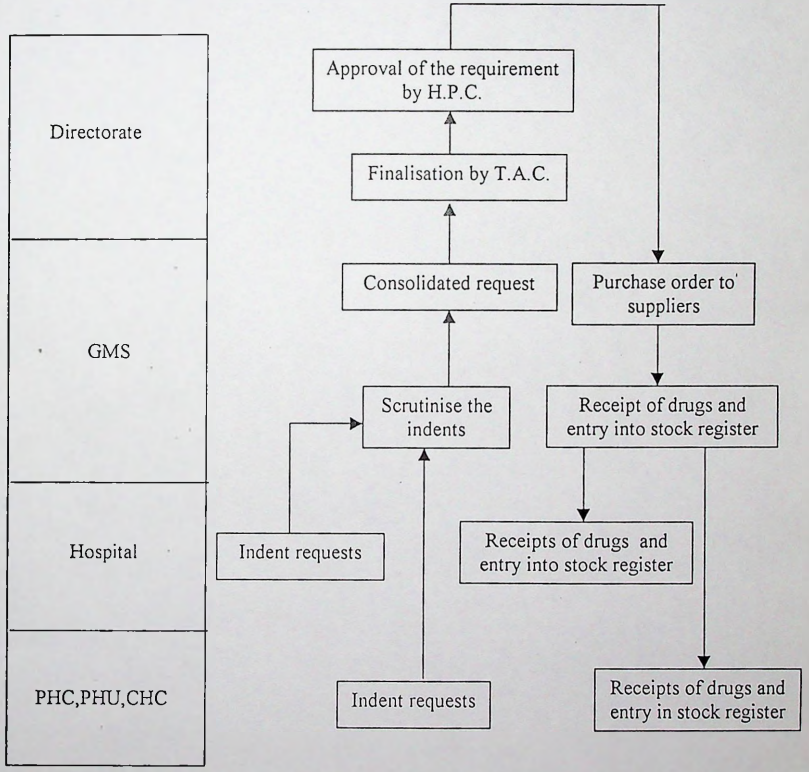
2.0. Functional Description

2.0.1. Organisation Chart:

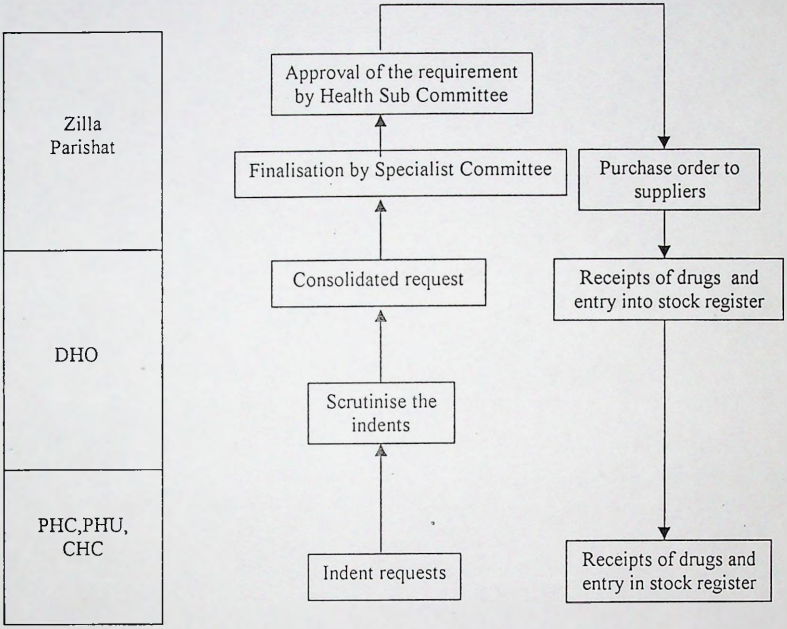


2.0.2.Existing system

2.0.2.1. at the directorate:



2.0.2.2. at the districts:



2.0.3. Proposed Set-up

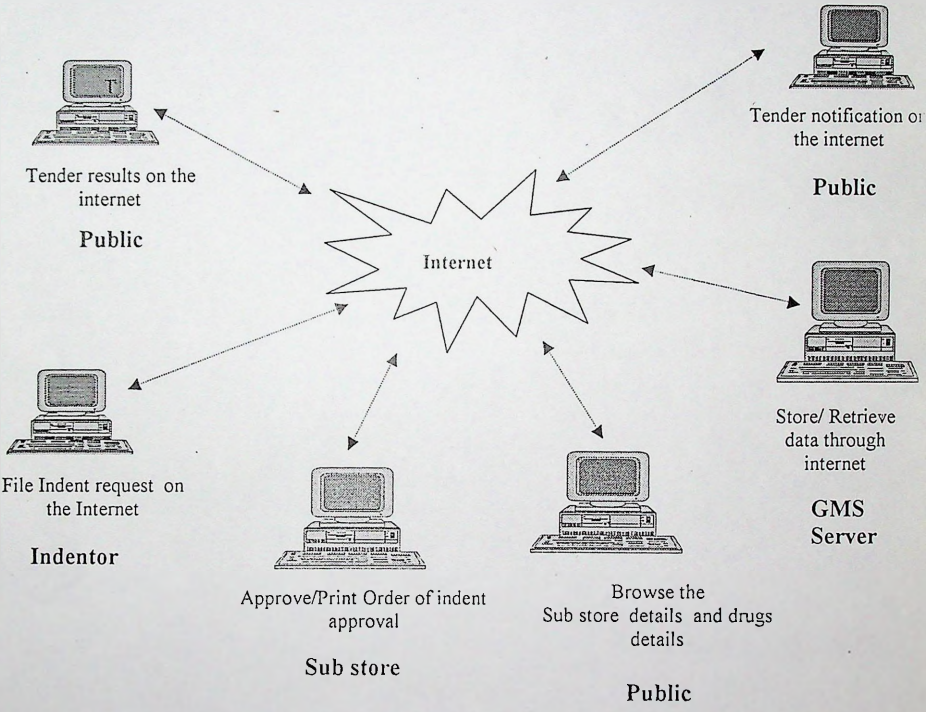
It is proposed to have one Server at the GMS to take care of the computerisation of all the activities of the GMS and sub stores. The server will be used to maintain the database of GMS activities and will carry out the networking and e-mail services of all the sub stores .

The GMS will be linked to web via NICNET with RF link connectivity/ LL/ VSAT which give 64 kbps / 2 Mbps data transfer.

It is also proposed to provide 5 nodes in GMS by giving one Pentium client system to each section to have access to carry out their functions on the computer.

All sub stores shall be provided with one Pentium system with printer and modem to do their work on computer in their office itself. All district sub stores will be connected with GMS through NICNET.

2.0.3.1. Inventory Monitoring System



- Easy monitoring of consumption of drugs
- Storing and retrieval of historic data
- Compilation of drug-wise, supplier-wise data by the computer
- Facilitates data mining
- Easier analysis of drug movement providing necessary information for decision making and planning the purchase of drugs
- Quick communication in case specific drug control and management.
- An access to communicate complaints from clinics.

2.0.3.2. Internet and E-mail Services

One of the computer systems acting as a server will be configured to handle the internet and e-mail services of GMS and all the district sub stores. It will maintain the e-mail addresses and mailboxes of GMS and all the district sub stores. Thus it helps building up faster and easy communication.

The sections of GMS and district sub stores can use effectively e-mail service so that the information/circulars/letters can reach fast and reliably to the destination.

It will also be able to take care the transfer of data between GMS and district sub stores. All the district sub stores can access the internet also.

The networking of the district sub stores with the GMS will be done using dial up mode of operation through the NICNET.

2.0.3.3. Web based information

A Web site will be hosted by NIC for Government Medical Stores at its head office. This web site will contain the drugs availability position in sub-stores. The institutions can access this site.

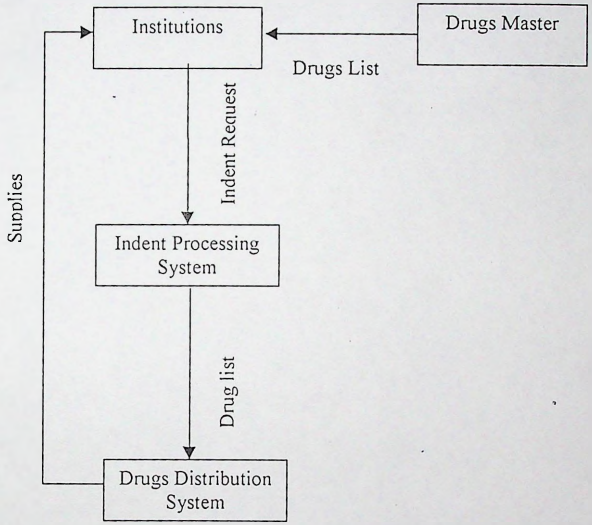
Web based applications will be provided to the offices/officials of the department to query the information and compare their stocks with others or any other related information.

Benefits :

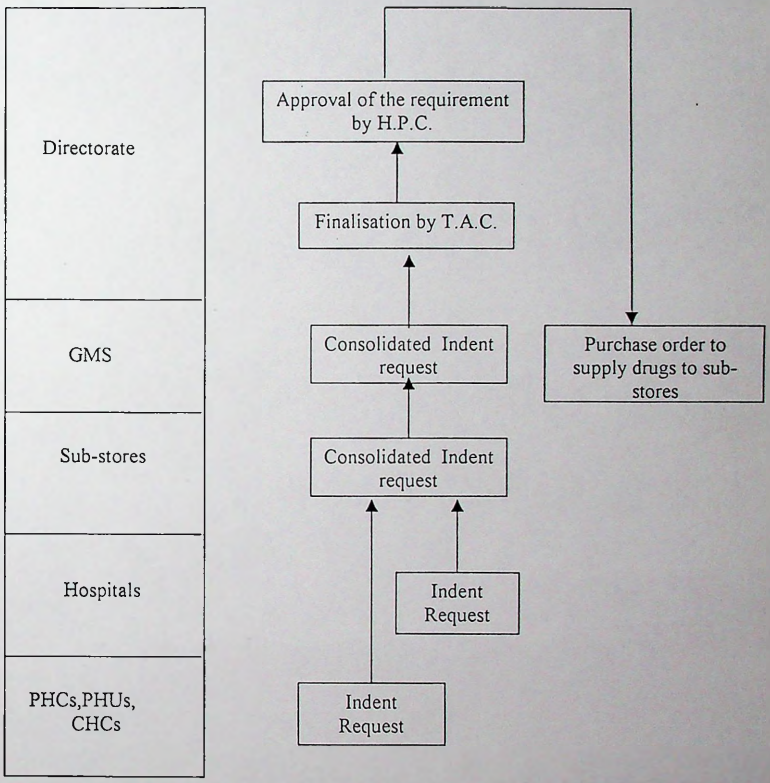
Some of the benefits of the proposed system are :

- Availability of the information centrally
- On –line generation of statistical reports.
- Easy monitoring of stock position of drugs

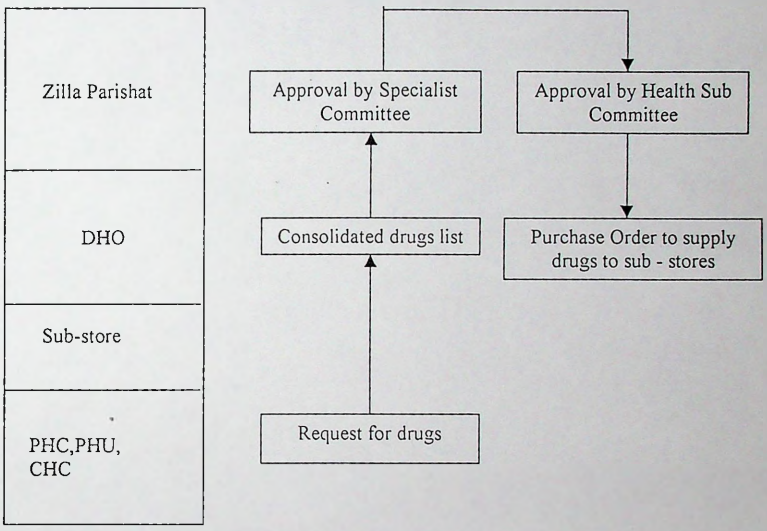
2.0.3.4. Drugs Inventory at the sub stores:



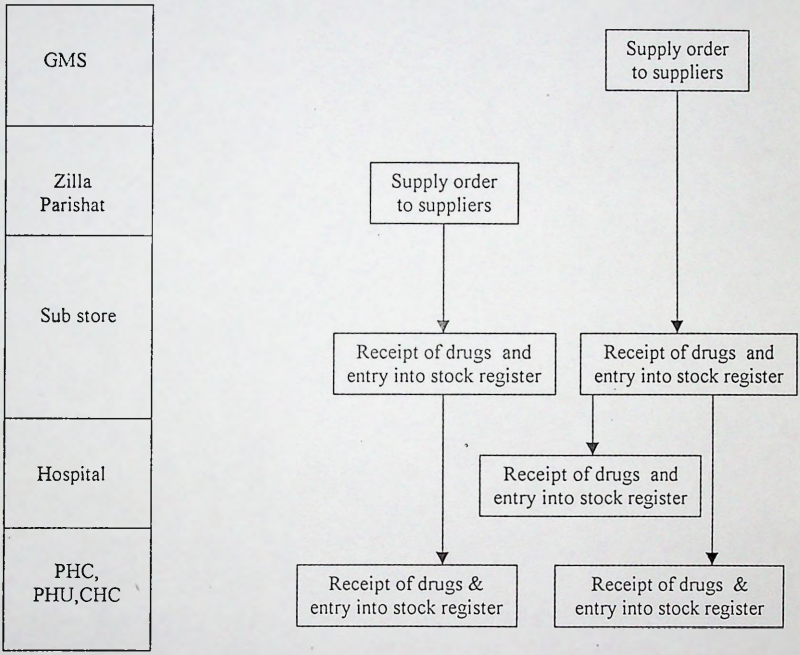
2.0.3.5. Purchase system at the Directorate



2.0.3.6. Purchase System at the districts



2.0.3.7. Distribution System at the Sub stores



The sub stores maintain the stock received from both ZP and GMS separately and distribute the same to the health institutions according to the terms and conditions laid down for distribution.

3.0. Project Execution Scenario

3.0.1. Infrastructure Requirement

The department has to provide the following infrastructure requirements to the computer centre at the GMS as well as sub stores.

The site specifications for the GMS computer centre is are follows:

- Vinyl flooring for the computer
- If the room height is beyond 12 feet, false ceiling has to be provided.
- Two 1.5 Ton Air Conditioners with stabilizers are to be fixed for clean environment and to maintain temperature.
- Single phase KEB input power to be provided with circuit breaker on 15/5 Amp. Universal sockets 2 Nos to connect UPS.
- UPS outlets having 4 Nos. Of 5 AMP 3 pin socket with switch to be provided with each distribution box at computer room and for clients. 3 distribution boxes in computer room and one each for clients proposed.
- Separate computer graded clean earth should be made with a pit and the grounding to be transmitted to the power sockets of KEB inlets for UPS. Voltage between ground and neutral should be less than 3 volts.
- Preferably a separate phase should be drawn for AC unit. The power outlet should be terminated with the circuit breaker of the 20 Amps capacity and heavy duty 15 Amps socket.

The district substore should provide clean, dust free room/place to install the Computers. It should provide separate proper grounding to computer.

The computer table, chair, printer table and pedestal fan have to be provided to every client computer at the GMS. Two steel almirahs are required at the computer centre to keep computer related items.

One telephone connection has to be provided to the district computer centre to establish the networking connection with local NIC office.

One telephone connection has to be provided to the district computer centre to establish the networking connection with local NIC office.

3.0.2. Manpower

1. It is necessary to identify/ nominate one senior officer as a nodal officer at the GMS. The nodal officer will take care the implementation of the software by coordinating and pursuing with the other officers and staff. He will organise activities at the computer centre. He will assist the Joint Director at the Government Medical Stores in the computerisation work. He will interact with the institutions and the Directorate office in respect of computerisation activities.

2. The department may recruit/hire one technical person to take care of the maintenance of systems at the GMS, implementation of the software. The technical person will also help the department in conducting the training programs. And also three data entry operators may be taken for initial one year to handle the data entry.

3. The department may also recruit /hire one data entry operator for each of the sub stores on contract basis for the first year to take care of the maintenance of systems at the sub stores, implementation of the software. After one year, the staff at the sub stores are expected to use the systems themselves.

The minimum educational qualification required for the technical person is

B.Sc. with 3 years experience in the computer field

Or

B.Sc., PGDCA

Or

M.Sc. With computer Knowledge

The GMS may work out to post two clerks/typists at the computer center and put them exclusively on the computer related activities. Subsequently the concerned section's staff can be asked to do their work on the computer. The selected typists/ clerks will assist other staff in their computer related work.

It is proposed to use the existing staff to handle the regular operations of the Government Medical Stores computerization with proper training after one year.

3.0.3. Training

For the effective utilization of the computers and proper implementation of the computer packages, it is essential to create awareness in the officers and staff of the department. To achieve this it is necessary to train the officers and staff on the computers. This may be done in phases.

The department may organise the computer training program by sending the officers and staff to private training agencies on the following topics for 6-7 days.

i. Fundamentals of Computer
ii. Windows 2000
iii. MS - Office 2000
iv. E-Mail Services

NIC will take care of training on the application software developed for the department.

3.0.4. Cost estimate :

The following estimates show the cost of computer hardware, software and other items.

For the GMS office

Items	Quantity	Approximate Cost in Rs. Lakhs
SERVER - Pentium III , 600 MHz or above, 256 MB RAM, 2x9 GB HDD (SCSI), CD-ROM, DAT Drive, 1.44 MB FDD, 4/8 GB DAT	1	1.50
CLIENTS- Pentium III,667 MHz or above , 10 GB Hard disk (IDE) 64 MB RAM, 1.44 MB FDD, CD ROM	5	2.50
Printers –		
High Speed Laser Printer	1	1.40
Dot Matrix Printer	5	0.75
Inkjet Printers	1	0.07
Scanner	1	0.30
CD writer	1	0.20
UPS		
7.5 KVA online UPS with 30 minutes backup	1	1.75
1 KVA online UPS with 30 minutes backup	1	0.40
Modem - 56.6 KBPS, External	2	0.12
Software		
MS – Windows NT Server Enterprise (25 Users license)	1	0.96
MS- SQL Server 7.0 Enterprise (25 Users license)	1	1.82
MS Office 2000 Professional	6	0.90
MS Visual Studio 6.0 Enterprise edition	1	0.40
C-DAC ISM Soft Kannada software	5	0.10
Mdeamon (50 Users license)	1	0.23
MS Proxy	1	0.22
High speed connectivity RF/LL/VSAT – IP Advantage (any one of them)	1	8.00
Total :		**21.62**

LL – Leased Line through DOT

At district sub stores:

Items	Quantity	Approximate Cost in Rs. Lakhs
COMPUTER-Pentium III, 667 MHz or above, 64 MB RAM, 10 GB Hard disk (IDE), 1.44 MB FDD, CD ROM	27	13.50
Dot Matrix Printer 132 cols, 24 pin, 240 cps	27	4.05
UPS 1 KVA online with 30 minutes backup	27	10.80
Modem 56 Kbps, External	27	1.62
SOFTWARE MS – Office 2000 Standard ISM –Soft Kannada	 27 27	 4.05 0.54
Internet Connection	27	0.81
Total :		35.37

The following estimate will show the cost of infrastructure and manpower.

For the GMS office

Items	Approximate Cost in Rs. Lakhs
Site preparation, furniture, Telephone etc	2.00
Man Power One Programming Assistant and three Data Entry Operators from man power agency for an initial period of one year	2.50
Total :	4.50

At the sub stores :

Items	Quantity	Approximate Cost in Rs. Lakhs
Site preparation, furniture, Telephone etc	27	13.50
Man Power One Data Entry Operator from man power agency for an initial period of one year	27	13.50
Total :		**27.00**

Total cost of Hardware, software, Infrastructure & Manpower (GMS and Sub Stores)	:	Rs 88.49 Lakhs
10% handling charges for NICSI for the items to be supplied by NICSI	:	Rs.4.96 Lakhs
Transportation charges on software to be supplied by NICSI	:	Rs.1.10 Lakhs
10 % sales tax on the software to be supplied by NICSI (or 4% sales tax with form D)		Rs. 0.84 Lakhs
10 % Post budget increment on hardware cost	:	Rs.4.74 Lakhs
Grand Total	:	**Rs. 100.13 Lakhs**

Recurring Charges

AMC on hardware	: 7 % of cost of Hardware
Satellite connectivity Charges	: Rs.2.00 Lakhs per annum

AMC for the VSAT will be taken up by NIC. All other AMCs for the equipments i.e, the hardware, operating system support and RF link/ Leased Line (as the case may be) to be directly handled by the department with the vendor.

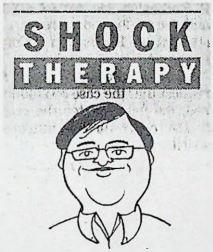
A prescription that worked

IE 19/11/98

THERE used to be a time when no news was good news. As we prepare for the next millennium, media gatekeepers have turned this bit of received wisdom on its head — today, good news is no news, unless it's a no-news day. One such piece of good news that never got reported has got the World Health Organisation excited like never before. The Delhi Model, in fact, is the new buzzword in Geneva, apart, of course, in Chandigarh, Chennai and Calcutta. What is this Delhi Model all about, and why is it going to be replicated in Thailand, Myanmar, Vietnam, Laos and Kampuchea? Well, simply because it is a common-sense solution to a chronic malady of our healthcare delivery system.

Just one out of five people going to government-run hospitals for treatment get the free medicines that is due to them. It really doesn't matter, then, if the state provides them free treatment, for the money they spend on drugs and what hospitals call consumables (which can be a syringe or a stent) is enough to drive them back to the clutches of their village fatcat or factory foreman. No wonder each cycle of illness pushes the unseen, unheard majority farther into the morass of poverty. Even in Delhi, before 1992, though 30-35 percent of the national capital territory's health budget was being spent on medicines to be distributed free, chronic shortages were forcing patients to make their own arrangements.

The system of hospital-based procurement of medicines, in fact, was riddled with all the flaws that are present at all levels of the public health-care delivery system. Medicines were being procured a couple of months before their expiry dates so that they could be junked and the endless flow of orders to manufacturers maintained; expensive alternatives were invariably preferred and prescribed; non-essential drugs were being stocked up in numbers that had no basis in the demand for them; traditional medicines were being bought just because the government had said so and not because doctors were prescribing them; and reputed firms were being discouraged because clerks sat over bills to extract their cuts. Public money, in other words, was being despatched down the tubes — the same money that could be spent buying drugs that never seem to be around at hospital stores.



SOURISH BHATTACHARYYA

Today, the Delhi government saves 30 percent of its budget for medicines and this money is ploughed back into procuring more medicines. Translated into money, it means a budget of Rs 40 crore getting you medicines worth Rs 50 crore, something unimaginable in a government set-up. In people terms, it means that the money saved on the purchase of 250 mg amoxycillin capsules enabling government hospitals to procure nine million chloroquin tablets for their malaria control programmes. Similarly, for every ten tablets of the anti-tubercular drug rifampicin (450 mg) that the Delhi hospitals bought this year, they saved Rs 6.30, which meant they had Rs 2.8 lakh more in their kitty to get more of this chronically scarce medicine. One can keep listing examples, but the point of this good news is that it takes just a couple of people with clear intentions and a clear head to make a difference to a system we keep writing off.

But how did this become possible? It took just one public-spirited medical administrator, Ranjit Roy Chaudhury, Emeritus Scientist at the National Institute of Immunology, New Delhi, who doubles as health adviser to the Delhi government, to make it happen. Teaming up with C. R. Vaidyanathan, a former Union Health Secretary, and R. Parameswar, former Deputy Comptroller and Auditor General, he set in motion a system that cut waste and struck at the vested interests that allowed it to fester. All that this troika did was prepare a list of 250 essential drugs good enough for 90 percent of the ailments treated at public hospitals; shortlist companies for the supply of these medicines (any firm with a turnover of less than Rs 8 crore, the *mohalla* manufacturer, in other words, was kept out of the bidding process); fix rates for the drugs to be purchased; and encourage doctors to prescribe only these medicines so that they were easily available to the intended beneficiaries.

The new system had two implications. One, it was easier for the government to flex its bargaining muscle because now the companies were talking bulk orders. Two, drug purchases from now on were to be both need-based and people-oriented, and not governed by whimsical circulars or corrupt clerks. The list was transparent and the rules were clear, which is why the Delhi high court refused to entertain a petition moved by aggrieved manufacturers thriving in the old system. And the confidence the system created among top drug companies was evident in their participation in the centralised bidding process, encouraged by the new rule making it mandatory for hospitals to clear their bills within a month.

An exercise by the Delhi government to assess the new system's success has exposed some shocking examples of waste that need reiteration. The study, conducted by an independent agency, revealed startling differences in prices at which drugs had been purchased by the Delhi government and the Central government respectively — for amoxycillin syrup, for instance, the price differential was Rs 3.95, and it shot up to Rs 15.60 when a comparison was made with the government-owned Super Bazar. It's a pity, really, that in four years the Delhi Model has found more takers abroad than in India. Maybe even the Health Ministry believes good news is no news.

DR-2.

The cable conundrum

Even as the conditional access system for cable television viewing is all set to be made a statutory requirement, the potential impact of the proposed changes on the industry and on consumers is the subject of an intense debate.

AMULYA GOPALAKRISHNAN
in New Delhi
DIONNE BUNSHA
in Mumbai

MOVING from the back alleys to the corridors of Parliament, cable wars are now being fought in the national arena. This battle is likely to change the face of the cable and satellite TV industry in India.

The Lok Sabha unanimously passed the Cable Television Networks (Regulation) Amendment Bill in May. But by the time the Bill reached the Rajya Sabha, it was enveloped in an intense debate on its viability and its potential impact on the industry and consumers. With the debate yet to be resolved, the proposed law may now be introduced through an ordinance. While it is strongly resisted by broadcasters, the Information and Broadcasting Ministry sees the amendment as being vital to bringing transparency and regulation to the chaotic Indian cable television market. This piece of legislation introduces, for the first time, a Conditional Access System (CAS) that enables consumers to buy their cable channels *a la carte*, rather than having to pay for the entire slew foisted on them by cable operators.

Large cable distributors like the Hindujas' Incable have been lobbying hard and long to get the Bill passed. If passed, subscribers to cable television would only be able to view pay channels through special set-top boxes. They would be billed on the basis of the number of pay channels they select, rather than being held liable for a monthly lump sum in accordance with the cable operators' own choice of channels.

The consumers' right to choose is the logic put forward by the Union Ministry of Information and Broadcasting in introducing the law. Pay channels are transmitted in an encrypted or scrambled form, and with CAS, those who do not wish to view them would receive a basic tier of Free To Air (FTA) channels at a reduced price. In order to protect public access to major entertainment and information content, the government plans to include a 'must-carry' clause in the FTA category. This means a genre-wise breakup, ensuring that people who opt to settle for the basic tier are not deprived of a staple diet including general entertainment, news, film, music channels and the like.

Satellite broadcasters who now offer a bouquet of channels – some FTA and some pay – have reportedly been working behind the scenes to stall the Bill in Parliament. They fear that they will lose advertising revenue with the introduction of CAS. Less popular channels, which are now aired with other pay channels, may get less advertising support. They may even have to transform themselves into FTA to remain relevant, making them even more dependent on advertising.

Anil Baijal, a senior official at the I&B Ministry who was involved in drafting the Bill, says that the CAS will put people in control: "They can pay minimal rates for the FTA basic tier, and select pay channels depending on their interest." Also, set-top boxes would bring in far greater transparency. They would provide a real picture of media consumption habits, and eliminate problems such as under-reporting of the number of subscribers by cable operators and inflated ratings by broadcasters. The system will also help the government plan for entertainment tax accruals in a realistic fashion. Cable operators are required to announce the prices of FTA and pay channels.

The pricing and regulation of the basic tier and the cost of the new technology, as well as the practical issues involved in implementing CAS, have been thrashed out by a consultative process involving the government, broadcasters, cable associations and consumer groups. A Task Force was set up in July 2001 to identify ways to implement addressable cable systems, and evolve standards for the new technology required. According to the latest NRS (National Readership Survey) figures, there are around 45 million cabled homes in India. Of these, set-top box manufacturers estimate, about 10 per cent would choose pay channels. They calculate an average cost of Rs.1,500 to Rs.2,000 for an analog set-top box and about Rs 5,000 for a digital one, says the Ministry.

Some of the fiercest opposition to CAS has come from the usual suspects – Star, Sony and Zee, the three big broadcasters whose audiences will now be splintered. If they remain pay-channels, their subscription as well as advertising revenue could take a beating if people do not take to the new technology. Also, with the ratings game becoming more transparent, their advertisement earnings will be directly affected. This means that special interest channels cannot ride piggyback on the popularity of other channels in the same bouquet. Someone in rural India, for instance, could choose the widely-watched Star Plus without having to pay for Star World, which remains popular only with urban upper-class audiences.

Naturally, this could radically disrupt the marketing strategy of broadcasters, who stand to lose both advertising and distribution revenues if people do not opt for set-top boxes. Broadcast networks now have to decide whether to rely more on advertising or subscription for their revenue, and cannot straddle both as they have been doing all this while. Analysts feel that this may put pressure on many current pay-channels to go FTA, in order to maintain their reach and ratings.

However, Shantonu Aditya, who heads Sony Entertainment, denied this possibility. "We believe that the One Alliance bouquet consisting of SET, MAX, AXN, Discovery, CNBC and Animal Planet is a robust bouquet and all the channels have dedicated viewers and each channel can stand by itself as well. There is no question of going Free to Air."

CAS has definitely ensured a more competitive era for big broadcasters,

of human lifespan over which the drug is likely to be administered therapeutically...etc. etc."

According to a fact sheet on NN622 issued by Novo Nordisk on July 26, all genotoxic tests on the compound were negative, indicating that the drug in all likelihood does not have any genotoxic carcinogenicity potential. A genotoxic compound affects the genetic material. A non-genotoxic carcinogen requires a long exposure period, and when a drug is meant for chronic use, its potential non-genotoxic carcinogenicity needs to be ruled out. The long-term carcinogenicity studies on NN622 were being carried out from this perspective. In the Indian context, the very fact that such studies were being conducted means that they should conform to Article 3.5 of Schedule Y.

Novo Nordisk has violated this requirement on two counts. One involves the choice of rat as one of the species, when according to the company's own statements, spontaneous tumours are known to arise in rats with many of the currently marketed drugs. Also, in response to the *Frontline* questionnaire, Kapur stated that a similar drug that has been marketed had resulted in tumours in rats. Given this situation, conforming to Schedule Y would call for the choice of a species other than rats. Two, the average life-span of bred mice is about two to three years. Assuming that the average period over which a Type 2 diabetes drug will be administered would be half the human lifespan, the carcinogenicity data needed for permission for clinical trials should span at least a year, and not six months as in the case of the data submitted by the company.

The company has claimed that the tumours occurred after the mice were exposed for a period of time equivalent to between half and full life expectancy. The patients, on the other hand, were exposed to a maximum of six to seven months, equivalent to about 0.5-1 per cent of human life-span. In the Indian case, since the Phase III trials had begun only in March, the period of exposure was only four months. Therefore, according to the company, the risks for the human subjects of trials are minimal.

The issue is not so much the risk of exposure but the ethics of conducting trials by the company. "You cannot proceed with a general assumption that tumours seen in rats are spontaneous," points out Bal. "Spontaneous tumours are dependent on the class of drugs being tested, dosage and several other factors. We have seen spontaneous tumours in dogs for certain drugs."

Clearly, the company cannot have it both ways. If it was known that spontaneous rat tumours are likely, the species should not have been used at all. If not, ethics demanded that the cause of rat tumours be established – determine whether they were indeed spontaneous tumours – before continuing with the trials.

More fundamentally, the company would seem to have not fulfilled even the basic requirement for conducting Phase III trials under Schedule Y. The Schedule says: "If the drug is a new drug substance discovered in India and not marketed in any other country, Phase III data should be obtained on at least 500 persons distributed over 10 to 15 centres." By choosing to have only 130 patients, distributed across eight centres, Novo Nordisk violated this regulation.

Legally Novo Nordisk cannot be questioned because it had obtained the DCGI's clearance for its clinical trials. The DCGI has, however, refused to answer Frontline's questions on the subject. ICMR sources say that when the council asked the DCGI why the application was not referred to the ICMR and under what circumstances the approval was given, the DCGI stated that the clearance was given since this was an international study and involved multi-country trials. In particular, the DCGI would have to explain why trials were allowed even after it was informed of rat tumours in February.

According to Novo Nordisk, the risk of exposure to humans participating in trials was negligible on two counts. First, the duration of exposure was much less than the period over which the animals were exposed. Second, the tumours may be rodent-specific. Novo Nordisk has argued that rodent urine is significantly different in composition from human urine and it is possible that tumours were caused by a mechanism leading to the formation of crystals in the rodent urine. The formation of such macro- or micro-crystals might eventually be found to be the cause of the carcinogenicity findings in the urinary tract system in the rodent, in which case, the mechanism would be of no relevance to humans, the company has stated.

In any case, the company's fact sheet has stated that all patients will be called for an end-of-trial visit. The company has suggested that patients have a urine sample taken a year after the drug trials in order to document any adverse drug reaction (ADR). However, in response to an e-mail question, the company refused to provide details of the in-built liability clause in the Patient Consent Form and whether the company would bear the costs of treatment if any ADR linked to NN622 were to be detected. It merely said: "Novo Nordisk will work according to the liability clauses valid in the individual protocols and patient consent forms."

Break up of patients in Phase III trials of NN622 in country-groups:

- United States/Canada – 650
- Latin America – 200
- Australia/New Zealand – 100
- European Union countries (Scandinavia, United Kingdom, France, Italy, Belgium, Austria, Germany, Ireland, The Netherlands) – 800
- Non-E.U. European countries (Estonia, Switzerland, Hungary, Poland. Slovenia) – 250
- Asia (India, Hong Kong, Malaysia, Singapore, Philippines, Taiwan, Thailand) - 550; (130 in India alone spread over eight centres.)

THE Swiss company Novartis Pharma AG had entered into an agreement with Novo Nordisk in July 2001 for obtaining commercial rights over NN622 in the United States, Canada and Mexico against some milestone payments to the latter. However, Novartis terminated the agreement in October 2001. There has been speculation in pharma business circles that perhaps Novartis had some inkling early on of the problems relating to animal tests.

The DRL-Novo Nordisk licensing agreement was the first instance of an Indian drug discovery being licensed to a foreign multinational for the international market. It was hailed as an indication of the emerging Indian R&D potential in the ongoing globalisation in the pharma sector. The setback may dent that image somewhat but does not lower that potential. What the issue has brought to light is how ethics are sidestepped in favour of overriding commercial interests and how the regulatory mechanisms of the country are becoming weaker even as MNCs enter the Indian market in a big way. In this context, it would be unwise to implement the recent recommendation of the Planning Commission Working Group to ease regulations on clinical trials and revise Schedule Y accordingly without a thorough revamping of the functioning of the DCGI itself. ■

III trials. (See box)

Refuting allegations of illegal and unethical clinical trials, the company stated that the Phase III trials had received approval in all countries in accordance with internationally accepted as well as domestic laws and guidelines governing such trials. "Adequate short-term as well as long-term animal toxicity studies as required including those under Schedule Y of the Indian Drugs and Cosmetics Act, at the current stage of the development of the drug, were provided when the trials were approved," it said.

However, statements made by Novo Nordisk with regard to the nature of these animal trials have been contradictory. While suspending the Phase III trials, the company had described the animal studies as "preclinical" ones, which, by definition, should mean studies conducted before all phases of human trials. "Preclinical carcinogenicity studies," the July 22 release said, "are an integral part of the development of new drugs for chronic use. The purpose of doing preclinical carcinogenicity studies in animals is to investigate if a new drug has potential for causing tumours after long exposure in animals. Due to complexity of conducting state-of-the-art preclinical carcinogenicity studies data from such studies do not usually become available until very late in Phase III clinical development." The last sentence would seem self-contradictory.

However, an August 14 company release, issued in response to news reports in the Indian media, stated that the mouse that had developed tumour had been treated with ragaglitazar for almost two years. Given that Phase II trials had begun in September 2000, it is clear that the animal tests could not have been "preclinical", even assuming that the term is meant to indicate only the starting date, as Phase I trials should have lasted at least six to eight months. So in all likelihood, the long-term carcinogenicity studies (in rats and mice) were initiated well after the human trials had started. (The company did not provide dates and other details of Phase I and Phase II trials that were sought through an e-mail query.)

The apparent contradiction may seem somewhat academic because, in any case, the results of animal trials were not available before the human trials. But therein lies the crux of the matter, an issue of ethics – whether human trials should be initiated before results of animal trials relating to long-term carcinogenicity become available.

Countering criticism that the animal trials were not initiated well in advance, the release further said: "Some types of animal studies must be performed before starting human trials... These studies show whether the new medication has any unwarranted side effects which develop in less than six months of treatment. Safety data from six-month toxicity studies on two animal species (rat and dog) were made available to the authorities as required by law, before the human studies were initiated...The carcinogenicity studies must be performed on compounds that are developed where treatment of patients is expected to exceed more than six months. According to international guidelines, these types of long-term carcinogenicity studies need not be conducted prior to entering Phase III development. The study data is only required at the time of (marketing) approval of the medicine."

Said Bhargava: "I do not care about laws and regulations. It is simply unethical to begin human trials before animal tests are over. I can understand (this argument) in the case of HIV or cancer where there is no treatment available and it is in human interest to reach a new potential drug quickly to the people. But diabetes is not incurable and there are a whole lot of drugs."

"The existing system of guidelines for clinical trials and long-term carcinogenicity studies do not address the case of drug development for chronic use adequately. Even the guidelines of the Indian Council of Medical Research (ICMR) lack clarity in this respect," points out Vineeta Bal of the National Institute of Immunology (NII), New Delhi, who has been concerned with ethical issues in biomedical research.

Vineeta Bal added: "It is precisely for drugs meant for chronic use that long-term carcinogenicity results should be known before you begin clinical trials. Generally, such animal studies will take about three to four years. Companies are not willing to wait that long. So they carry out such studies in parallel with clinical trials, which is not ethical. There could be some flexibility in the case of a disease like HIV. But this flexibility has to be made more specific instead of the existing vagueness, which companies exploit to their advantage."

Said Vasantha Muthuswamy of the ICMR: "We insist on animal test results as per the requirements of the Schedule Y of the Indian Drugs and Cosmetics Act to be available before clinical trials can be approved whenever a drug is referred to us. While the referral process is meant to be mandatory, some cases are sent to us and some are not. This particular case did not come to us." However, there is inherent vagueness and an apparent inconsistency in Schedule Y with regard to carcinogenicity studies. As a result, it is open to interpretation and it may be argued – as indeed Novo Nordisk has – that the company had complied with the requirements under Schedule Y.

A CLOSER reading of the Schedule shows that Novo Nordisk has not complied with other aspects of the regulations as well. In Schedule Y, under Animal Toxicity (Appendix I, Item 4), a clear distinction has been made between long-term animal toxicity data and mutagenicity/carcinogenicity data that are required to be submitted for obtaining clearance for clinical trials (Article 1.2). Long-term toxicity studies are required to be carried out in at least two mammalian species, one of which should be non-rodent. The Schedule also specifies (Appendix III) that for drugs to be administered (orally, parenterally or transdermally) to humans for a period longer than 3 months, animal test data (in the two species) over a period of six months are required to be submitted if the clearance required is for Phase III and/or marketing permission (MP).

As the press release of August 14 has stated, it is this 6-month data (in rat and dog) that the company had supplied to the Drug Controller General of India (DCGI) in order to get approval for clinical trials under the Indian law. The response of Anil Kapur, Managing Director of Novo Nordisk India Pvt. Ltd, to *Frontline*'s e-mail questionnaire makes it clear that the term long-term toxicity has been interpreted to include carcinogenicity as well. If it was a question of semantics alone, it could be argued that carcinogenicity is a facet of long-term toxicity and, therefore, requirements under Schedule Y have been met. But the requirements of mutagenicity/carcinogenicity studies data are different and have been specified in Article 3.5 of Schedule Y. It states: "These studies are required to be carried out if the drug or its metabolite is related to a known carcinogen or when the nature and action of the drug is such as to suggest a carcinogenic/mutagenic potential. For carcinogenicity studies, at least two species should be used. These species should not have a high incidence of spontaneous tumours and should preferably be known to metabolise the drug in the same manner as humans... The drug should be administered 7 days a week for a fraction of the lifespan comparable to the fraction

DR-2.

Drug trials and questions

The suspension of clinical trials of a promising new anti-diabetes drug in humans following reports of drug-induced tumours in laboratory mice raises a host of ethical issues.

R. RAMACHANDRAN

ETHICS and commercial interests often do not go together. One industrial sector where this conflict is perhaps most evident is pharmaceuticals. It is not uncommon for pharmaceutical companies to tend to exploit regulatory loopholes in a bid to enter the market quickly when the perceived commercial potential for a promising novel drug is big. A case in point is the recent controversial worldwide clinical trials by a multinational company of a new anti-diabetes drug discovered in India.

After several months of Phase III clinical trials of the drug ragaglitazar in 2,550 individuals across 32 countries, the Danish pharmaceutical multinational Novo Nordisk suspended the trials on July 22 after the discovery of urinary bladder tumour in mice on July 8. The drug, code-named NN622 by the company, was discovered by the Hyderabad-based drug company Dr. Reddy's Laboratories (DRL) and was licensed out to Novo Nordisk in August 1998. Before licensing, the drug was called DRF-2725 by the Indian company and, according to the DRL spokesman, had undergone "preclinical and some preliminary toxicology studies".

The objective of any Phase III trials is to obtain sufficient data about the efficacy and safety of the drug in a large number of patients of both sexes in multiple centres usually in comparison with a standard drug and/or placebo if a standard drug does not exist. On successful completion of Phase III trials, permission is granted to market the drug. In the present case, of the 2,550 persons, about 1,100 had received NN622 while the rest had received another drug, or a placebo, according to a company statement.

Ragaglitazar (NN622/DRF-2725) is a dual-action insulin sensitiser for the treatment of Type 2 diabetes. Insulin sensitisers are substances that stimulate the body's ability to utilise insulin. It is characterised as a "dual-action" drug because of its ability to regulate both sugar and fat levels in blood. In medical jargon, the drug is a "PPAR (peroxisome proliferator-activated receptor) alpha and gamma agonist". It is stated to be chemically and pharmacologically different from currently marketed "PPAR agonist" anti-diabetic drugs and constitutes a new class of insulin sensitisers.

According to media reports, Phase II trials of the drug began in September 2000 and were completed in September 2001, when the company announced that the trials had provided clinical proof of the concept for NN622 and said that it had decided to initiate Phase III trials. Novo Nordisk claimed that in pre-clinical animal tests and Phase I and Phase II human trials, NN622 had demonstrated "significant potential to regulate blood glucose and diabetic dyslipidaemia (or abnormal blood lipid levels)". Phase III trials began in November 2001.

The company claimed that the compound would be among the first to reach the market from a new generation of dual-action sensitisers under development. According to market sources, the nearest competitor to NN622 was Glaxo-SmithKline's Farglitazar (GI262570), which was also withdrawn recently owing to a different kind of adverse reaction. Apparently, the Glaxo drug was ahead of Novo Nordisk in the development cycle. Therefore, NN622 would have been the first to hit the market had Phase III trials reached completion.

The company release of July 22 said: "Novo Nordisk's decision was taken in response to findings of urine bladder tumours in one mouse and a number of rats treated with ragaglitazar. All current clinical trials involving ragaglitazar have been stopped and all planned new clinical trials have been postponed, while preliminary data from studies in rats and mice are being investigated."

Apparently, tumours had been seen in a number of rats in February itself. However, clinical trials were continued because, according to the company, many drugs currently available in the market have been shown to cause tumours in rats and so the findings were not considered to be alarming. A Novo Nordisk release added: "It is a known fact that the development of such tumours in rats is species-specific and does not have any implications for humans. Nevertheless, this data was immediately shared by Novo Nordisk with the regulatory authorities and the trial continued with the knowledge and consent of the regulatory authorities concerned."

According to the company, all the patients were asked to reassess their continued participation in clinical trials, and sign a new Patient Informed Consent Form, which included information about the tumours found in rats. "(Considering) the fact that tumours have now been reported in two species, it was not ethical to continue trials in humans until it can be documented that the mechanism by which these tumours develop is specific to rodents," the release said.

However, the company refrained from disclosing the names of the countries and the centres where the trials had been going on. Details about Indian subjects participating in the trials would perhaps not have come to light but for the fact that, through a PTI story of August 13, Pushpa Bhargava, the eminent biologist and former director of the Centre for Cellular and Molecular Biology (CCMB), Hyderabad, questioned the ethics of carrying out human trials before the animal trials were completed.

As a member of the institutional ethics committee of the Nizam Institute of Medical Sciences (NIMS), Hyderabad, Bhargava had reasons to be concerned as the NIMS was one of the Indian centres participating in the Phase III trials of NN622. According to Novo Nordisk, which responded immediately with a press release, 130 persons from India were part of the suspended NN622 trials and half of them would have received doses of NN622. In response to an e-mailed questionnaire from *Frontline*, Novo Nordisk provided a partial break-up of the number of patients participating in Phase III trials in country groups rather than individual countries. It also refused to give any more information beyond stating that eight Indian centres were involved in the Phase

DR-2.

GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

PALACE ROAD, BANGALORE-560001.

WORLD BANK ASSISTANCE
- CAPACITY BUILDING OF
DRUGS TESTING LABORATORY

WORLD BANK ASSISTANCE - CAPACITY BUILDING OF DRUGS TESTING LABORATORY, DRUGS CONTROL DEPARTMENT, GOVERNMENT OF KARNATAKA.

PROPOSAL AT A GLANCE

Expenditure in Lakhs

Head	One time capital expenditure.	Per annum recurring expenditure.	Total recurr--ing expendi--ture for 5 years.
a) Precision instruments/equipment	230.00*	---	----
b) Technical Staff	----	48.80	244.00
c) Construction of additional space for laboratory.	250.00	---	----
d) Infrastructure for the laboratory.	20.00	---	----
e) Furniture	20.00		
f) Operating cost (consumables and service charges)	----	20.00	100.00
g) Training of Analysts	----	2.00	10.00
h) Library and References Section (a) Establishment of "NICNET" (b) Journals & Reference Books.	5.00 ----	--- 5.00	---- 25.00
i) Maintenance of equipment'. '	----	* *	30.00* *
j) Providing transport facilities (including maintenance & staff)	10.00	6.00	30.00
k) Computerisation	50.00	10.00	50.00***
l) IEC activity to be kept at the disposal Government of India.	***15.00	- -	---
m) Sampling and Travel expenses.		20.00	100.00
Total:	600.00		489.00

*To be purchased in a phased manner in 3 years. (25% is added due to foreign exchange fluctuations to the original proposal)

* * To be spent at the rate of Ist year - 2.00 lakhs
IInd year - 4.00 lakhs
IIrd year - 6.00 lakhs
IVth year - 8.00 lakhs
Vth year - 10.00 lakhs

TOTAL ASSISTANCE SOUGHT IN LAKHS

	LABORATORY
A. CAPITAL EXPENDITURE	250.00
B. ONE TIME EXPENDITURE INCLUDING HI-TECH EQUIPMENT .	350.00
C. RECURRING EXPENDITURE FOR 5 YEARS.	489.00
Total:	1089.00

TOTAL: Rs.1089.00 lakhs.

ABSTRACT OF EXPENDITURE

I. ONE TIME EXPENDITURE - Rs.479.00 Lakhs

HEAD	Rs.in lakhs
1) Instruments	230.00
2) Construction	250.00
3) Infrastructure	20.00
4) Furniture	20.00
5) Establishment of "Nicnet"	5.00
6) Transport facility	10.00
7) Computerisation	50.00
8) I.E.c.Activity	15.00
TOTAL	600.00

II. RECURRING EXPENDITURE - RS. 489.00 LAKHS

STAFF			OTHERS		
Head	Per annum	Per 5 Years	Head	Per annum	Per 5 years
Drugs Testing Laboratory – Technical Staff	48.80	244.00	a) Journals and periodicals. b) Operating cost. c) Maintenance of instruments. d) Training of Analysts. e) Maintenance of vehicle including salary of drivers f) Computerisation	5.00 20.00 6.00 (average) 2.00 6.00 10.00	25.00 100.00 30.00 10.00 30.00 50.00
TOTAL	48.80	244.00	TOTAL	49.00	245.00

Grand Total: Rs.600.00 + Rs.489.00 = Rs.1,089.00 Lakhs

SUMMARY OF POSTS TO BE CREATED UNDER WORLD BANK ASSISTANCE SCHEME

DRUGS TESTING LABORATORY

Sl.No.	Designation	No.of posts
1.	Technical Officer	1
2.	Senior Chemist	5
3.	Junior Chemist	20
4.	Laboratory Supervisor	10
5.	Laboratory Attender	10

Drugs Controller

WORLD BANK ASSISTANCE – CAPACITY BUILDING EXPANSIOIN OF DRUGS TESTING LABORATORY OF DRUGS CONTROL DEPARTMENT, GOVERNMENT OF KARNATAKA.

The Drugs Control Department, Government of Karnataka has been entrusted with the responsibility of overseeing the quality of Drugs and Cosmetics. Drugs Industry in the recent years has recorded Phinomenal growth and the turnover of drug formulations and bulk drugs is in the order of more than 10,000 crores per annum in the country. India being a vast country and regulation mechanism over the manufacture rests with the concerned State Drugs Controllers there has been an increased need to exercise stricter vigilance over the quality of the drugs.

The Drugs Control Department has been functioning in Karnataka State since 1965. The department has three wings namely, Enforcement Wing, Drugs Testing Laboratory and Pharmacy Education (i.e., Board of Examining Authority and Government College of Pharmacy). As a result it has not been possible to increase the capacity of the laboratory to take up analysis of increased number of samples and to update with modern sophisticated instruments.

After careful consideration and examination of all aspects, this proposal has been prepared involving a total expenditure of (a) Capital expenditure Rs.250.00 lakhs for providing additional space for laboratory (b) One time expenditure of Rs.350.00 lakhs for purchase Hi-tech equipments including developing infrastructure and (c) a recurring expenditure of Rs.489.00 lakhs at the rate of Rs.97.80 lakhs per annum. A brief note under each head is given to illustrate the proposal.

(a) Instruments and equipment,
(b) Technical Staff,
(c) Construction of Additional Space for laboratory,
(d) Infrastructure,
(e) Furniture for Laboratories,
(f) Operating costs,
(g) Training of Analysts,
(h) Library and reference Section,
(j) Maintenance of equipment.
(j) Providing transport facility
(k) Computerisation
(l) IEC activity to be kept at the disposal of Government of India.
(m) Sampling and Travel expenses.

Karnataka State has been a model state despite various limitations. The aim of the department is to provide an excellent facility particularly in the field of Test and Analysis so that every kind of drug can be analysed without any delay. Present capacity of the laboratory in terms of number of samples which can be analysed is around 2,000 – 2,500 which is inadequate and as such the capacity has to be increased so that the field officers can draw more samples in the course of discharge of their duties. Inspite of efforts there is delay in the test and analysis of samples resulting in backlog of samples. The department is confident of overcoming the delay if the proposals contained herein are implemented.

(a) INSTRUMENTS AND EQUIPMENT

It is proposed to equip the laboratory with modern and sophisticated instruments for precise, quick and accurate analysis. The total expenditure (one time capital expenditure) is estimated to be around Rs.230.00 lakhs. The expenditure is proposed to be incurred in a phased manner in three years. This step will increase the efficiency of the laboratory in terms of capacity. The list of instruments proposed to be procured are shown in ANNEXURE-I.

(b) TECHNICAL STAFF

While equipping the laboratories as proposed above and thereby increasing the capacity it is essential to provide adequate technical staff. Hence, the department proposes to create additional technical staff of the following cadres.

Name of the Cadre	Post/s
1) Technical Officer (Instruments maintenance)	1
2) Senior Chemists	5
3) Junior Chemists	20
4) Laboratory Supervisors	10
5) Laboratory Attenders	10

The anticipated expenditure towards additional technical staff is around Rs. 48.80 lakhs per annum which comes to Rs. 244.00 lakhs for 5 years – details shown in ANNEXURE-II.

(c) CONSTRUCTION OF ADDITIONAL SPACE FOR THE LABORATORY

In view of the proposal to acquire additional sophisticated instruments as well as to recruit additional technical staff, there is need to provide additional space to house the equipment and to allot work space. Hence, it is proposed to construct an additional 2,730 sq. mts. on the existing building complex.

The department has its own land and building. There is enough scope to take up additional construction so that another 2,730 sq. mts. area can be built.

The construction cost works out to approximately Rs.250.00 lakh.

(d) INFRASTRUCTURE FOR NEW SECTIONS

In order to provide necessary infrastructure such as partitions, gas, electricity, sanitary connections, air-conditioning and generators a one time capital expenditure of Rs.20.00 lakhs is expected to be incurred.

(e) FURNITURE FOR LABORATORY

The Laboratories needs necessary furniture and works benches etc. Expenditure towards providing furniture to the laboratory on one time basis is estimated to be around Rs.20.00 lakhs.

(f) OPERATING COSTS

In the day to day analytical work, consumables such as Glass wares, Chemicals and Solvents are essential. In addition expenses towards service facilities such as Electricity and Gas have to be met with. Laboratory needs to procure reference standards from authentic sources which is an essential requirement in drug analysis. An estimated annual expenditure of Rs.20.00 lakhs under this head is expected to be incurred which comes to Rs.100.00 lakhs for five years.

(g) TRAINING OF ANALYSTS/TECHNICAL STAFF

It is essential that analysts and other technical staff working in the laboratory are sent for refresher course/training periodically to update their knowledge. An expenditure of Rs.2.00 lakhs per annum is expected to be incurred which comes to Rs.10.00 lakhs for five years.

(h) LIBRARY AND REFERENCE SECTION

For any laboratory to functioin, the library and reference facilities are of utmost importance. It is proposed to modernise the library by linking with "NICNET" facililty and to subscribe to various journals (National and International) on various aspects of analysis of Drugs and Cosmetics. The anticipated expenditure towards this head is around Rs.30.00 lakhs (Rs.5.00 lakhs towards one time expenditure to establish "NICNET" and Rs.25.00 lakhs towards recurring expenditure for 5 years for subscribing to Journals and Books).

(j) MAINTENANCE OF INSTRUMENTS AND EQUIPMENT

Periodical servicing and replacement of parts whenever required for instruments forms annual maintenance feature. A total expenditure of Rs.30.00 lakhs for 5 years is earmarked at the rate of:

YEAR	RS.IN LAKHS
1st	2.00
2nd	4.00
3rd	6.00
4th	8.00
5th	10.00

(j) PROVIDING TRANSPORT FACILITY

With a view to exercise stringent quality control over drugs it is necessary that samples are collected even from remote areas at the quickest possible time. It will be practically difficult for the inspectorate staff to depend upon public transport of wide coverage. Therefore it is proposed to purchase two transport vehicles for sampling purpose at one time expenditure of Rs.10.00 lakhs. A recurring expenditure of a sum of Rs.30.00 lakhs at the rate of Rs.6.00 lakhs per annum towards maintenance cost fuel and driver salary has been earmarked.

(k) COMPUTERISATION

From the point of convenience as well as axes to information, it has become necessary a computerized the entire activity of Drugs Testing Laboratory. This will result in increased efficiency it has been proposed to computerized the laboratory at a one time expenditure of Rs.50.00 lakhs and a recurring expenditure of Rs.50.00 lakhs at the rate of Rs.10.00 lakhs per annum is anticipated for this purpose.

(l) IEC ACTIVITY TO BE KEPT AT THE DISPOSAL OF GOVERNMENT OF INDIA

A sum of Rs.20.00 lakhs (one time expenditure) is proposed to be kept at the disposal of Government of India for IEC activity.

(m) SAMPLING AND TRAVELLING EXPENSES

Since the Drugs Testing laboratory, Karnataka ia a statutory laboratory, analysis of legal samples are carried out. As per the Drugs and Cosmetics Act only the Drugs Inspectors have to draw samples and while drawing samples fair price for the samples have to be tendered. As it is proposed to increase the sampling a recurring expenditure of Rs.100.00 lakhs at the rate of Rs.20.00 lakhs per annum has been earmarked towards cost of sampling and travel expenses towards drawing of samples.

(R.ANANDARAJASHEKAR)
DRUGS CONTROLLER FOR THE
STATE OF KARNATAKA, BANGALORE.

ANNEXURE-I

List of Analytical Instruments proposed to modernise Drugs Testing Laboratory.

Government of Karnataka, Bangalore.

Sl.No.	Instrument	Utility
1.	UV Spectrophotometer with Library (1)	Identification and Quantification of drugs
2.	HPLC (1)	-do-
3.	HPLC Columns (10)	Accessory to HPLC
4.	Computer and Printer for HPLC	-do-
5.	HPLC Filtration Kit	Accessory to HPLC
6.	Computer based Integrators for HPLC and GC	Accessory for the above.
7.	Distilled water plant with Fractionating Columns(2)	Preparation of distilled water.
8.	Tablet Dissolution Tester(2)	For carrying out dissolution test of tablets and capsules.
9.	Tensile Testing Machine	Measurement of Tensile strength of Adhesive Tapes, Candoms, Switches etc.
10.	Autotitrator (1)	Required for K Titrations & Potentio metri.
11.	I.T.I.R. with Library	Identificiation & Quantification of drugs.
12.	Polarimeter	Testing of Optically active compounds.
13.	Centrifuge	Analysis of Blood & Blood Products.
14.	B.O.D.Incubator(2)	Sterililty test.
15.	Laminar Flow Bench	Micro-biological testing of drugs.
16.	Top Loading Balances(2) with digital printer.	Precision weighing.
17.	Tele Thermo meter.	Pyrogen testing.
18.	Elisaprinter with reader	Testing of Blood & Blood Products
19.	Refrigerator with deep freezer(2)	Storage of reference standards and for routine work.
20.	Refractor (1)	Refractive Index of certain drugs.
21.	Gas Chromatograph	Quantitative estimation of drugs.
22.	Columns for Gas Chromatograph	Accessory for the above.
23.	Travelling Microscope	Medical devices testing
24.	Water Purification system	To prepare HPLC grade water.
25.	Reverse Osmosis System	Preparation of water of distilled water.

26.	Automic Absorption Spectrophotometer.	Trace elements analysis.
27.	Particle sizer	Measurement of articles in IV fluids
28.	N.M.R.	For confirming purity & structure of drugs.
29.	Laboratory information and management systems software.	Useful for Automatic data Acquisition & instrument control.
30.	Un-interruptible power supplies (20 KVA)	To get continuous power supply.
31.	Spectroflouro photometer	Flouroseoence Analysis.
32.	Polygraph with Operating table.	Pharmacological testing of drugs.

ANNEXURE-II

Statement indicating the total expenditure that would be incurred for the creation of proposed additional posts on the basis of salary and other allowances at the entry stage under capacity building of the Drugs Testing Laboratory

Sl. No	Name of the post	No.of posts requi -red	Pay scale Rs.	Salary and allowances per month per post calculated on the basis of mean basic pay for promotional posts and minimum basic pay for direct recruitment posts. Rs.	Rs.	Rs.	Rs.	Rs.	Total per annum per post Rs.	Total for five years Rs.
1	2	3	4	5 Basic Pay	6 D.A.	7 H.R.A	8 C.C.A	9 Total	10	11
1.	Technical Officer	1	8000-13440	10,720	3,960	1,179	200	16,065	1,92,780	9,63,900
2.	Senior Chemist	5	6300-11840	8,762	3,242	964	200	13,168 x5	7,90,080	39,50,400
3.	Junior Chemist	20	5575-10620	5,575	2,063	613	200	8,451 x20	20,28,240	1,01,41,200
4.	Lab.Supervisor	10	4575-8400	6,572	2,432	723	150	9,877 x 10	11,85,240	59,26,200
5.	Lab. Attender	10	2775-4950	3,790	1,402	417	90	5,699 x10	6,83,880	34,19,400
	TOTAL								48,80,220	2,44,01,100

ANNEXURE-III

ESTIMATE FOR PROPOSED CONSTRUCTION OF ADDITIONAL ACCOMODATION FOR LABORATORY AND RESEARCH AND DEVELOPMENT WING AT DRUGS TESTING LABORATORY, PALACE ROAD, BANGALORE.

Line Estimate

1	Construction of building at rear side of the main building rear side quardrangle. A. BLOCK: (GF, FF, SF & TF) 4 x 34.0 x 9.00 1,224.00 sq.mt. B. BLOCK: (GF, FF, SF & TF) 4 x 19.0 x 9.00 684.00 sq.mt. C. BLOCK : For construction of existing animal house for SF & TF 2 x 24.60 x 16.00 787.20 sq.mt. D. BLOCK: Ramp to connect the main building and animal house and lift room. 2 x 8.30 x 2.10 34.86 sq.mt. Total 2,730.06 sq.mt. at Rs.6,000/- sq.mt.	Rs.1,63,80,360 or Rounded to Rs.164.00 lakhs
2.	Providing wall panelling with accuostic arrangement, false Ceiling, Veniyel flooring etc. in the existing auditorium. for 264 sq.mt	Rs. 12.00 lakhs
3.	Providing Dias in Auditorium including sitting arrangements	Rs. 15.00 lakhs
4.	Providing additional lift arrangements for `D' Block	Rs. 15.00 lakhs
5.	Providing A.C. arrangements	Rs. 12.00 lakhs
6.	Electrification charges LS	Rs. 15.00 lakhs
7.	Providing water supply and sanitary arrangements LS	Rs. 15.00 lakhs
8.	Miscellaneous and rounding off including escalation of rates LS	Rs. 2.00 lakhs
	TOTAL	Rs.250.00 lakhs

DR-2.

The GPHF-Minilab®

Protection Against Counterfeits and Substandard Drug Products

Simple Test Methods for the Quality Assurance of Pharmaceuticals

Gesundheitshilfe Dritte Welt · German Pharma Health Fund e.V.

for CHC lib
Drug resource file
Jo
14/6/-3

Medical Mission Institute

Counterfeit and Substandard *Pharmaceuticals*

Counterfeiting of pharmaceuticals and the proliferation of substandard drugs constitute a serious health risk for the population around the world. Experts assume that as many as seven percent of the world's total sale of drugs is already being counterfeited. Most hit are the people living in developing countries for whom high quality and inexpensive drugs are not readily available and where the means for an effective drug quality control system are not yet fully in place.

Based on this situation, the German Pharma Health Fund e.V. (GPHF), a non profit making organization established by research based pharmaceutical companies in Germany, has developed some easy-to-use test methods that are designed to protect the people in developing countries against the, frequently fatal, consequences of taking counterfeited or substandard pharmaceutical drug products. This developing work has been done in close cooperation with Prof. Peter Pachaly, School of Pharmacy at University of Bonn and Prof. Klaus Fleischer, Department of Tropical Medicine at the Medical Mission Institute in Würzburg, Germany.

The Objective: *Provision of Easy-to-use and Versatile Test Methods*

The objective of the GPHF-funded project is the provision of simple test methods which makes it possible to identify substandard or counterfeited pharmaceuticals under the specific conditions encountered in developing countries. The method in question should be inexpensive, transportable, versatile and used reliably even by less experienced local personnel in developing countries.

After several years of development, the GPHF-Minilab® was subjected to lengthy field testing in Kenya, Tanzania, Ghana and on the Philippines between 1997 and 1998. These tests have shown that the Minilab is a practical and effective tool for the identification and quality assurance of pharmaceutical drug products.

The trials have confirmed also that all procedures employed by the Minilab can be performed without any problems in primary health care stations, hospitals and pharmacies even when based in rural areas. Furthermore, all methods in use are also suited for customs officials based at harbours, airports or any other port of entries. Thus, the GPHF-Minilab® is a very helpful and important tool for all government authorities, professional bodies and non-governmental organisations working in public health care and being responsible for a constant supply of high quality drugs in developing countries.

Verifying Drug Quality:
Four Simple Tests Are Required Only

The Minilab's test scheme employs a set of four physical and chemical tests in order to decide on the quality of a given drug product:

1. Sophisticated visual inspection scheme on solid dosage forms including the associated packaging material for a timely rejection of rough counterfeits.

2. Simple tablet and capsule disintegration tests for a preliminary assessment of deficiencies related to drug solubility and availibility.

3. Simplified colour reactions for a quick check of any drug present, thus ensuring the drug's identity.

4. Easy-to use thin layer chromatographic assays for a quick check of any quantities of drug present, thus ensuring the drug's potency.

Attention Focussed
on Counterfeit Drugs

Based on the Essential Drug List of the World Health Organization (WHO) and prevailing practice, fifteen of the most used drugs have been selected which are also known to be liable for frequent counterfeiting. The short list of the GPHF-Minilab© does include many essential antibiotics and antiparasitics as well as some analgetic and anti-inflammatory drugs many of which are instantly life-threatened if diluted down to nothing:

- acetylsalicylic acid
- amoxicillin
- ampicillin
- chloramphenicol
- chloroquine
- cloxacillin
- co-trimoxazole
- erythromycin
- mebendazole
- metamizole
- metronidazole
- paracetamol
- penicillin V
- prednisolone
- tetracycline

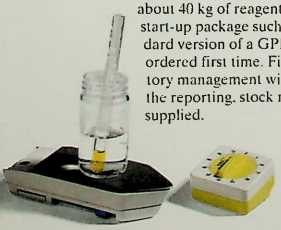
A Complete Laboratory
Assembled in Two Cases

The GPHF-Minilab® has been designed in such a way that all the labware required fits into two mobile units each having the size of a standard suitcase and weighing about 10 kg when fully loaded. The GPHF-Minilab® can be operated without an external power supply if required. Both, the low weight and independence from power makes the GPHF-Minilab® a truly mobile system and fit for use in the field.

The GPHF-Minilab® is equipped with a full set of secondary standards for reference purposes and contains all the necessary laboratory accessories in order to perform all tests on the spot without any restrictions. The equipment includes, for example, caliper rules, test-tubes including rack, pipettes, precoated TLC plates, developing chambers, all glass containers and vials in different sizes for mixing and battery-powered UV handlamps of various preset wavelengths for an easy detection of drugs.

The GPHF-Minilab® comes with two manuals written in plain English and full of descriptive pictures and illustrations (about 130) explaining all analytical methods and operation procedures taking the form of a step by step guide (Volume I 'Colour Reactions', Volume II 'Thin Layer Chromatography'). All procedures are also provided in a summarized version on laminated sheets resistant to spillage for routine bench work.

Alongside the GPHF-Minilab® are travelling about 40 kg of reagents and solvents as a start-up package such completing the standard version of a GPHF-Minilab® when ordered first time. Finally, a reliable laboratory management will be facilitated using the reporting, stock record and order forms supplied.



Drug Quality Control
at Low Cost

The overall priority during the GPHF-Minilab® development was to present reliable test methods employing a simple and versatile technology which would make the GPHF-Minilab® affordable to everybody. After intensive development work and product sourcing the entire test system of the GPHF-Minilab® can be offered at a bought-in price of 2,570 US$ (2,260 EURO) excluding any taxes, shipping costs and customs fees.

The quantities of reagents and solvents supplied in the start-up package are sufficient to support at least 3,000 colour reactions in order to verify the drugs' identity and 1,000 TLC runs in order to verify their potency thus ensuring that the costs for one quality check are about 1.3 US$ or 1.0 EURO only. Replacement of consumables is required from time to time, maintenance, however, not. All analytical reagents and the equipment are carefully selected so to ensure that they are locally available and that the GPHF-Minilab® is permanently fit for use.

The GPHF-Minilab® will be supplied to all interested parties willing to undertake permanent efforts to monitor their drug supplies consistently. It is primarily dedicated to people who are working in the public health care system of developing countries and are directly responsible for a constant supply of high quality drugs.

Minilab Training:
Well Advised and Recommended

Special efforts were made to keep all operation procedures of the GPHF-Minilab® as simple as possible. However, the German Pharma Health Fund (GPHF) and the Medical Mission Institute recommend an introductory training course regarding the proper use of the Minilab's analytical techniques especially for less experienced local staff involved in day-to-day drug analysis.

Continuous training at relatively low costs will be offered

- at the training centre of the Medical Mission Institute in Würzburg, Germany. (Duration: 1 to 5 days depending on the actual background knowledge of the trainees)
- at training centres of the Medical Mission Institute or any other GPHF partner organization in developing countries (Duration: 5 to 10 days depending on the actual background knowledge of the trainees)
- on request by the GPHF-Minilab® Project Manager.

For further details on the GPHF-Minilab® contact:

German Pharma Health Fund e.V. (GPHF)
P.O.Box 150 123·60061 Frankfurt/Main·Germany
Tel./Fax: Int. ++49-69-63153257
Internet: http://www.gphf.org

Missionsärztliches Institut Würzburg (MIW)
- ApproTech Lehrlabor -
Hermann Schell-Str. 7
97074 Würzburg·Germany
Tel./Fax: Int. ++49-931-80485-15/-25

or

Technologie Transfer Marburg (TTM)
in die Dritte Welt e.V.
Auf der Kupferschmiede 1
35091 Cölbe·Germany
Tel./Fax: Int. ++49-6421-87373-0/-73

who is a licensed distributor of the GPHF-Minilab®.

Published by: German Pharma Health Fund e.V. (GPHF)
Concept/Editor: Christian von Berg (MS&L)
Design: Christopher Wahrenberg
1st edition, August 1998

Main Identity

From: "sanajorc, renu and chinu" <sanajorc@icenet.net>
To: "Dr Dabade" <drdabade@sancharnet.in>; "Sudarshan H" <vgkk@vsnl.com>; "Shyamala Bhaskaran" <vani3@hotmail.com>; <shyamanarang@hotmail.com>; <esparun@bgl.vsnl.net.in>; "Community Health Cell" <sochara@vsnl.com>; <van@vsnl.com>; <prasanna_ald@yahoo.com>; "Prasanna, PHM Secretariat" <phmsec@touchtelindia.net>
Cc: "Anant Phadke" <amol_p@vsnl.com>, <robsroy@vsnl.net>, <jss_ganiyari@rediffmail.com>
Sent: Tuesday, August 19, 2003 9:20 AM
Subject: Re: URGENT- Find Col Gopinath

1) IDMA, OPPI to move SC against NPPA deadline for price revision

FPP News Bureau - New Delhi

See at http://www.expressphamapulse.com/20030320/cor01002.shtml

2) Glaxo moves SC over price changes for 'old' drugs

Feb 22, 2003: New Delhi: Multinational Pharma major GlaxoSmithKline last week filed a special leave petition (SLP) in the Supreme Court, contesting the November 12 order by the Karnataka High Court which said that prices of controlled medicines notified by the government would apply to all batches of medicines, old and new, with the retail dispenser, irrespective of when they were released to the market. The HC order, which caught the entire pharma industry unaware, can be of serious consequence if the government decides to strictly implement it and defend the high court in the SC.

Pharma industry bodies IDMA and OPPI have already approached the government for a friendly resolution of the issue. The industry is hopeful that the government had not favoured the HC order, which was based on the writ petition filed by GSK as coercive action was taken against the company by local drug authorities in Varanasi for violating the notified prices for batches of medicines released prior to the government order.

Healthcare likely

Lds - Drug Policy file
Jw
18/8

GN
19/8

8/19/03

Main Identity

From: sanajprc renu and chinu <sanajprc@icenet.net>
To: "Dr Dabade" <drdabade@sancharnet.in>; "Sudarshan H" <vgkk@vsnl.com>; "Shyamala Bhaskaran" <vani3@hotmail.com>; <shyamanarang@hotmail.com>; <esparun@bol.vsnl.net.in>; "Community Health Cell" <sochara@vsnl.com>; <van@vsnl.com>; <prasanna_aid@yahoo.com>; "Prasanna, PHM Secretariat" <phmsec@touchtelindia.net>
Sent: Tuesday, August 19, 2003 8:00 AM
Subject: News

DECCAN HERALD
Wednesday, November 13, 2002

National
State
District
City
Business
Foreign
Charkha
Sports
Edit Page

Economy & Business
Science & Technology
Youth Herald
Sportszone
Avenues
Foreign
Panorama
Spectrum
Living
She
Open Sesame
Sunday Spotlight
Sunday Herald
Articulations
Entertainment

Net Chat
Yesterday's Edition
Archives
E-mail to Editor
Deccan Herald
Advertising
Seminar

Directive to Centre on pharma policy

DH News Service BANGALORE, Nov 12

The implementation of Centre's 'Pharmaceutical Policy-2002' received a setback today with the Karnataka High Court directing the Centre not to implement the policy till a list of essential and lifes-aving drugs is prepared and such essential drugs are brought into the basket of essential drugs under price control mechanism.

The High Court also directed the Ministry of Health and Family Welfare to review essential and lifesaving drugs while also taking into consideration such new drugs, before implementing the policy.

A division bench consisting of Chief Justice N K Jain and Jus-tice V G Sabhahit passed the above order on a public interest writ petition filed by Lt Col (Retd) K S Gopinath and B V Bhaskar of Bangalore questioning the constitutional validity of the policy.

The petitioners had contended that the new policy was framed like a 'business policy' and if allowed to be enforced, it would take away life-saving and essential drugs out of the limit of Drugs Price Control Order (DPCO) which was highly detrimental to the public interest. The petitioners further argued that the basis for DPCO which was mentioned in the new policy was clearly arbitrary and takes into account the sales turn over of a particular drug and not the volume of the sale.

Their argument was that if the DPCO was promulgated on the basis of the impugned policy, then the price control would be left to the whims and

Lib - Dang Bldg File
Fw
19/8

TH
19/8

8/19/03

fancies of the pharmaceutical manufacturers and hence the policy was violative of Article 21 read with Article 47 of the Constitution and Sec 3 of the

Essential Commodities Act

Appearing for the Centre, additional solicitor general, V T Gopalan had argued that the policy was framed keeping in mind the WTO agreements and globalisation of economy.

He contended it was not open for the petitioner to question the very policy of the Centre. He had also submitted that the government was yet to come out with the DPCO while stating that the Government would not give away its power on drug pricing.

Writing the judgement for the bench, Chief Justice Jain ruled. "the price control mechanism adopted in the policy to deter-mine drugs under price control was arbitrary as it defeats the entire purpose of equitable distribution and availability of essential drugs at a fair price."

DR-2

Main Identity

From: "Pinelle Lechlak" <On5449@in-box.net>
To: <sue.spence@pacificnet.net>
Sent: Sunday, August 24, 2003 8:52 AM
Subject: We Offer The Lowest Prices On The Internet

Discount Prescription Drugs Are Here!
Visit Our Website And See How Much You Can Save!

We are proud to provide affordable health care!

We understand that the high cost of pharmaceuticals can prevent you from obtaining the medications you need, negatively impacting your standard of living and quality of life

Never Pay High Prices On Prescription Drugs Again!

No more future mailing here
r8AWP15LNcvBLI3615Q4HYm

Lit Drug file
Fw
19

25/8

Medicinal mishaps

Aspirin and non-steroidal anti-inflammatory drugs

Prepared by J. Dowden, Editor, and A. Rohan, Secretary, Adverse Drug Reactions Advisory Committee, Canberra

Aspirin has been available without prescription for many years. Although it is readily available, it is not free of adverse effects. Some patients have reactions to aspirin which may have presenting symptoms ranging from a skin reaction to angioedema and shock.

Hypersensitivity to aspirin is more frequent in patients with asthma. An analysis of spontaneous reports received by the Adverse Drug Reactions Advisory Committee indicates that, of the 47 cases of bronchospasm associated with ingestion of aspirin, 30 patients had a history of asthma. Furthermore, 16 of these 30 asthmatic individuals were known to be allergic to aspirin.

While health professionals will generally be aware of the risks associated with this class of drug, patients may not have this knowledge. Patients with aspirin hypersensitivity, particularly if they are asthmatic, should be aware that aspirin can trigger bronchospasm. Patients (and even some health care workers) may also not realise that other non-steroidal anti-inflammatory drugs (NSAIDs) are pharmacologically related to aspirin and can cause the same adverse reactions, especially in those who have had a previous allergy to aspirin.

A recent case highlights the issue of cross-reactivity:

> A 49-year-old man with asthma and known hypersensitivity to aspirin was given a single indomethacin 100 mg suppository for back pain. This suppository was given while he was a hospital inpatient. He experienced acute respiratory distress with laboured breathing and hypercapnia. He lapsed into semi-consciousness and required urgent respiratory support involving intubation and assisted ventilation in intensive care. He subsequently recovered from the episode.

With the increased availability of NSAIDs over the counter, there is an increased potential for adverse reactions. While consumer product information may help to warn about cross-sensitivity, health professionals can also alert patients they know to be hypersensitive.

RATIONAL DRUG BULLETIN

Fluoroquinolones--Tendinitis Alert

-Avijit Hazra

The fluoroquinolones are a recently synthesized group of fluorinated antimicrobial drugs that have followed from the earlier quinolones like nalidixic acid and cinoxacin. Unlike the older generation quinolones, the fluoroquinolones have much broader antibacterial spectrum and more favourable action profiles. In addition to rapidly killing most common Gram-positive and Gram-negative bacteria, they can inhibit various intracellular pathogens such as *Brucella, Chlamydia, Legionella, Mycobacterium* spp. Ciprofloxacin, ofloxacin, pefloxacin and sparfloxacin have good activity against staphylococci, including methicillin resistant stains. They are also active against *Pseudomonas aeruginosa* and enterococci. Ofloxacin and pefloxacin are under evaluation for the treatment of leprosy. The potent antibacterial activity of fluoroquinolones owes considerably to their unique mode of action. However except for sparfloxacin, fluoroquinolones are not active against anaerobes and are less effective against pneumococci.

As a group the fluoroquinolones are relatively safe drugs. The known adverse drug reaction (ADRs) are summarised in Table 1. Their potency, broad spectrum and relative safety have led to wide clinical use in diverse contitions like gonorrhoea, chlamydial genital tract infections, urinary tract infections, shigellosis, respiratory tract infections (less effective in community acquired pneumonia), infections of bones, joints and soft tissues and atypical mycobacterial infections. They are also used for antibacterial prophylaxis in neutropenic patients. In the US, in a single year (1995), retail pharmacists filled 14.4 million prescriptions for this group of antibiotics alone. In India, exact figures are not available, but going by the proliferation of brands, their use is already widespread. The fluoroquinolones currently available in the Indian market are ciprofloxacin, lomefloxacin, norfloxacin, ofloxacin, pefloxacin and sparfloxacin.

In the context of expanding use and vigorous promotion of fluroquinolones it is important to note that a new and potentially serious ADR attributed to these drugs has come to light, namely tendinitis and tendon rupture. The salient features are as follows :

- Tendinitis following the use of fluoroquinolones has been reported from a number of countries including Australia, Belgium, France, UK and USA.
- The Achiles tendon is most commonly involved and the involvement is often bilateral. Other affected tendons include the rotator cuff of the shoulder, the long tendon of the biceps, the long extensor of the thumb and various small tendons of the hand.
- Reports so far have implicated most of the available fluoroquinolones including ciprofloxacin, enoxacin, lomefloxacin, norfloxacin, ofloxacin and pefloxacin. It remains to be seen whether the latest introduction, sparfloxacin shares this drawback.
- The risk of tendinitis appears to be greater with old age, concomitant use of corticosteroid drugs and renal dysfunction.
- The time to onset of inflammation is variable, ranging from a day to several months after the initiation of therapy. In a large proportion of cases tendinitis has developed within a week.
- The reaction has occured at usual therapeutic doses and also at higher doses. Clear dose dependence is yet to be seen.
- Tendinitis has resulted in tendon rupture. Rupture of the Achilles tendon is a serious complication that disables the patient for a long time and often requires hospitalisation.
- Even without rupture, the inflammation may take long to settle, which it eventually does. Treatment is mostly conservative, through bed rest and physiotherapy. A ruptured Achilles tendon may require immobilization in a cast.
- To avoid serious complications it has been recommended that the offending drug should be withdrawn at the first sign of inflammation.

The reported incidence of tendinitis is low compared to the volume of fluoroquinolone usage. However most criteria of causality appear to be fulfilled and the consequences can be serious. Prescribers need to be aware of this possibility. We expect that Indian manufacturers will take cognizance of the fact and voluntarily include a warning in the patient package inserts for the benefit of the users.

Table 1 : Adverse drug reactions and special precautions in the use of fluoroquinolones

- Common reactions : Anorexia, nausea, gastrointestinal upset, headache, dizziness, skin rashes
- Less common and rare reactions : Photosensitivity reaction, serious hypersensitivity reaction like anaphylaxis, central nervous system (CNS) manifestations such as hallucinations, delirium or seizures, asymptomatic rise of blood urea nitrogen, creatinine, and liver enzymes, jaundice, leukopenia, thrombocytopenia and other blood dyscrasias.
- Concomitant use of asprin like drugs may potentiate the CNS stimulant effect of flouroquinolones leading to seizures.
- Flouroquinolones such as ciprofloxacin and enoxacin impair theophylline clearance. Toxicity may appear on concurrent use.
- May potentiate the toxicity of cyclosporin, digoxin and warfarin.
- History of epilepsy, severe hepatic disease or renal insufficiency requires cautions use.
- Flouroquinolones are not recommended for use in children under 15yrs. because of the tendency to produce arthropathy in this age group
- In general their use is not recommended during pregnancy and lactation because they have shown genotoxicity in animals and are excreted in breast milk. Experience of use in these conditions is limited.
- New adverse drug reaction; **Tendintions and tendon rupture.**

PEFLOXACIN

- **CATEGORY :** A fluoroquinolone with broad spectrum of activity.
- **ACTION :** Bactericidal activity against Gram-negative and Gram-positive organisms. Methicillin-sensitive Staph. aureus susceptible. Mycobacteria show moderate susceptibility. Not avctive against anaerobic organisms.
  Action by inhibition of bacterial DNA gyrase and prevention of supercoiling of DNA.
- **PHARMACOKINETICS :** Rapid and complete oral absorption. Time to reach peak levels 1 - 1.5 hours Food slows absorption. Widely distributed into tissues and body fluids. Effective diffusion into CSF. Plasma protein binding 20-30%. Extensively (90%) metabolised and one of the metabolites is norfloxacin. Renal clearance low. Half-life is 6.0 to 13 hours. Liver disease increases plasma levels but renal impairment has no effect.
- **INDICATIONS :** Intraabdominal and gynaecological infections, Bacteraemia, severe systemic infections, gonorrhoea.
- **DOSAGE :** Adults 400 mg 2 or 3 times a day orally or IV. In severe infections a loading dose of 800 mg can be given. Dose reduction in severe liver disease.
- **CONTRAINDICATIONS :** Quinolone hypersensitivity, pregnancy and lactation, children under 15 and G6PD deficiency.
- **ADVERSE REACTIONS :** Usually mild and transient nausea, vomiting, gastric pain, skin reactions, CNS effects, photosensitisation.
- **CAUTION :** In patients with history of epilepsy, CNS damage and severe cerebrovascular disease, liver disease. Hypersensitivity reastions may occur.
- **INTERACTION :** Alterations in theiphylline kinetics, increase in oral anticoagulant effect. Rifampicin reduces and cimetidine increases half-life of pefloxacin. Convulsions may occur when NSAIDs are used concomitantly.
  Food especially milk and yogurt may reduce absorption

Information on a fluoroquinolone in :
CIMS Drug Profiles 1993;2 (4) : 21

References :

1. The Achilles heel of fluoroquinolones. Australion Adverse Drug Reactions Bulletin 1997; 16 (2): 7.
2. Sasich LD, Wolfe SM. Petition by Public Citizen's Health Research Group to US FDA to require a warning on all fluoroquinolone antibiotics. Public Citizen 1996; August 1.
3. Huston KA. Letter : Achilles Tendinitis and tendon rupture due to fluoroquinolone antibiotics. New England Journal of Medicine 1994; 331: 748.
4. Pierfitte C, Gillet P, Royer RJ. Letter : More on fluoroquinolone antibiotics and tendon rupture. New England Journal of Medicine 1995; 332: 193.
5. Szarfman A, Chen M, Blum MD. Letter: More on fluoroquinolone antibiotics and tendon rupture. New England Journal of Medicine 1995; 332: 193.

RATIONAL DRUG BULLETIN

Zinc Supplementation : Side-stepping the Real Problem

Avijit Hazra

Zinc is an essential micrountrient that occurs in all tissues of the body and subserves diverse functions. It is a constituent of various enzyme systems and is essential to normal cellular metabolism, cell division, sexual development, intestinal function, immune function and perhaps also taste and vision.

The average adult human body contains around 3 g zinc but there is no substantial store. A daily dietary supply is therefore essential. Red meat, liver, fish, egg and sea foods are rich in readily absorbable zinc. Plant foods, including cereals, are frugal sources. Moreover the phytates and lignin in vegetable matter impede the absorption of zinc. Phosphates, calcium and copper can also interfere with zinc absorption. Overall only small proportion of dietary zinc is absorbed. Body zinc is 99% intracellular and plasma zinc level averages 100 µg/dl (15 µmol/l). Excretion is mostly in faeces with only traces appearing in urine. The US recommended daily dietary allowance for zinc is 5 mg for infants, 10 mg for children, 15 mg for adult men and 12 mg for adult woman (+ 3 mg during pregnancy; + 7 mg during the first 6 months of lactation and + 4 mg during the next 6 months). The UK reference nutrient intake is somewhat lower at 9.5 mg and 7 mg per day for adult men and woman respectively.

A spectrun of zinc deficiency signs and symptoms have been reported over the past 3 decades. These include anorexia, stunted growth, delayed sexual development, hypogonadism, hypospermia, disorders of keratinization, hair loss, impaired immune function, chronic diarrhoea, impaired wound healing, night blindness and reduced taste sensation. Biochemical abnormalities include reduction of plasma zinc, alkaline phosphatase and testosterone levels; impaired T-cell function and reduced RNA polymerase activity in various tissues. The point to note here is that most of these manifestations are of well established zinc deficiency correlating with significantly lowered plasma zinc levels. Mild deficiency is difficult to diagnose, whether clinically or through laboratory tests.

Certain individuals are at high risk of zinc deficiency :

- Persons with acrodermatitis enteropathica — a genetic disorder in which zinc absorption is grossly reduced.
- Pregnant women on marginal diet, though a clearcut zinc deficiency is yet to be demonstrated during pregnancy.
- Poorly fed infants, particularly at the time of weaning.
- Children with protein-energy malnutrition.
- Children with diarrhoea. A vicious cycle of chronic diarrhoea and zinc loss may be set up since diarrhoea can be both cause and effect of zinc deficiency. Moreover the associated defect in cellular immunity may predispose to diarrhoeal infections.
- Adolescents with the habit of eating soil and dirt (geophagia — an unusual cause of zinc deficiency which can however be very severe).
- Chronic alcoholics.
- Patients on total parenteral nutrition (TPN).
- Patients on long-term penicillamine therapy.

Other chronic infections, strict vegetarianism and old age are regarded as potential risk factors for zinc deficiency.

Zinc supplementation is necessary when a clear-cut zinc deficiency exists. Such supplementation has restored plasma concentrations in children receiving intensive hospital treatment of kwashiorkor. Zinc supplementation may also reduce the intensity and duration of acute diarrhoeal episodes in children. In acrodermatitis enteropathica, large oral doses of zinc (30 - 45 mg/day) may bypass the mucosal absorption block. However excess zinc is not without toxicity. Doses in excess of 200 mg/day are emetic and around 1 g/day may be fatal. It has been recommended that chronic supplementation in excess of 15 mg/day should only be under careful medical supervision. Impairment of copper status has been reported in healthy volunteers receiving modest doses and patients given 150 - 300 mg/day have developed frank hypocupraemia, microcytosis and neutropenia.

The practice of routine zinc supplementation is however bereft of sound therapeutic rationale. Clear-cut zinc deficiency is relatively uncommon. Marginal deficiency is almost impossible to diagnose without plasma level determination, which facility is not readily available in our situation. Although zinc contributes to protective immunity in diarrhoea, it is not recommended for routine treatment or prophylaxis. The precise mode of action and status of zinc are unknown and other trace elements may well contribute to the integrity of a physiological system as complex as the intestinal mucosa. As already mentioned, unequivocal zinc deficiency has not been documented during pregnancy. The risk in the elderly is modest. More studies are needed.

Unfortunately the practice of zinc supplementation has 'caught-on' in India and is tending towards ridiculous proportions, particularly in urban practice. **Table 1** presents zinc preparations currently available in the India market. Some facts immediately become obvious :

1. The sheer number of brands is amazing and the list is far from exhaustive.
2. The zinc content per unit dose varies widely.

Table 1 : Zinc containing formulations in the Indian market

Brand	Zinc content per unit dose		Per unit cost
HIFI SOFTULES	Zinc sulfate (anhydrous)	15 mg / capsule	Rs. 1.20
OSIFORT	Zinc sulfate	20 mg / capsule	Rs. 1.20
NEUROGARD	Zinc sulfate	100 mg / tablet	Rs. 1.21
BECOZINC	Zinc sulfate monohydrate	54.93 mg / capsule	Rs. 1.25
SUPRADYN	Zinc sulfate	2.2 mg / tablet	Rs. 1.29
B-COLEN Z	Elemental zinc	22.5 mg / capsule	Rs. 1.30
Z & B	Zinc sulfate monohydrate ≡ Elemental zinc	15 mg / capsule	Rs. 1.38
FEFOL-Z	Zinc sulfate monohydrate	61.8 mg / capsule	Rs. 1.39
XENEX FORTE	Elemental zinc	20 mg / capsule	Rs. 1.60
ALPROVIT	Zinc sulfate	8 mg / 15 ml	Rs. 2.36
KINETONE LIQUID	Elemental zinc	9.23 mg / 14 ml	Rs. 2.45
BECOZINC SYRUP	Zinc gluconate ≡ Elemental zinc	15 mg / 15 ml	Rs. 2.48
GLOBAC LIQUID	Zinc sulfate	30 mg / 15 ml	Rs. 2.51
AQUAMIN LIQUID	Elemental zinc	1.5 mg / 15 ml	Rs. 2.78
ANTOXID	Zinc sulfate monohydrate	27.45 mg / capsule	Rs. 2.80
HI-FE SYRUP	Zinc sulfate	7 mg / 15 mll	Rs. 2.88
GLOBIRON SYRUP	Zinc sulfate	7 mg / 15 ml	Rs. 2.99
GRD BIX granules	Elemental zinc	22.5 mg / 20 g	Rs. 3.69
RIDAGE	Zinc sulfate monohydrate	27.45 mg / tablet	Rs. 4.00
PRAMILAC power	Elemental zinc	5.6 mg / 15 g	Rs. 4.58
REVITAL	Zinc sulfate	0.5 mg / capsule	Rs. 4.95
SYU GRANULES	Zinc sulfate monohydrate ≡ Elemental zinc	7.5 mg / 15 g	Rs. 4.25
REVITAL LIQUID	Zinc sulfate	0.5 mg / 10 ml	Rs. 5.43
ECOPROT PLUS granules	Elemental zinc	15 mg / 20 g	Rs. 8.30

Data source : Current Index of Medical Specialities (CIMS), Vol 20, No. 2 (May-Aug), 1997

3. Price range is also wide. Tablets and capsules cost the least per unit dose, liquids (other than paediatric drops) are more expensive while granules and powders generally cost the most.

All of these brands are compound formulations containing, in addition to zinc, iron, other minerals,vitamins, amino acids, proteins or other ingredients. Many are intended for anaemia or nutritional supplementation with the zinc component being vigorously promoted as bonus for growing children, expectant or nursing mothers, the elderly and the convalescent. Some are punched together as antioxidants and some as general stress relievers. Curiously there is not one single-ingredient preparation for the prescriber who diagnoses a clear-cut case of zinc deficiency. To provide 20 mg of elemental zinc (a dose considered minimum for supplementation in adults) many of these brands will require more than one unit dose per day. Obviously, if these drugs were used specifically for zinc supplementation, the cost of one day's treatment would cover the cost of 1 egg or 30 g of animal food with most, and 2 eggs or 60 g of animal food with many. Food supplementation might therefore be more rational and more economical than drugs unless a clear-cut zinc deficiency is documented. In the latter case, with few exceptions like TPN or acrodermatitis, short-term supplmentation would probably suffice while the nutritional status is improved.

In the final analysis therefore, the money that is spent on supplemental drugs might be better utilized in improving the nutritional status with food. A determined commitment to fundamentals, effective use of oral rehydration, encouragement of breast feeding, improvement of hygiene and nutrition education comprise a better and more long-lasting solution to the problem of zinc deficiency most of the time and in the majority of patients.

References :

1. Olson RE, Berdanier CD. Microminerals. In : Munson PL, Mueller RA, Breese GR, eds. Principles of Pharmacology : Basic Concepts & Clinical Applications. New York : Chapman & Hall, 1995 : 997-1023.
2. Falchuk KH. Disturbances in trace element metabolism. Isselbacher KJ, Braunwald E, Wilson JD, Martin JB, Fauci AS, Kasper DL. Harrison's Principles of Internal Medicine. 13th ed. Vol 1. New York : McGraw-Hill Inc., 1994 : 481-4.
3. Childhood morbidity, immunity and micronutrients. WHO Drug Information 1996 ; 10 (1) : 12-6
4. Sazawal S, Black R, Bhan M, et al. Zinc supplementation in young children with acute diarrhea in India. New England Journal of Medicine 1995 ; 33 : 869-74

Using drugs in gastritis and peptic ulcer disease

The advent of potent antiulcer drugs has greatly reduced the prevalence and the morbidity from peptic ulcer disease (PUD). Nevertheless, the problem has not disappeared and is likely to stay with us in the foreseeable future. The incidence of gastritis is probably greater than frank endoscopically confirmed ulceration. Both gastritis and PUD may be iatrogenic in origin, resulting from the use of ulcerogenic agents, most notably the non-steroidal anti-inflammatory drugs (NSAIDs). Phenylbutazone, oxyphenbutazone and azapropazone carry the maximum risk, paracetamol and ibuprofen are relatively safe while naproxen, ketoprofen, flurbiprofen, diclofenac, piroxicam and indomethacin pose intermadiate risk. Some of the newer NSAIDs, namely nabumetone and nimesulide, may also be safe in this respect but experience with them is still limited. The following table lists drugs which should be used with extra care or avoided altogether in suspected gastritis or PUD. Some of these drugs are ulcerogenic by themselves, some aggravate existing disease while the anticoagulants and thrombolytics pose the danger of serious bleeding. Corticosteroids can cause silent perforation of ulcers. It should be noted that, apart from drugs, excess of smoking, alcohol and caffeinated beverages may also predispose to ulceration.

Table : Status of drugs in peptic ulcer disease

Contraindicated	To be used with caution
Acipimox	Anticholinesterases e.g. Neostigmine, Pyridostigmine
Amantadine	Betahistine
Anticoagulants, oral e.g. Warfarin	Diethylpropion
Baclofen	Mazindol
Corticosteroids	Methysergide
Dipyridamole	Nicotine, transdermal
Estramustine	Nicotinic acid
Heparin	Phentermine
NSAIDs	Potassium chloride
Reserpine	Probenecid
Thrombolytic agents e.g. Alteplase, Streptokinase	Sulfinpyrazone

Subscription for next issue onwards (eight pages each Bulletin) annually inclusive of postage :
India-
Students : Rs. 30.00 Professionals/Individuals : Rs. 50.00 Institutions and Organisations : Rs. 70.00
Foreign- U.S. $5.00

**PUBLISHED BY : Community Development Medicinal Unit, 47/1B Garcha Road, Calcutta-700 019.
Phone : (033) 474 8553, Fax : (033) 475 5668, Printed at : PRINTMATIX, 71 Elliot Road, Calcutta-16, Ph. : 29 5484**

Community Health Cell

From: jo <jvargnese@cmai.org>
To: "bha" <bha-ncc@yahoogroups.com>
Sent: Monday, April 05, 2004 7:29 PM
Subject: [bha-ncc] Fw: Essential Drug List Karnataka for information

4/12/04

All Karnataka govt hospitals, PHCs to follow ED list submitted by State Pharmacy Council

Wednesday, April 07, 2004 09:00 IST
Our Bureau, Bangalore

Karnataka government has accepted an essential drug list recommend by the State Pharmacy Council. In a major initiative by the State government, all government hospitals and the 2,555 primary health centers have to put into use the essential drug list with immediate effect.

Although the recommendations for the essential drug list was made by the Karnataka Pharmacy Council, a major initiative was taken in this regard by the members of an NGO of medical specialists. Drug Action Forum (DAF), Karnataka

"The implementation of the essential drug list in government medical centers is one of the first steps towards rationalization of drug use. In fact Karnataka is one among the few states along with Delhi, Rajasthan, Haryana and Tamil Nadu to accept essential drug list", Dr. Prakash C Rao, vice president, DAF, Karnataka told pharmabiz.com

"The situation is dangerous and a major cause for concern as combination drugs are mostly a shotgun therapy where in the event of a side effect it would be difficult to pin point which drug is the cause of the reaction. Often ingredients in the combination drug are not recalled by the doctors. There have been several representations made by DAF, Karnataka against the sale of non-essential drugs to the Drugs Controller General of India and former drugs controller Anand Rajashekar on various occasions," informed Dr. Prakash Rao.

The main reasons for increased sales of non-essential drugs are attributed to the nexus between pharmaceutical companies and medical practitioners, poor vigilance of the state drugs control departments and lack of initiative by the government, points out DAF Karnataka.

The World Health Organization (WHO) recommends most of the drugs should be single ingredients except for a few combinations like Trimethoprim +Sulphamethoxazole (Septram or Bactrim). But the reality is that most of the available combinations like EMFLAN Plus which contains Ibuprofen 400mg and Paracetamol 325 mg (both pain killers) are useless and cannot double the effect of pain relief. Such combinations only add to the cost of therapy and increases the side effects, pointed out Dr. Prakash Rao.

Any doctor would be in a better position to combine two different drugs to the patient. Hence available combination drugs now available in the market are useless. Doctors prescribe combination drugs because of aggressive promotion by the pharma sector. There is low therapeutic awareness among doctors who are at the mercy of the drug companies for the details of the drugs and their efficacy, he averred.

DAF Karantaka has a list of some of the harmful combination drugs which include Baxin, Cifran CT (Antibiotics), Atocard D Prosolar (Anti Hypertensive), Corbutyl, Micropyrine, Cofenac, Esgipyrine and Combiflam (Analegesics), Dipsalic, Betnovate N, Zole F and Quadriderm (Dermatology), Spasmindon, Meftal Spas and Collimax (Antispasmodics), Tritacam Plus, Sedyl, Flexidol and Vesperex (Anti psychiatric), Asmapox, Asmatone, Grilinctus Biv, Cadiphyllate Elixer, Sedonal, Teural (Anti respiratory), Digene Gel, Moticare MPS, Logasolid and Helibact (Anti Ulcer).

Dr. Prakash Rao also brought forth the issue of anemia in pregnant women where the most popular drug in single ingredient form is ferrous sulphate and folic acid. However, numerous expensive and ineffective ferrous salts, formulations of iron polymaltose and carbonyl iron are marketed.

Despite the British Pharmacopeia excluding hemoglobin as a drug for human use world wide, in India, it is sold under brand names: Globiron, Hemfast and Heppforte. Hemoglobin in combination of vitamins, minerals and proteins: Fescvit, Heamup, Vitcofol, Iberol, RB Tone, Cherry capsules, Ultiron, Celron, Hepaboglobin, Dumaculos, Hb-Rich, Lysrix, Hifi Softules, Anaemidex, Autrin and Tonoferon are also ineffective, according to DAF.

12/4

To
- RM
- Lib - national drugs file

RM 16/4

DAF, Karnataka warn doctors and patients to exercise restraint over the use of anti cold remedies such as Action 500, Contact CC, Coldguard, Colscold, Coldarin, Escold, Rinostat, Coldoff, Decolgin, Vicks Vaporub, Febrex Plus, Doletus, Colgin Plus, CF Cold, Cimaryl, Actifed, Coldact, Cosavil and Dristran because these contain caffeine and Quinine which cause side effects.

To control the situation, DAF, Karnataka recommends a multi-pronged approach in association with the drugs control department, medical practitioners and consumers where regular and frequent education and awareness programmes are organized in every district. It calls for a strict vigilance by the state drugs control department on the sale of drugs and to increase the number of Adverse Drug Reaction cells in the country. Another suggestion is to include Rational Drug Use as a subject in medical colleges to educate doctors on the dangerous reactions of non-essential drugs.

The healing paradox

There is a need to develop and refine the magic of the physician-patient relationship that complements the precise pharmacologic interventions that may be prescribed.

ABRAHAM VERGHESE

AS a practicing physician, I confess that I learn about the latest medical breakthroughs while reading my morning paper. When my office mail eventually brings me the original study, my pleasure in the journal's pristine cover and untouched pages has been diminished because the tidings arrived before the messenger. But here is why I cannot complain: the science reported in my newspaper is genuinely newsworthy, deserving its place alongside matters of state and economy. For example, two weeks ago we learned of a promising approach to the prevention of cervical cancer – a vaccine against one type of papilloma virus that is an antecedent to this malignancy. Imagine that. A vaccine for cancer! On the same day as that announcement came the first report of a vaccine that might prevent genital herpes. And then there's the ongoing news of the unravelling of the human genome in all its amazing complexity. History will draw a line here: Before Genome and After Genome. The Rosetta stone has been found and applied to the sacred scroll, and it promises important breakfast reading for years to come.

But my morning paper, laden with science, also carries evidence of our distrust of science and our search for another kind of healing. You've seen it: a full-page advertisement for a product that you know is too good to be true. The text has large type, a before-and-after picture, no listing of the contents of the product and a blizzard of endorsements from "scientists" and "patients" that take the place of data. These products are life extenders, fat fighters, growth-hormone releasers, relievers of limb pains, rebuilders of muscle and bone and sometimes all of the above together. I think of them as quark drugs, phantoms that if they could be studied in careful trials would soon lose the "r" for a "c" and be revealed for what they are.

But the market for such remedies is huge. Indeed, estimates are that nearly half of all adult Americans use some sort of dietary supplement, and the sales of these products in 2000 amounted to more than $15 billion! I plead guilty: echinacea and ginkgo have made appearances in my medicine cabinet, as I reached for magic for some ailment or other. I had no guidance, no data of the sort a scientist should accept, no package insert. I tried them on faith. Alas, they did nothing.

The good news is that many such treatments are being systematically and carefully studied through the aegis of the National Institutes of Health; what we know thus far is that few products live up to their claims, many have the potential for toxicity and the quality control on this stuff is awful. Here is the bad news: 70 per cent of us would take these products anyway, even if they were shown to be no better than snake oil. Even as science measurably changes our life and extends our life spans, as a society we are suspicious of science.

I am not a crusader against alternative medicines or its practitioners. I am all for things that make us feel better and that don't hurt us. But I do wonder at the paradox of even the most rational of us being drawn to these bottles with pictures of ugly tubers and weed-like plants on them. Why do we become dreamy-eyed hearing the songs of the New Age pied pipers whose melodies interweave quantum physics and the workings of the colon in beautiful but completely fictional ways? Like revivalist preachers, they invite our faith, our willingness to search for magic in ancient, undecipherable Oriental practices (as opposed to the new, quite decipherable, Western practices). In return they offer nostrums, tonics, tapes, books, diets, retreats, mantras, votive candles and cruises; they bring colour, fragrance and incense to an illness experience that otherwise plays out in black and white.

In this golden age of science, disease and treatment have become demystified. If you went to a doctor clutching your stomach in days of old, the doctor, after a good bit of probing and hemming and hawing, would retreat to the dispensary and with great ceremony compound a *mistura carminativa*, vividly coloured in a medicinal bottle. Short of surgery or an autopsy, no one would be precisely certain what you had. But come clutching your stomach to a medical doctor these days, and after a careful history and exam, the doctor can "see" your gallbladder, measure the distress of your pancreas, examine the lining of your colon and much, much more if need be and then institute the precise cure.

Therein lies the rub: we are perhaps in search of something more than a cure – call it healing. If you were robbed one day, and if by the next day the robber was caught and all your goods returned to you, you would only feel partly restored; you would be "cured" but not "healed"; your sense of psychic violation would remain. Similarly with illness, a cure is good, but we want the healing as well. we want the magic that good physicians provide with their personality, their empathy and their reassurance. Perhaps these were qualities that existed in abundance in the pre-penicillin days when there was little else to do. But in these days of gene therapy, increasing specialisation, managed care and major time constraints, there is a tendency to focus on the illness, the cure, the magic of saving a life.

Science needs to be more cognisant of the other magic, the healing if you will, even as we reach for the proven cures. We need to develop and refine that magic of the physician-patient relationship that complements the precise pharmacologic interventions we may prescribe: we need to ensure the wholeness of our encounter with patients; we need to not lose sight of the word "caring" in our care of the patient. And doggedly, in this fashion, one patient at a time, we can restore faith in the fantastic advances of science we are privileged to witness. ■

Abraham Verghese is a professor of medicine and director of the Centre for Medical Humanities and Ethics at the University of Texas Health Science Centre, San Antonio. His latest book is The Tennis Partner.

New York Times Service

Collective instincts

New studies suggest that many animals practise democracy, going by their propensity to make group rather than individual decisions.

JAMES GORMAN

WHEN red deer stand up and honeybees dance, they are not simply stretching their legs or indicating where the nectar is, according to a new study. As bizarre as it may seem, they are voting on whether to move to greener pastures or richer flowers. The process is unconscious, the researchers say. No deer counts votes or checks ballots; bees do not know the difference between a dimple and a chad. But no one deer or bee or buffalo decides when the group moves. If democracy means that actions are taken based not on a ruler's preference, but the preferences of a majority, then animals have democracy.

Not surprisingly, decisions based on majority preferences tend to fit in with what most individuals in the group want. But, the researchers say, this is not a mere tautology. An analysis based on some hefty mathematical models that they developed shows that democracy in groups of animals can have a tangible survival edge over despotism.

Dr. Tim Roper of the University of Sussex in Brighton, United Kingdom, did the research with Dr. Larissa Conradt and reported it in the current issue of *Nature*.

"There are human cases of decision-making to which our model would be relevant," Roper said, like "small groups making rather simple decisions." But the question – how the decision gets made – is the same. And although human groups, and individual animals, have been well studied, little attention has been paid to decision-making by groups of animals.

Dr. Thomas D. Seeley of Cornell, whose research on bees was cited in the paper, said that most of the study on animal decision-making had been at the individual level, and although there seemed to be groups that decided, *en masse*, to act, "there's really been no theory about why you would expect the decision-making to be democratic, or distributed." Seeley said that the paper was "a good first step" that could lead to other research.

Conradt and Roper did their research in two parts. First they reviewed earlier research to determine whether various group decisions were being directed by one individual or seemed to come from the group as a whole. For example, observations of group behaviour showed that red deer moved when more than 60 per cent of adults stood up – that is, voted with their feet. In African buffalo, he said, adult females made the decisions, voting with the direction of their gaze. Whooper swans voted with head movements. They would move when a large number made low-intensity movements, or when a smaller number made high-intensity movements.

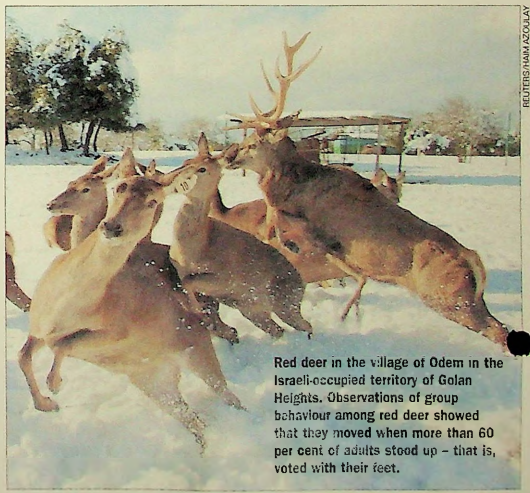
Somehow, unconsciously, the animals sense when enough of them get the urge to go. It is certainly a decision by a majority, but what to call it is another question.

The more complicated aspect of the research involved mathematical models that Conradt and Roper developed to analyse the benefits to animal groups, of different ways of decision-making that they described as democratic or despotic. In essence the models compared costs to individuals in the event of not getting to do things when they wanted to. Having to wait or hurry up was considered a cost, and the presumption was that for animals as for people, time is money or food or something important to survival.

These are abstract models, and not ways to process the previous research. And what they show is that when majorities decide, more individuals get what they want, and that should translate into better survival. There could, of course, be situations with incredibly smart or sensitive despots that maximise the benefit to the group, but Conradt and Roper did not come up with them. Roper said the research was meant to suggest a new way of looking at decision-making and a new area for research. The models apply only to animals that make group decisions.

It may be that some animals, like domestic cats, for instance, do not vote, do not care to vote and have no interest in any sort of group activity. They were not, however, a subject of the paper. Roper and Conradt modelled democracy and despotism. They did not consider anarchy. ■

New York Times Service



REUTERS/HAMZA AZOULAY

Red deer in the village of Odem in the Israeli-occupied territory of Golan Heights. Observations of group behaviour among red deer showed that they moved when more than 60 per cent of adults stood up – that is, voted with their feet.

D12-2.

World Trade Organization finally agrees cheap drugs deal

Fiona Fleck *Geneva*

A long awaited trade deal to give poor nations access to cheap lifesaving drugs for diseases such as AIDS, malaria, and tuberculosis was agreed on 30 August after eight months of stalling—which was mainly due to US objections.

Negotiators from the 146 member nations of the World Trade Organization (WTO) who hammered out the deal hailed it as a major breakthrough.

"All people of good will and good conscience will be very happy today with the decision that the WTO members have made," said Amina Chawahir Mohamed, Kenya's ambassador to the Geneva based body. "It's especially good news for the people of Africa, who desperately need access to affordable medicine."

Some aid organisations criticised the deal. Médecins Sans Frontières said it "threw up new legal, economic, and political obstacles" to poor countries wanting to import cheap generic copies of patented drugs and that it was "designed to offer comfort to the US and the Western pharmaceutical industry."

Until now, under a WTO system known as the compulsory licence, patents for lifesaving drugs could be waived only for countries that could produce cheap generic drugs themselves.

The deal is a breakthrough because trade rules have now been altered to allow poor countries—most of which do not have their own drugs industry—to issue a compulsory licence to a third country, such as India or Brazil, to produce cheap generic drugs and to import these to address a public health crisis.

WTO member nations had originally agreed to give poor countries better access to cheap drugs at the WTO ministerial meeting in Doha, Qatar, in November 2001 (*BMJ* 2001 ;323: 1146[Free Full Text]). But because of difficult negotiations in trying to balance humanitarian concerns and business interests, the deal has only just been concluded in time for trade ministers to give it their blessing at their next biennial meeting, on 10-14 September in Cancun, Mexico.

The breakthrough agreement came after a plea from African nations in the form of a joint statement to negotiators saying that nearly 2.2 million Africans had died from AIDS and other major diseases since talks became deadlocked on 16 December.

African vote.

"For us, the request by the African countries was a decisive factor. All of us couldn't fail to be touched by that," said Luis Felipe de Seixas Correa, Brazil's ambassador to the WTO.

Washington had opposed the original deal hammered out in December, fearing that cheap drugs intended for poor countries could be diverted back to developing countries and undermine the drugs industry, even though most countries agree that such a scenario is unlikely.

But trade negotiators addressed US concerns with a statement saying that rules allowing countries to override patents "should be used in good faith to protect public health... [and] not be an instrument to pursue industrial or commercial policy objectives."

The statement also calls for special measures to prevent drugs being smuggled into rich countries, including special packaging or differently coloured tablets.

.....

186, 217

Drugs could still be costly under World Trade Organization deal

Fiona Fleck

Geneva

A landmark deal that allows poor countries without any manufacturing capability of their own to waive international trade rules and import cheap copies of patented drugs is likey to be a complex procedure that may not reduce prices enough, experts say.

UN secretary general Kofi Annan issued a statement to the World Trade Organization meeting in Cancun, Mexico, last week, after the deal was clinched in Geneva, saying that it was a "moral imperative" for each of the organisation's 146 member countries to implement the agreement without delay.

Although the organisation's meeting in Cancun ended in disarray when members could not agree on the reduction of subsidies to farmers in the developed world and representatives of African countries walked out, the agreement regarding cheaper drugs for developing countries was unaffected.

Campaigners for cheaper drugs welcomed the fact that the agreement had been reached (6 September, p 517) and that it applied to all drugs but warned that the new procedure could be time consuming and bureaucratic and that the drugs may still be too expensive.

Dr Jonathan Quick, director of essential drugs and medicines at the World Health Organization in Geneva, said the deal was only part of the solution to the problem of getting affordable drugs to the people that need them, such as people with AIDS and HIV in the poorest African countries. Other issues included distribution and a lack of qualified staff.

"Now we have the deal. It's the start we have and we're looking ahead," Dr Quick said. He added: "The point is to implement it, monitor it, see if it works, and adjust it if it doesn't."

Campaigners fear that poor countries in Africa, Asia, and Latin America that could benefit from the deal may have to go through unnecessary red tape to prove that they have no manufacturing capability of their own.

blocks in acquiring.

Also, generic drug manufacturers fear that they may get tangled up in red tape, which could be a disincentive to manufacture the drugs and could slow down the process. Campaigners say it is unrealistic to require manufacturers to declare that they are producing drugs for humanitarian not business purposes, but they hope that this requirement will be treated as a formality.

blocks in producing.

Campaigners also fear that rules on making the drugs' packaging distinctive, so that cheap copies of patented drugs cannot be mistaken for the originals and diverted to developed countries, could push up costs.

However, even when these problems have been dealt with the price of the drugs might be too high for some of the world's poorest countries.

"It is now imperative for countries to put the agreement to the test by taking full advantage of all the flexibilities contained in the agreement to increase access to medicines for their populations," the charity Médecins Sans Frontières, which has lobbied hard for better access to drugs, said in a statement.

test case.

For example, small African countries could group together and place a joint order with a manufacturer of generic drugs to make it a viable business proposition for the company.

D12-2.

BMJ 2003;327 (20 September)

Editor's choice

A bad week for drug companies?

The United States is hugely important for drug companies. The pharmaceutical market is worth more than $150bn, and annual spending has been rising by almost 20% a year (p 642). Prices are not regulated in the way they are in many other countries, and companies are allowed to advertise directly to consumers—so boosting consumption. But now the cost of drugs has become an important political issue, and a bill has been introduced into Congress that would require government agencies to gather evidence "comparing effectiveness [and] cost effectiveness" of the most commonly prescribed drugs "relative to other drugs or treatments for the same disease."

Bill in US Congress.

The bill aims to reduce costs, but it could also improve quality. The proposal is to conduct many more head to head trials of common treatments—trials like the ALLHAT (antihypertensive and lipid lowering to prevent heart attack trial), which showed that diuretics are just as good as much more expensive drugs for treating hypertension. The whole world stands to benefit from such trials.

The industry is lobbying against the bill, but its problems are much deeper than congressional irritations. Companies are failing to produce enough new drugs, and the investment bank Dresdner Kleinwort Wasserstein thinks that the industry is operating a business model that is unsustainable (*Guardian* 12 September 2003). Companies have on average been producing three "new molecular entities" a year, but the bank predicts this will decrease to 0.3 per company. The industry has been increasing sales by 12%-15% for 30 years, with half of the increase coming from raised prices. Now globalisation and political endeavours are making such price increases impossible.

Industry's response.

The answer, the bank suggests, is further mergers —only mergers with a difference. Companies should now concentrate on particular therapeutic areas—cardiovascular, cancer, etc. This could give them "dominance" (which sounds like a polite word for a monopoly) in those areas. The result could be just a handful of companies.

The bill before Congress stops short of proposing that a drug would have to be shown to be better than other drugs before being given a licence. Europe doesn't require such a demonstration either, but the National Institute for Clinical Excellence (NICE) in England and Wales looks for evidence that a treatment is appreciably better than what is already available before advocating its use in the NHS, which is most of the market in Britain. NICE has just been independently evaluated by the World Health Organization, and an important recommendation is that it "break its close links with the drug industry and make its processes more transparent" (p 637). The institute has set new standards of transparency, but drug companies have insisted on some of their material being confidential. The material should be made publicly available.

UK practice

Richard Smith, *editor*

BMJ 2003;327:642 (20 September)

News

US politicians want federal funding to discover cost effectiveness of new drugs

Ray Moynihan

Washington, DC

A bill before the US Congress calls on health authorities to investigate whether expensive new drugs offer value for money, by comparing their risks and benefits with other treatments and older drugs.

new bill
HR 2356

Currently new drugs are approved on the basis of their superiority over a placebo, with no requirement to show an advantage over existing treatments or cheaper generic pills.

If passed, the new legislation would see US taxpayers spending $75m (£47m; €67m) in 2004 to fund studies of the cost effectiveness of the nation's most expensive classes of drugs—something done routinely in other countries but a move that is bitterly opposed by the drug industry in the United States.

Annual spending on prescription drugs is rising by almost 20% a year in the United States, where it is now in excess of $150bn. The cost of drugs is one of the fastest growing components of overall healthcare costs, which are also rapidly rising and becoming a key political issue in the race for the White House.

A group of Democrat and Republican politicians introduced the latest bill into the House of Representatives in June. Specifically the bill requires that the federally funded National Institutes of Health and the Agency for Healthcare Quality and Research gather scientific evidence "comparing effectiveness, cost-effectiveness, and, where appropriate, comparative safety" of the costliest and most commonly used prescription drugs "relative to other drugs or treatments for the same disease or condition."

The bill, known as HR 2356, does not call for a change in the way new drugs are approved by the Food and Drug Administration, but it does demand more information on whether a new drug is worth its price once it is on the market, particularly when compared with other available treatments.

One of the bill's sponsors, Jo Ann Emerson, a Missouri Republican, said that the studies would provide basic information to doctors and their patients about which drugs were best for them. The results could also be used to inform decisions on coverage by private and public insurers, including Medicare, which provides health care to people aged over 65. "I believe we have to do everything possible to use the principles of market competition to get prices of drugs down. This is one way to do that," Ms Emerson said.

2440, Rayburn House Office Building. Washington, DC 20515

Jeff Trewhitt, a spokesman for the industry group Pharmaceutical Research and Manufacturers of America, said the studies being proposed in the new bill were highly subjective and that people "advocating cost effectiveness studies are often advocates of spending less." When asked about the industry's lobbying efforts to undermine the bill, he said, "We are watching it."

Ms Emerson, who has sponsored other bills to reduce drug costs, said that although the industry was quietly lobbying to kill her latest bill there was a good chance that some version of the plan for cost

effectiveness studies would be passed by both the House of Representatives and the Senate and be sent to the president for approval later this year.

Australia has had laws for almost a decade requiring studies of the cost effectiveness of any new drug by comparing it with existing treatments before the drug can be listed on the publicly funded pharmaceutical benefits scheme.

Australia.

Australia's system, which has been the target of sustained attack by elements within the drugs industry, has become something of a global model for how to obtain value for money in prescription drugs. Compared with other countries Australia pays a low price for "me too" drugs while paying closer to the average for truly innovative drugs, and across all categories of drug it pays less than half the price paid in the United States.

In the United Kingdom the National Institute for Clinical Excellence now regularly bases its decisions regarding new drugs on evidence based evaluation of their effectiveness and cost effectiveness, comparing their costs, risks, and benefits with other treatments. An example is the recent guidance on glitazones for type 2 diabetes, which used cost effectiveness analysis to recommend against using the expensive new drugs as a second line treatment in combination with metformin or a sulphonylurea, except in certain restricted circumstances.

UK.

In British Columbia similar evidence based comparisons underpin the reference pricing programme used to price some classes of prescription drugs. In this programme several drugs in a class are compared: if they are essentially similar the subsidy offered to the public is based on the cheapest price in the class, and consumers pay for any difference if their doctor chooses a dearer drug.

British Columbia.

Like the systems in Australia and the United Kingdom and the proposed plan in the United States, British Columbia's programme has been heavily attacked by the drug industry.

The studies used in the Canadian programme are provided by an organisation based at the University of British Columbia called the Therapeutics Initiative, and its managing director, Dr Jim Wright, says that what is really needed is "head to head" trials that compare different drugs, rather than studies that simply compare a drug with a placebo.

supporting the US planned Bill

Like other experts around the world, Dr Wright argues that such head to head studies should be mandatory after a new drug has been approved. "It's essential to know the benefits and harms of newer therapies, compared to the best available existing treatment," he said, giving as a good example a recent trial, the antihypertensive and lipid lowering to prevent heart attack trial (ALLHAT) of different antihypertensive drugs (*JAMA* 2002; 288: 2981-97[Abstract/Free Full Text]). Recent analysis of ALLHAT results indicate that the United States could save more than $430m a year if doctors favoured the older and cheaper thiazide drugs.

Example.

Mr Trewhitt said that ALLHAT had already been contradicted by a subsequent trial and that head to head studies would slow down the delivery of drugs to new patients.

NICE is told to break its close links with drug industry

Zosia Kmietowicz

London

The National Institute for Clinical Excellence (NICE) has been advised by an independent review to break its close links with the drug industry and to make its processes more transparent.

Experts from the World Health Organization who carried out the review have advised NICE that, to avoid any possible bias, pharmaceutical physicians should not be members of committees that make judgments on particular drugs or devices.

problem

Kees de Joncheere, regional adviser for health technology and pharmaceuticals at WHO, said that although he understood that pharmaceutical physicians could offer useful input about how and why trials were conducted, a physician from one company on a committee that is appraising another company's product cannot always be independent. Instead manufacturers' views should be represented through the consultation process, he said.

alternative

Moreover, if it wished to be truly transparent NICE needed to examine whether it could continue to include confidential materials in its appraisals process, said the review.

"We recognise that NICE has set new standards in the consideration of stakeholder inputs and transparency, including provision of documents and information, via the NICE website. However, to gain access to key information NICE also accepts material designated as confidential. In the main this comes from the pharmaceutical industry," said Mr de Joncheere.

"Whilst we welcome the steps they have taken to push these boundaries with the industry, NICE should reconcile this inherent contradiction," he said.

NICE, which has been recommending drugs and devices to the NHS in England and Wales since 1999, invited WHO to conduct an independent review of its work after advice from the House of Commons Health Select Committee last year.

Recent

Altogether the review team made 28 recommendations on all aspects of how NICE is run, from its defining principles to its selection of topics and appeals process.

Michael Rawlins, NICE's chairman, said the findings from the WHO team would feed into a review of methods and appraisals currently being conducted by the institute. The board was also considering making three key documents that were currently kept confidential open to the public, he said. These are the overview of each drug or device appraised, comments received on draft overviews, and the contents of appeals.

However, disclosing confidential materials from drug companies might be more difficult, as it might jeopardise any future publication, he said.

The WHO report, *Technology Appraisal Programme of the National Institute for Clinical Excellence*, is accessible at www.nice.org.uk

Prescription Drug Comparative Effectiveness Act of 2003 (Introduced in House) US

HR 2356 IH

108th CONGRESS
1st Session
H. R. 2356

To require the National Institutes of Health to conduct research, and the Agency for Healthcare Research and Quality to conduct studies, on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of expenditures or use by individuals in federally funded health programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

June 5, 2003

Mr. ALLEN (for himself, Mrs. EMERSON, Mr. BERRY, Mr. BEREUTER, Mr. WAXMAN, Mr. BURTON of Indiana, Mr. DAVIS of Florida, Mr. GUTKNECHT, Mr. SNYDER, Mrs. BONO, Mr. COOPER, and Mr. WAMP) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To require the National Institutes of Health to conduct research, and the Agency for Healthcare Research and Quality to conduct studies, on the comparative effectiveness and cost-effectiveness of prescription drugs that account for high levels of expenditures or use by individuals in federally funded health programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Prescription Drug Comparative Effectiveness Act of 2003'.

SEC. 2. NIH RESEARCH AND AHRQ STUDY ON EFFECTIVENESS OF CERTAIN PRESCRIPTION DRUGS.

(a) IN GENERAL-

(1) RESEARCH BY NIH- The Director of the National Institutes of Health, in coordination with the Director of the Agency for Healthcare Research and Quality, shall conduct research, which may include clinical research, to develop valid scientific evidence regarding the comparative effectiveness, cost-effectiveness, and, where appropriate, comparative safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition.

(2) ANALYSIS BY AHRQ-

(A) IN GENERAL- The Director of the Agency for Healthcare Research and Quality, taking into consideration the research of the National Institutes of Health under this section, shall use evidence-based practice centers to conduct studies or other analyses of the comparative effectiveness, cost-effectiveness, and, where appropriate, comparative

safety of covered prescription drugs relative to other drugs and treatments for the same disease or condition.

(B) SAFETY- In any analysis of comparative effectiveness or cost-effectiveness under this subparagraph, the Director of the Agency for Healthcare Research and Quality shall include a discussion of available information on relative safety.

(3) STANDARDS- The Director of the Agency for Healthcare Research and Quality, in consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, and stakeholders, shall develop standards for the design and conduct of cost-effectiveness studies under this subsection.

(b) COVERED PRESCRIPTION DRUGS- For purposes of this section, the term 'covered prescription drugs' means prescription drugs that, as determined by the Director of the Agency for Healthcare Research and Quality in consultation with the Administrator of the Centers for Medicare & Medicaid Services, account for high levels of expenditures or use by individuals in federally funded health programs, including Medicare and Medicaid.

(c) ANNUAL REPORT- Each year the Director of the Agency for Healthcare Research and Quality shall prepare a report on the results of the research, studies, and analyses conducted by the National Institutes of Health and the Agency for Healthcare Research and Quality under this section and submit the report to the following:

(1) The Congress.
(2) The Secretary of Defense.
(3) The Secretary of Health and Human Services.
(4) The Secretary of Veterans Affairs.
(5) The Administrator of the Centers for Medicare & Medicaid Services.
(6) The Director of the Indian Health Service.
(7) The Director of the National Institutes of Health.
(8) The Director of the Office of Personnel Management.

(d) REPORTS FOR PRACTITIONERS- As soon as possible, but not later than a year after the completion of any study pursuant to subsection (a)(2), the Director of the Agency for Healthcare Research and Quality shall--

(1) prepare a report on the results of such study for the purpose of informing health care practitioners; and
(2) transmit the report to the Director of the National Institutes of Health.

(e) NIH INTERNET SITE- The Director of the National Institutes of Health shall publish on the Institutes' Internet site, and through other means that will facilitate access by practitioners, each report prepared under subsection (c) or (d) by the Director of the Agency for Healthcare Research and Quality.

(f) EVIDENCE- In carrying out this section, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality shall consider only methodologically sound studies, giving preference to studies for which the Directors have access to sufficient underlying data and analysis to address any significant concerns about methodology or the reliability of data.

(g) AUTHORIZATIONS OF APPROPRIATIONS-

(1) NIH- There are authorized to be appropriated to the National Institutes of Health to carry out this section $50,000,000 for fiscal year 2004, and such sums as may be necessary for fiscal years thereafter.

(2) AHRQ- There are authorized to be appropriated to the Agency for Healthcare Research and Quality to carry out this section $25,000,000 for fiscal year 2004, and such sums as may be necessary for fiscal years thereafter.

DR-2.

SYNOPSIS

1. Petitioners are leading non-profit NGOs working in the field of public health.

2. They noticed SLP (C) No 3668/2003 filed by Union of India against the order of the Karnataka High Court restraining the U.O.I. from giving effect to the Pharmaceutical Policy (PP) 2002 on the grounds that from the list of 74 drugs found in the 1995 price control order some are likely to be omitted when the fresh list is prepared in accordance with the PP 2002.

3. They also noticed SLPs (c) 6652 of 2003 and 6638/2003 filed by the Indian Drug Manufacturers Association and the Organisation of Pharmaceuticals Producers of India respectively seeking to impugn the High Court order. Permission has been granted to file the SLPs and notice has been issued.

4. All these petitions proceed on the erroneous footing that the DPCO order of 1995 is sacrosanct, not informing the Hon'ble court that both the World Health Organisation and the Union of India have in 2003 released their lists of Essential Medicines (Annexures P1 and P2).

5. WHO Guidelines for National Drug Policies, the National Health Policy 2002 and the Union of India Pharmaceutical Policy 2002 have the aim of ensuring the availability of essential medicines at affordable prices to the population, and in particular, to the poor.

6. It is the petitioners' case that this entire list of essential medicines ought to be under price control for reasons set out in the petition. Unfortunately a vast range of essential drugs is just not available at affordable prices and rampant profiteering exists.

7. There is a public health crisis in India. India accounts for 30% of the world's TB cases, has the second highest of HIV infected cases, one third of the world's leprosy cases, 19 crore illness episodes of diarrhea per year in the under-five population (which cause one third of the mortality of under-fives), and a steep rise in non-communicable diseases like diabetes, hypertension, heart disease and cancer. Hypertension and diabetes affected people in India together account for more than 6 crores, larger than the population of many European nations. Medical expenses is the second largest cause of rural indebtedness. India has one of the lowest rates in the world for access to affordable essential drugs.

8. This crisis was recognized in the National Health Policy 2002 document which noted that "the availability of essential drugs is minimal, the public health services dysfunctional, the supply of drugs grossly inadequate, and patients purchase drugs privately."

9. Public health investment declined from 1.3% of GDP in 1990 to 0.9% (1999). India's public expenditure on health is one of the lowest in the world.

10. On the other hand the country has been flooded with over 60,000 drugs and formulations by 20,000 manufacturers. Most developed countries have a much smaller list of approved drugs and formulations. The WHO Model List of Essential Medicines 2003 contains only 325 drugs, which are considered adequate to meet the priority health care needs of populations.

11. Petitioners share the concern of the citizens of India regarding widespread sales of spurious, substandard and drugs beyond expiry date and point out the uncontrolled number of formulations add to the complexity of the problem and urgent action in this area is required.

12. The fault lies in the fact that it is not the Ministry of Health and Family Welfare but the Ministry of Chemicals and Fertilisers, which has from the Drug Price Control Order (1979 to 1987 to 1995) reduced the number of drugs under DPCO from 347 to 142 to 76 respectively. This has adversely affected access to safe, affordable and essential drugs for the public and has had grave economic and health consequences for the poor.

13. Petitioners have pointed out that for many public health problems the drugs required though in the essential list of medicines are not under price control.

14. Petitioners have pointed out that no criteria of scientific pharmacology has been used in deciding drugs for drugs in price control in the DPCO 1995 – many of which are non-essential, outdated, and even hazardous.

15. That essential drugs such as oral dehydration solution (for diarrhea), drugs for anemia (which is a major public health problem especially in women in children), vaccines for important infectious diseases like rabies, hepatitis B, drugs for HIV disease non-communicable diseases like heart disease, cancer, are not in the DPCO list of 1995. That the drugs for TB, malaria, leprosy, hypertension are poorly represented in the DPCO list of 1995.

16. Even drugs under price control have flouted the orders and have widely varying prices.

17. Elsewhere, and specifically, Canada has had its Patented Medicines Prices Review Board, France has its Transparency Commission and Economic Committee on Medicines, Egypt has all drugs under price control, Italy has restricted wholesale margins, Germany has its reference pricing system, and some system of price monitoring and price regulation prevails in Japan, Netherlands, China, Indonesia, Colombia and so on. In some of these countries drug pricing is tied with national health system reimbursements and or insurance schemes. In the absence of either in India, the havoc on the majority of the population can well be imagined. Petitioners have pointed out that establishment of National Drug Authority as envisaged by the Hathi Committee and later reiterated by the 1986 and 1994 policies is imperative.

18. The government in its previous policy documents has accepted the responsibility of keeping a check on the price of all drugs and formulations. However in reality apart from the list of price-controlled drugs, there is virtually no control over the price of other drugs and formulations. Even in the case of price controlled drugs which number only 76, violations of price control occur. We urge the court to take cognizance of the marked variation in the prices of the drugs both under price control and outside it, which clearly points to profiteering at the cost of people, and direct the authorities to take action.

19. The Indian pharmaceutical market with over 20,000 producers, 100,000 formulations, a poorly developed quality control infrastructure and an ineffective and apathetic drug regulatory system is virtually unregulated in many of its activities.

20. The pharmaceutical sector being a critical sector dealing with the lives of people needs regulation not only in pricing, but also in the area of rationality, safety, efficacy and quality of the products it manufactures.

21. It is therefore, important that this Hon'ble Court direct the government to control the

manufacture of irrational drugs and formulations, which form a majority of the formulations. These waste the meagre resources of a poor population.

22. The pharmaceutical sector needs stricter regulation with regard to drug quality, availability of hazardous drugs and banned drugs.

23. Petitioners have pointed out that there is a good case for abolishing all excise duties, sales tax and other local taxes in manufacture and sale of essential drugs.

Dates

1975 Hathi Committee releases its report with a list of 116 essential drugs.

1977 WHO releases its Model List of Essential Drugs

1978 Alma-Ata Charter on Comprehensive Primary Health Care of which access to Essential Drugs was one of the eight components of Primary Health Care – declaration signed by 134 Governments including India.

1979 The Drug Price Control Order (DPCO) list of drugs under price control contains 347 drugs.

1987 The DPCO list is pruned to 142 drugs by the Ministry of Chemicals and Fertilisers.

1995 The DPCO list is further pruned to 76 drugs.

1996 The U.O.I releases the first National Essential Drugs List.

2002 The Ministry of Chemicals and Fertilisers releases the Pharmaceutical Policy 2002 document.

12.11.02 Karnataka High Court makes an order in W.P. 21618 of 2002 staying the pharmaceutical policy 2002.

2003 WHO releases its " WHO Model List of Essential Medicines 2003"

2003 U.O.I. releases its "National List of Essential Medicines 2003".

10.3.03 SLP(C) 3668/2003 is filed by U.O.I. impugning the order of the Karnataka High Court dated 12.11.02. Notice is issued.

1.8.03 SLPs 6652/2003 and 6638/2003 are filed by the Indian Drug Manufacturers Association and the Organisation of Pharmaceutical Producers of India respectively. Permission is granted to file SLPs. Notice is issued.

1.9.03 The present writ petition is filed.

WHO/EDM/QSM/99.4

Medical products and the Internet

A guide to finding reliable information

World Health Organization
Geneva 1999

WHO/EDM/QSM/99.4
Original: English
Distribution: General

Medical products and the Internet

A guide to finding reliable information

Regulatory Support Series, No. 8

World Health Organization
Geneva 1999

Introduction

The Fifty-first World Health Assembly (Resolution WHA51.9, May 1998) requested the Director-General of WHO to develop a guide on medical products and the Internet. The guide was intended to serve as a model for Member States to adapt into locally meaningful advice for Internet users in order to help them to obtain reliable, independent and comparable information on medicinal products. The guide in this booklet has been prepared to meet the Health Assembly request. It has been developed in consultation with drug regulatory authorities, drug information experts, consumer organizations, and the pharmaceutical industry. It is a model guide, designed to be translated into national languages and modified as the local situation may require.

WHO would be grateful to receive any comments on experience gained from the practical use of the guide which would help in developing it further. Contact information appears below.

***Department of Essential Drugs and Other Medicines* (EDM)**
World Health Organization
1211 Geneva 27, Switzerland
email: reggiv@who.ch

Finally, national health authorities - such as drug regulatory agencies - and WHO are working together to address the illegal advertising and sale of medical products through the Internet. It is important that Internet users report suspected illegal activities and problem cases to their national health authorities.

Summary of key points

- **If used properly, the Internet allows quick and easy access to health information.** It provides useful information on such topics as diseases, conditions, therapies, medical products, and health and medical organizations and institutions (see Point 1).

- The information you obtain from the Internet can be helpful when you consult your doctor or other health care provider about your disease or condition. But the **guidance from the Internet should not replace consultation with your health care provider** (see Point 2).

- Although it is often difficult to determine, you still need to **verify the source of information** available on the Internet (see Point 2).

- Information that sounds too good to be true, in particular, requires verification and careful assessment (see Point 3).

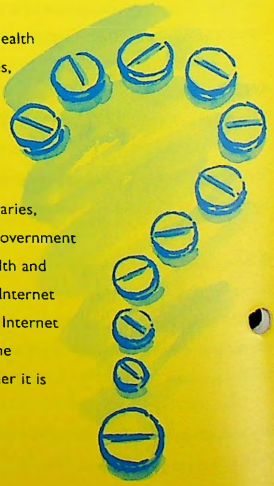
- Be cautious about buying medical products via the Internet. In many countries, selling or buying medical products via the Internet may at present be an illegal activity. **You are strongly advised to obtain your medical products through legitimate distribution channels** such as pharmacies (see Point 4).

- **Consult your doctor** or other health care professional before you decide to treat yourself (see Point 5).

POINT 1

The Internet is a valuable source of information, but be sure you know and trust the source

The Internet is a valuable source of health information on topics such as diseases, conditions, therapies, medical products, and health and medical organizations. When used properly, it allows quick and easy access to such information from on-line medical libraries, universities, health associations and government agencies. However, the quality of health and medical product information on the Internet varies, and it is often difficult for the Internet user to identify the true source of the information and to determine whether it is reliable, complete and up to date.



POINT 2

Finding reliable health and medical information on the Internet

Reliable sources of health and medical information are available on the Internet. This information can be helpful when you consult your health care provider about your disease or condition, though it should not replace such consultation (see Point V). As you search for and evaluate information, however, keep these considerations in mind:

It may be difficult to determine the source of the information you find on a site and to verify that source. If you are not familiar with the source of information, you may be able to find out more about it from health care professionals or reliable organizations with which you are familiar. Your own reliable sources may be able to give you help to evaluate the reliability and quality of the web site information.

Looking at a web site? Check the following:

- **Is there clear indication of the name and contact address of the web site owner?**
- **Is it clear which organization(s) contribute funding, services, or other support to the web site?**
- **If advertising or sponsorship is a source of funding, is this clearly stated?**
- **Is this a site for consumers, health professionals, or some other audience?**
- **When was the information displayed last updated?**

There are many health and medical sites on the Internet which do provide good information that may not be easily available from other media. They may be designed for health professionals or for consumers. However, even information from reliable sources may require special training in order to evaluate it properly and to determine whether the information applies to your disease or condition. The information provided by these web sites covers such topics as:

- Research being conducted on a particular disease or a condition - including rare diseases - and related clinical trials;
- New product approvals by health authorities in your country for a specific disease or condition;
- General information about diseases or conditions, such as high blood pressure, arthritis or obesity;
- Support groups for people with certain diseases and conditions, such as HIV/AIDS or cancer;
- Lists of international, national and local organizations that provide support and information for a disease or condition.

Health authorities and organizations in each country can provide a list of sites with links to reliable sources of health and medical information. Additionally, several private organizations are actively searching for ways to ensure the quality of information on the Internet. Internet users may be interested in following or participating in these discussions and reading what others have to say on this topic. The following box lists two examples of organizations that are conducting such activities. National authorities should identify and list additional organizations and reliable web sites known to them.

***Health on the Net Foundation*: http:\\www.hon.ch**

***Internet Healthcare Coalition*: http:\\www.ihc.net**

POINT 3

Finding reliable medical product information on the Internet

The Internet also offers information on medical products. As you search for and evaluate product information, however, keep these considerations in mind:

- If information sounds too good to be true, it probably is. The following lists some warning signs that medical product information may not be truthful:
- Advertisements or information that use phrases such as *"scientific breakthrough"*, *"miraculous cure"*, *"exclusive product"*, *"secret formula"*, *"ancient ingredient"*, *"without risk"*, *"anti-ageing"*, *"improve sexual performance"*, and *"all natural"*
- Case histories from "cured" customers claiming amazing results. When you see a testimonial, ask for proof of its "typical" nature;
- A list of symptoms and diseases it is claimed the product cures - for example, claims that one product can cure or treat HIV/AIDS, cancer, arthritis, Alzheimer's disease, wrinkles, weight problems, memory loss, and so on
- Advertisements that tout the latest trendy ingredient in the news headlines
- Claims that the product is available from only one source, for a limited time
- Testimonials from "famous" medical experts
- Claims of "no risk" or lack of any risk information - remember: no product or treatment is completely risk-free
- Claims that a product is "scientifically proven" and "absolutely safe"

- Products with the same name may contain different ingredients in different countries. Therefore, when searching for information you should look at the International Nonproprietary Name (INN) of the active ingredients and not just the product name (brand name, trade name).

- Product information should be as complete as possible, and it should include at least the elements outlined in the following box:

Looking at product information?
A reliable web site will provide the following information:

- product name
- active ingredient(s)
- name of other ingredients known to cause problems to some people
- what to use the product for
- when not to use the product (for example, in pregnancy, allergies, interations with other medicines or foods)
- how to use the product
- possible undesired effects
- how to store the product
- manufacturer's name and contact information
- last update of the information

POINT 4

Be cautious about buying medical products on the Internet

Medical products are often offered for sale on the Internet. Offering for sale and selling medical products or buying medical products from another country via the Internet may be illegal. Therefore, before buying a product, you should find out if it is legal to do so. If you are considering buying medical products through the Internet, be cautious, because you may risk your health and waste your money. Consult your health care professional before self-treatment.

There are many reasons why medical products bought through the Internet could represent a danger to you, or at the least cause inconvenience or loss of money. Ten of these reasons are discussed here.

1 **Safety and efficacy assurance may be lacking** – In many countries, before medical products are approved, licensed or authorized for sale the companies that develop and market them must conduct research and demonstrate to a drug regulatory authority that the products are safe, effective and of good quality for human use. Although these authorized medical products may be available through the Internet, there may also be products for sale that have not been studied and evaluated according to the laws and regulations of your country. There is no assurance of safety and effectiveness for such unauthorized products. As an Internet user, you may find it difficult to distinguish between products that have met the requirements of your government and those that have not.

Information about medical products being developed and tested in humans is available on the Internet. If you have a disease or condition for which there is currently no treatment or cure, you may have searched for information about your disease or condition and read about these new products on the Internet. Although new products are often not available for prescription, sometimes a health care professional may prescribe a medication for you before approval, or discuss enrolling you in a clinical trial to study the product. It is important to understand that there may be additional risks to using such a product before approval, because the possible adverse effects (which may be serious or life-threatening) and the effectiveness and proper dosage schedule may not be known. In some cases, a prescription product may be unavailable in your country but approved for use in another. In such a case, your country may have special legal procedures allowing you to import prescribed medicines from abroad. This could be done with the help of your health care professional, through legitimate distribution channels.

2 **Instructions for use may be inadequate** – To be used properly and safely, medical products need to be accompanied by precise instructions. There is no assurance that a product obtained via the Internet will have the correct instructions for use, dosage and precautions. In

8 **Products bought across borders may not be allowed in your country** – Countries have different laws about what medical products can be sold and shipped across national borders. This means that it is possible that products that are not approved for marketing in your country or products that have been identified as a hazard to public health may not be allowed into your country if they are identified at entry. If you have already paid for the product, you may not be able to receive it or have its cost reimbursed. In addition, the prescription status of medical products varies from country to country. For instance, products that are available only on prescription in one country may be sold without prescription, or may even be unregulated, in another.

9 **Products with the same name may be different in different countries** – Internet users need to be aware that products with the same name may contain different ingredients in different countries. Therefore, you may be taking the wrong product. In addition, countries may have different standards for the quality of medical products and their manufacture. Products purchased across borders might not be exactly the same product or quality as in your own country.

10 **Your personal information may not remain confidential** – Many web sites require you to disclose personal medical data. Users must be aware that there is no assurance that this information will be kept confidential. Users who feel uncomfortable with the potential use of their personal data should purchase their medical products through conventional, legitimate distribution channels.

POINT 5

See your health care professional before you decide to treat yourself or change your medication

Even after finding reliable, truthful health or medical information on the Internet, it is important to go to your health care provider to discuss your disease or condition and the information you have found before you take steps to treat yourself. This is important for several reasons:

- Not all diseases and symptoms need medical treatment. You may be taking medicines or using medical products unnecessarily and exposing yourself to an unnecessary risk
- Many medications or other medical products may cause harm if they are used improperly. It is important to be under the care of a health care professional when using such products

Appropriate medication or appropriate medical treatment for your disease or symptoms is important to your health. Not every medication is appropriate for everyone. For example, some individuals may be allergic to certain medications.

A health care professional can help you to determine the best medicine or treatment for your disease or condition.

● A health care professional can provide guidance on how best to take your medication safely. For example, the effectiveness of some medications may be influenced by other products, such as other medications, alcohol or certain foods. Mixing your medication with these other products could strengthen or weaken the effect of the medication or cause an adverse reaction. This could be dangerous to your health or, at the very least, interfere with your timely recovery ● Patients with particular characteristics , such as pregnant or breast-feeding women, the elderly and children, have special concerns, needs and considerations when taking medication or using medical products. In particular, a number of medications are specifically known to cause harm to unborn children. Pregnant women should therefore be sure to consult a health care professional before self-treatment ● Any time you take medication or use a medical product it is important to inform your health care professional of any side-effects you may experience when using the product. By going through your health care professional for treatment, you can make sure that he or she will be better prepared to advise you or change the treatment if you do have an adverse reaction to a product ● By ordering medical products through the Internet you may deprive yourself of the opportunity for personal, professional care and advice from your doctor, pharmacist or other health care professional.

Other titles in the Regulatory Support Series:

- **Report of a Training Workshop for Drug Regulatory Officials on the Assessment of Applications for Marketing Authorizations.** Nicosia, 14-18 December 1997 (WHO/DMP/RGS/98.1)
- **How to Implement Computer-assisted Drug Registration.** (WHO/DMP/RGS/98.2)
- **SIAMED: Model System for Computer-assisted Drug Registration.** User manual. (WHO/DMP/RGS/98.3)
- **QCL: Model System for Handling Sample Information in a Quality Control Laboratory.** User manual. (WHO/DMP/RGS/98.4)
- **Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A Manual for a Drug Regulatory Authority.** (WHO/DMP/RGS/98.5)
- **Practical Guide to the Use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in the International Commerce.** (WHO/DMP/RGS/98.6) *in preparation*
- **SIAMED: Model System for Computer-assisted Drug Registration. Introduction and Brief Description of Functions and Facilities.** (WHO/DMP/RGS/98.7)

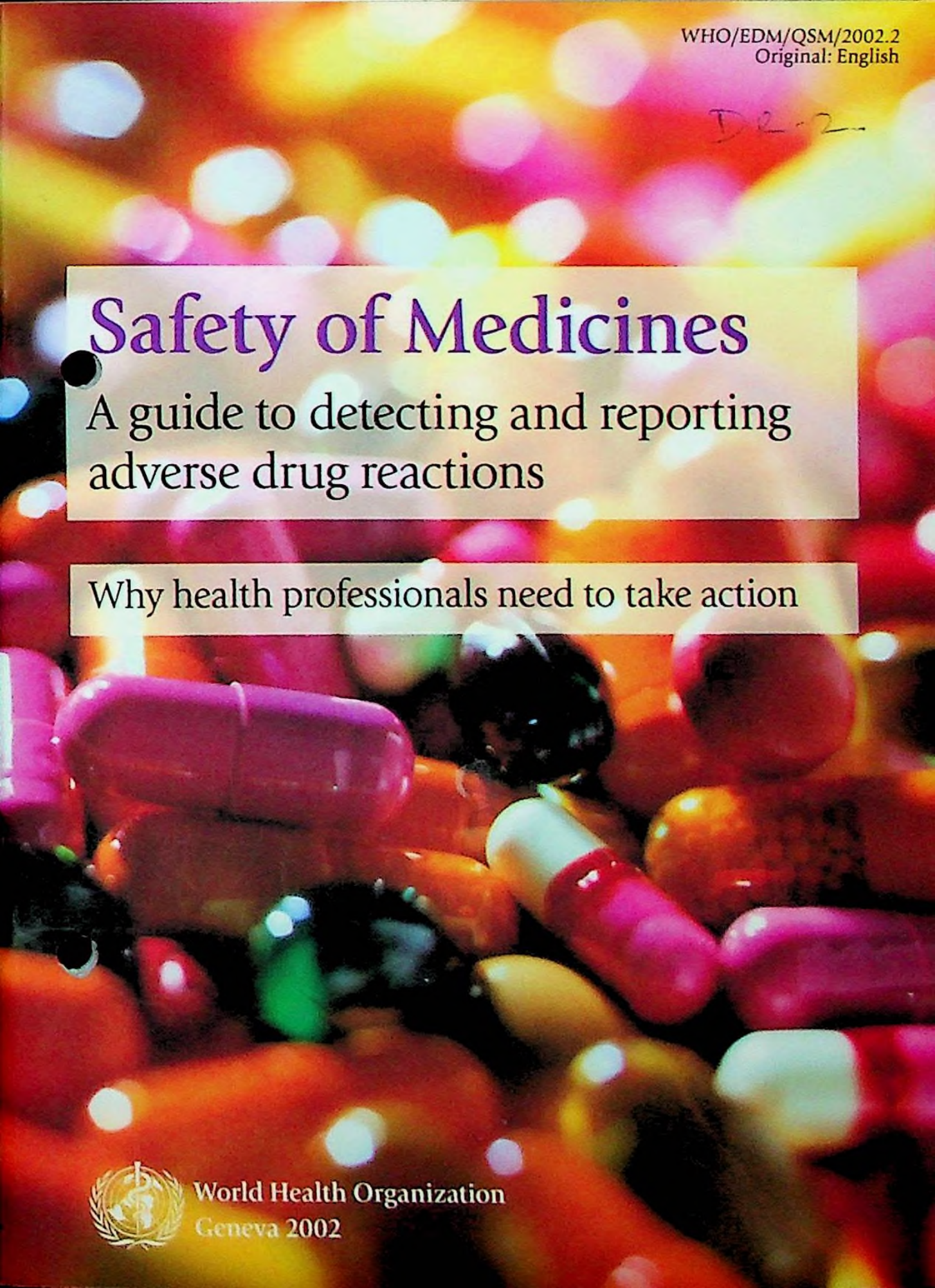
WHO/EDM/QSM/2002.2
Original: English

D2-2

Safety of Medicines

A guide to detecting and reporting adverse drug reactions

Why health professionals need to take action



World Health Organization
Geneva 2002

Safety of Medicines

A guide to detecting and reporting adverse drug reactions

Why health professionals need to take action

World Health Organization
Geneva 2002

Introduction

The purpose of this Guide is to help health professionals to participate in the very important process of continuous surveillance of safety and efficacy of the pharmaceutical products which are used in their clinical practice. Continuous evaluation of their benefit and harm will help to achieve the ultimate goal to make safer and more effective treatment available to patients.

The objectives of the Guide are to raise awareness of the magnitude of the drug safety problem and to convince health professionals that reporting of adverse reactions is their moral and professional obligation.

The ultimate goal of the Guide is to reduce drug morbidity and drug mortality by early detection of drug safety problems in patients and improving selection and rational use of drugs by health professionals.

It is a model guide which can be translated into national languages and modified as the local situation may require.

WHO would be grateful to receive any comments on experience gained from the practical use of the Guide which would help in developing it further. Please contact the Department of Essential Drugs and Medicines Policy (EDM) with your comments:

Dr Mary Couper
Department of Essential Drugs and Medicines Policy (EDM)
World Health Organization
1211 Geneva 27, Switzerland
email : couperm@who.int fax : + 41 22 791 4761

Glossary

The terms are from "Safety Monitoring of Medicinal Products"[1]

1. An *adverse drug reaction (ADR)* is 'a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man'.

   In this description it is of importance that it concerns the response of a patient, in which individual factors may play an important role, and that the phenomenon is noxious (an unexpected therapeutic response, for example, may be a side effect but not an adverse reaction).

2. An *unexpected adverse reaction* is 'an adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorisation, or expected from characteristics of the drug'.

3. A *drug* or *medicine* is 'a pharmaceutical product, used in or on the human body for the prevention, diagnosis or treatment of disease, or for the modification of physiological function'.

4. A *side effect* is 'any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug'.

   Essential elements in this definition are the pharmacological nature of the effect, that the phenomenon is unintended, and that there is no deliberate overdose.

5. An *adverse event* or *experience* is defined as 'any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment'.

   The basic point here is the coincidence in time without any suspicion of a causal relationship.

6. A *serious adverse event* is any event that:
   - ❖ Is fatal
   - ❖ Is life-threatening
   - ❖ Is permanently/significantly disabling
   - ❖ Requires or prolongs hospitalization
   - ❖ Causes a congenital anomaly
   - ❖ Requires intervention to prevent permanent impairment or damage
7. A *signal* refers to 'reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously'.

   Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information.

The magnitude of the problem

During the last decades it has been demonstrated by a number of studies that medicine morbidity and mortality is one of the major health problems which is beginning to be recognized by health professionals and the public. It has been estimated that such adverse drug reactions (ADRs) are the 4th to 6th largest cause for mortality in the USA,[2]. They result in the death of several thousands of patients each year, and many more suffer from ADRs. The percentage of hospital admissions due to adverse drug reactions in some countries is about or more than 10% [3],[4],[5].

Norway	11.5%
France	13.0%
UK	16.0%

In addition suitable services to treat ADRs impose a high financial burden on health care due to the hospital care of patients with drug related problems. Some countries spend up to 15-20% of their hospital budget dealing with drug complications[6].

Beside ADRs, medicine-related problems include also – drug abuse, misuse, poisoning, therapeutic failure and medication errors.

There is very limited information available on ADRs in developing countries and countries in transition. However, one may expect that the situation is worse rather than better. This problem is also caused by a lack, in some countries, of legislation and proper drug regulations, including ADR reporting, a large number of substandard and counterfeit products circulating in their markets, a lack of independent information and the irrational use of drugs.

Why postmarketing surveillance and reporting ADR is needed

The information collected during the pre-marketing phase of drug development is inevitably incomplete with regard to possible ADRs. This is mainly because :

- Tests in animals are insufficient to predict human safety;
- Patients used in clinical trials are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited;
- By the time of licensing exposure of less than 5000 human subjects to a drug allows only the more common ADR to be detected;
- At least 30,000 people need to be treated with a drug to be sure that you do not miss at least one patient with an ADR which has an incidence of 1 in 10,000 exposed individuals[7];
- Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available;

Thus, post-marketing surveillance is important to permit detection of less common, but sometimes very serious ADRs.

Therefore health professionals worldwide should report on ADRs as it can save lives of their patients and others.

Why pharmacovigilance is needed in every country

There are differences among countries (and even regions within countries) in the occurrence of ADRs and other drug-related problems. This may be due to differences in e.g.:

- diseases and prescribing practices;
- genetics, diet, traditions of the people;
- drug manufacturing processes used which influence pharmaceutical quality and composition;
- drug distribution and use including indications, dose and availability;
- the use of traditional and complementary drugs (e.g. herbal remedies) which may pose specific toxicological problems, when used alone or in combination with other drugs.

Data derived from within the country or region may have greater relevance and educational value and may encourage national regulatory decision-making. Information obtained in one country (e.g. the country of origin of the drug) may not be relevant to other parts of the world, where circumstances may differ.

Therefore, drug monitoring is of tremendous value as a tool for detecting ADRs and specifically in relation to counterfeit and substandard quality products. ADR monitoring is to help ensure that patients obtain safe and efficacious products.

The results of ADR monitoring have also a very important educational value.

How voluntary reporting on ADRs can prevent new medicine tragedies from developing

It took many decades before the deleterious effects of aspirin on the gastro-intestinal tract became apparent and almost as long before it was recognised that the protracted abuse of phenacetin could produce renal papillary necrosis; 35 years elapsed before it became clear that amydopyrine could cause agranulocytosis; and several years before the association of phocomelia with thalidomide became obvious[8].

Withdrawals from the market as a result of spontaneous reporting

INN (brand name)	Reason for withdrawal	Year of marketing	Year of withdrawal
bromfenac (Duract ®)	serious hepatotoxic effect	1997	1998
encainide (Enkaid ®)	excessive mortality	1987	1991
flosequinan (Manoplax ®)	excessive mortality	1992	1993
temafloxacin (Omniflox ®)	haemolytic anemia	1992	1992
benoxaprofen (Oraflex ®)	liver necrosis	1982	1982
mibefradil (Posicor ®)	multiple drug interaction	1997	1998
terfenadine (Seldane ®)	fatal cardiac arrythmias	1985	1998

After the "thalidomide tragedy" many countries have established drug monitoring systems for early detection and prevention of possible drug-related morbidity and mortality. Their success depends on the cooperation of the medical profession in reporting suspected ADRs, especially to new drugs.

Some examples demonstrate how very astute, alert and observant medical doctors have been helped to prevent the development of drug morbidity and drug mortality by reporting on suspected ADRs which resulted in the withdrawal of dangerous drugs from the market or in restriction of their use.

How voluntary reporting on ADRs can influence labelling

There are many examples of the importance of ADRs reporting in the improvement of information in labelling of many effective pharmaceutical products (new possible ADRs, contraindications, dosage etc.).

Cyclophosphamide has been on the market for several years in many countries. In January 2001 there were some new reactions included in the labels: Stevens Johnson syndrome and toxic epidermal necrolysis; they were not included in the Physician Desk Reference (PDR) 1995.

For example:

EPIDERMAL NECROLYSIS

ERYTHEMA MULTIFORME

STEVENS JOHNSON SYNDROME

Losartan was marketed in the USA since 1995. Some of the new reactions that have been discovered after launch and included in the PDR are:

VASCULITIS

PURPURA ALLERGIC

(incl. HENOCH-SCHOENLEIN PURPURA)

ANAPHYLACTIC SHOCK

ANAPHYLACTOID REACTION

Levofloxacin was launched in the USA in 1997. In February 2000 the label torsade de pointes was included.

Why health professionals are in the best position to detect and report on ADRs

The effectiveness of a national postmarketing surveillance programme is directly dependent on the active participation of health professionals. Health professionals are in the best position to report on suspected ADRs observed in their every day patient care.

All healthcare providers (physicians, pharmacists, nurses, dentists and others) should report ADRs as part of their professional responsibility, even if they are doubtful about the precise relationship with the given medication.

You can reduce the suffering and save thousands of patients lives by doing one thing:

Report suspected adverse drug reactions.

How to recognize ADRs

Since ADRs may act through the same physiological and pathological pathways as different diseases, they are difficult and sometimes impossible to distinguish. However, the following step-wise approach may be helpful in assessing possible drug-related ADRs:

1. Ensure that the medicine ordered is the medicine received and actually taken by the patient at the dose advised;
2. Verify that the onset of the suspected ADR was after the drug was taken, not before and discuss carefully the observation made by the patient;
3. Determine the time interval between the beginning of drug treatment and the onset of the event;
4. Evaluate the suspected ADR after discontinuing the drugs or reducing the dose and monitor the patient's status. If appropriate, restart the drug treatment and monitor recurrence of any adverse events.
5. Analyse the alternative causes (other than the drug) that could on their own have caused the reaction;
6. Use relevant up-to-date literature and personal experience as a health professional on drugs and their ADRs and verify if there are previous conclusive reports on this reaction. The National Pharmacovigilance Centre and Drug Information Centres are very important resources for obtaining information on ADR. The manufacturer of the drug can also be a resource to consult;
7. Report any suspected ADR to the person nominated for ADR reporting in the hospital or directly to the National ADR Centre.

What should be reported?

- For "new" drugs - report all suspected reactions, including minor ones. (In many countries drugs are still considered "new" up to five years after marketing authorization);
- For established or well-known drugs - report all serious or unexpected (unusual) suspected ADRs;
- Report if an increased frequency of a given reaction is observed;
- Report all suspected ADRs associated with drug-drug, drug-food or drug-food supplements (including herbal and complementary products) interactions;
- Report ADRs in special fields of interest such as drug abuse and drug use in pregnancy and during lactation;
- Report when suspected ADRs are associated with drug withdrawals;
- Report ADRs occurring from overdose or medication error;
- Report when there is a lack of efficacy or when suspected pharmaceutical defects are observed.

Thus, report all suspected adverse reactions that you consider of clinical importance as soon as possible!

References

1. Safety Monitoring of Medicinal Products. Guidelines for setting up and running a Pharmacovigilance Centre. Uppsala Monitoring Centre - WHO Collaborating Centre for International Drug Monitoring, EQUUS, London, 2000.
2. Lazarou J. et al., 1998. Incidence of ADR in hospitalized patients: a meta-analysis of prospective studies. JAMA, 1998, 279 (15) 1000-5.
3. Moore N et al. Frequency and cost of serious adverse drug reactions in a department of general medicine. Br J Clin Pharmacol 1998, 45(3), 301-308.
4. Imbs JL et al. Latrogenic medication: estimation of its prevalence in French public hospitals. Thérapie, 1999, 54(1) 21-27.
5. Griffin GP. The evaluation of human medicines control from a national to an international perspective. Ad Drug React Toxico Rev., 1998, 17(1), 19-50.
6. White T et al. Counting the cost of drug-related adverse events. Pharmacoeconomics, 1999, 15(5). 445-458.
7. Strom BL. Pharmacoepidemiology. 2nd ed. Chichester: John Wiley, 1994.
8. Venulet J. The Drug Monitoring Programme. In: Drug Surveillance, Geneva 1994, 13-21.

Useful Websites

WHO

www.who.int/medicines/

Section: Quality Assurance and Safety: Medicines

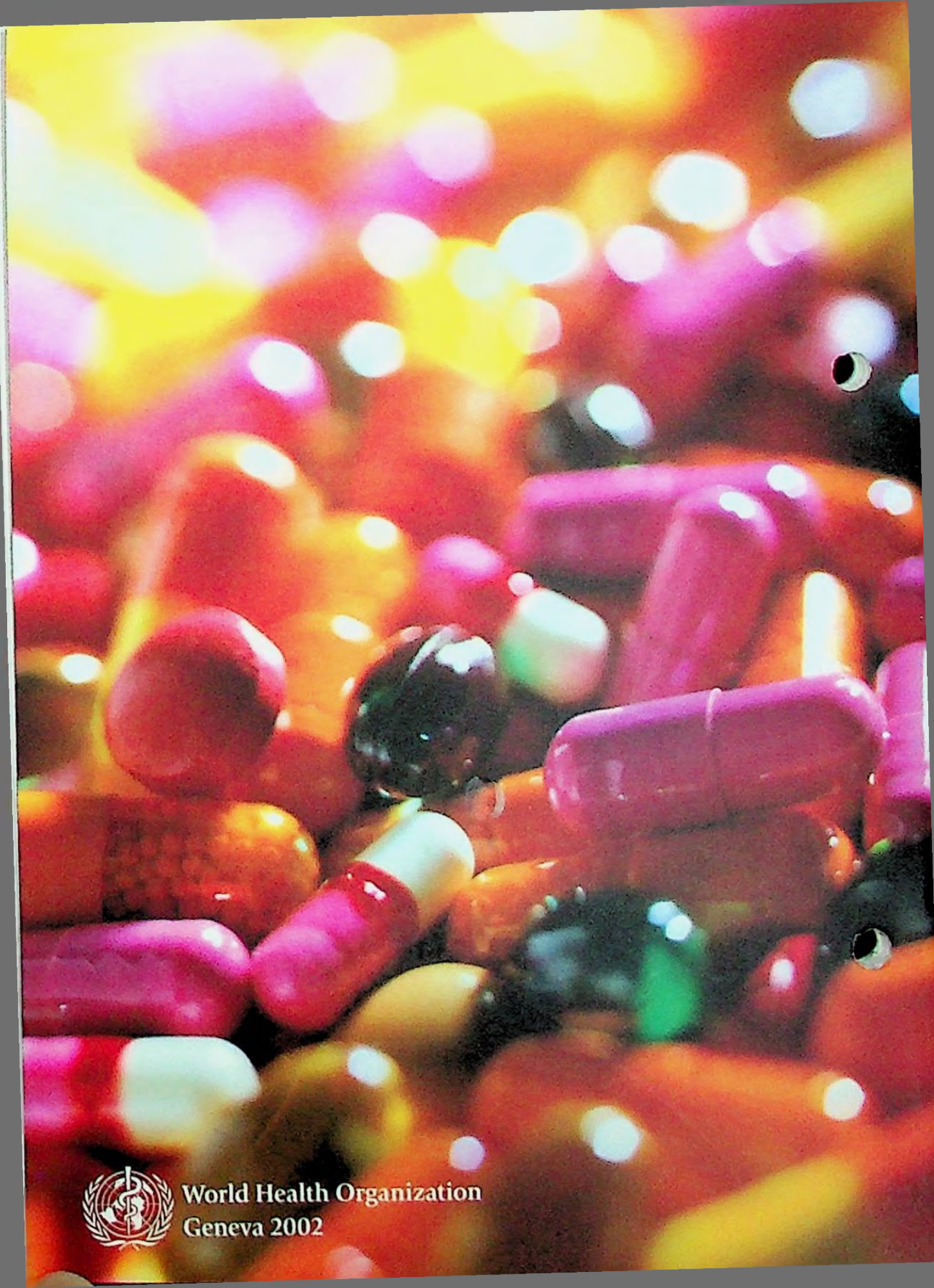
WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre)

www.who-umc.org

Acknowledgements

The document was prepared by Dr V.K. Lepakhin, Senior Clinical Adviser, Essential Drugs and Medicines Policy, WHO. The kind assistance and contributions are acknowledged from Dr M. Couper, Dr M. Everard, and Dr L. Rägo, WHO, Geneva, Switzerland; Professor R.H. Karim Al-Saudi, Jordan University of Science & Technology, Jordan; Ms Niamh Arthur, Irish Medicines Board, Dublin, Ireland; Dr A. Astakhova, Federal ADR Centre, Moscow, Russia; Dr I.R. Edwards & Dr S. Olsson, WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden; Dr Kenneth Hartigan-Go, Bureau of Food & Drugs, Department of Health, Manila, Philippines; Dr P. Honig, Center for Drug Evaulation and Research, FDA, USA; Dr N.A. Kshirsagar, King Edward VII Memorial Hospital, Bombay, India; Professor Dr R. Meyboom, LAREB Foundation, Netherlands; Professor Sang Guo-Wei, State Drug Administration, Beijing, China; Dr R. Santos, European Agency for Evaulation of Medical Products, UK; Dr Rachida Soulaymani-Bencheikh, Institut National d'Hygiène, Rabat, Morocco.

Coordination of document: Caroline Mullen, QSM, WHO
Design: Marilyn Langfeld



World Health Organization
Geneva 2002