PEOPLE IN THE DRUG ACTION

(Paper to be presented at TRICHY WORK SHOP on Drug Problems)

DR. V. BRAHMA REDDY

Currently we are dealing with a sensitive subject of drugs which are intended to save the lives, cure the illness and prevent the disease. In the historical perspective. they indeed played an important positive role in the arena of health. But this never undermines the crucial role of immunity and the role of food, water, sanitation, education and employment to butress the immunity directly or indirectly. This immunity continues through ages to be the uanguard to attain health and prevent and combat disease.

YET:

Drugs is one of the factors in the much bigger problem of health. But the miracles drugs did in the 1930's and 40s' have lead to the emphoria in the people that " there is a Pill for every ill " and thus a fertile ground has been created for the indiscriminate use of drugs whether needed or not. There are diseases that won't need drug treatment like cold, mild irritative cough, weakness after heavy work etc., were also profusely garlanded by drugs. This state of mind of the people was conveniently exploited by the agency which has substantial benefit in the form of profit by way of Marketing drugs. That agency is drug companies. There are Drug Multi-Nationals, Indian Monopoly Drug Houses, Indian Small Scale, Medium scale, Private Drug Industry and Indian Public Sector Drug Industry. Because of their gagantic economic structure and advanced promotional leverage, the multi-national Drug Industry has always got a lion share in the drug sales.

Here again, when we speak about the role of Drugs in the field of health, there are four agencies that come to interact with one another. They are the Government, the drug Companies, the Doctors and the people. We have got the right to request all the four agencies to stand for the rational attitude in the drug situation. But will they oblige us? or not? If so why?

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THE GOVERNMENT:

Let us first approach the Government and request:

After a heated discussion in the Parliament in the early 70s' about the role of drug Multinational the Government appointed a Parliamentary Committee by name Hathi Committee in 1974. The Committee submitted its report in April, 1975 with recommendations like nationalisation of drug multinationals, till then the equity to be brought down immediately to 40 % and later on to 26 % formation of National drug and therapeutics authority (NDTA) to monitor the drug issues, abolistion of brand names etc.,

That report was kept in attic safely by the G.O.I. Having known about the recommendations, the drug multinationals purchased all the copies of Hathi Committee report and destroyed outright... What the people talked about in those days. Now the Report is available only with a handfull of individuals and in a few public libraries. Has the G.O.I. a semblence of responsibility to reprint the report and make it available to the Public? Can I expect this?

In 1978, a new drug policy was announced in the Parliament by the then Central Government with the Hathi Recommendations in a much diluted and distorted form. Thus Hathi Committee Report defacto died long before Mr. Jaisukhlal Hathi. The G.O.I. is an active witness for this episode.

Now to frame the New Drug Policy N.D.P.D.C. has appointed a steering Commitee and the working groups. The Chairman for the Steering Committee is Mr. Mahendra Prasad, M.P., who has substantial interests in Aristo Pharmaceuticals, a drug firm. The Managing Directors of HOECHST, and E.MERCK drug multinationals are there in the Committee.

When the G.O.I. was asked to include other relevant people in the Steering Committee, so that it can attain proper representative character for credibility, the Minister State for Petroleum and Petro Chemicals retorts that Doctors are not experts, Medical Representatives are not experts, Druggists, Chemists are not experts, Pharmaceutical Employees are not experts, Scientists

are not experts, voluntarily organisations that are doing commendable work in the Drugs issue are not experts to advise the G.O.I. on New Drug Policy. So who are the experts then? Mr. Mahendra Prasad, Managing Directors of E. MERCK and HOECHST.

Inspite of the resistance by a lot of organisations and individuals, though some of them felt that their efforts stalled the G.O.I. to introduce the New Drug Policy, the G.O.I. proved its utter callousness on 18.12.1986 by announcing New Drug Policy in Press Conference, just after 7 days of Adjournment of Parliament. Thus not giving a chance even to Parliament members to discuss on this issue. This New Drug Policy was described by National Dailies as " Bonanza to the Drug Industry " and " Christmas Gift to Drug Companies". It contains liberal pricing, liberal imports, liberal licensing, in nutshell. Will this Govt. head to Public Openion?

The Drug Companies got stay orders on Brand name abolition issue, Banned Drug issue like EP Forte and drug prices issue etc. To cite an example, HOECHST was selling Baralgan Ketone at Rs.23,735/- per Kg in India. Somehow, the G.O.I. got sufficient information that it costs only Rs.1810/- per Kg and asked the HOECHST to reduce the Price. The Company agreed to reduce the Price to Rs.2000/- per Kg. (Thus accepting directly that it is over-pricing 12 times its cost) As the GOI insisted upon its figure, the companies went to the Court and cited its Fundamental right of Business and got stay order and enjoying Baralgan at a Cost of Rs.23,735/- per Kg. The legitemised right of the Company to cheat the people was not vacated by the Peoples' Government. Thus the Govt. by itself is not coming forward to safe guard the people in the drug issues. Instead steadfast doing things contrary to the Principle of working for the people. Even the requests of the aggreived agencies and the people are not cared for. This does not mean that we should abandon our principled fight against the GOI to make it oblige to the broader Public Interest.

THE DRUG COMPANIES:

After the arnaments industry, it is the drug industry that can fetch enormous profits. Hence the Drug Companies concentrate their might to make people purchase this Commodity called drugs.

In no other country 60,000 formulations of drugs are available in the Market, most of them are rather unnecessary, some even dangerous. Out of roughly Rs.2000/- Crores worth drugs sold here, nearly 500 crore worth drugs are seriously engaged in enriching the drains rather than the human bodies. The Drug Companies are not worried over this.

The Companies in USA have got the capacity to make President to sign two bills recently. " Drugs which are found harmful in American Citizens may well be permitted to export to Foreign Countries" " Drugs which are not tested hitherto in human-beings may also be permitted to export to third world countries" using the poor underdeveloped as the Guinesa pigs.

Even a powerful country like USA is Passing on strictures to Japanese goods to safeguard its companies-but the GOI is generous enough to import whatever non-sense drug availabile in the International Market under liberal imports? The drug companies are not interested here to scrape the Brand names because they get undue leverage in the market hold. Thus an asprin tablet of 3 ps. cost can be sold at 0.22ps, 25ps even 65ps. in different brand names. A Paracetamol tablet of 5ps cost can be sold at 22ps., 25ps. in different brand names. Even the companies misuse loan licensing to get their products manufactured by Smaller Companies. All this to sustain the " Brand Cult"

To create Brand Cult, they are using profusely the promotional techniques even spending to the tune of 20-23% of their total sales turnover on promotion alone. It is better to speak less about offering Fritzes, T.Vs., Scooters, Cars etc., to gullible doctors to get their products prescribed. Equally well it is true they are never handicapped by conscience in bribing top people in the Governments to manipulate bulk state orders.

Currently, the Multinational lobby in drug industry is actively pressing the GOI to join Paris Convention of drug patents to prevent Indian Companies to utilise alternate process to manufacture the same final product. If once the final drug is reserved, by the patent right of Paris Convention, we cannot even prepare by alternate process also. This is to seriously undermine the self-reliance of Indian Drug Industry-- is upto everybody's guess.

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In this aspect, the Indian Private drug Industry voiced by I.D.M.A. and the Multinational Lobby represented by O.P.P.I. are at Logger-heads. Everyone knows that in our country, the Public Sector Drug Industry has alone effected the reduction of drug prices and forced the multinationals to start manufacturing units-- a step to self-reliance. Now this component of the drug Industry is at Peril, running into losses of Crores of Rupees, working at only 30 % capacity. This is to the rejoice of the Multinational drug industry. The GOI by way of liberal imports and delicensing playing silently into the hands of multi-nationals. At this face, can I expect the " Businessmen to behave as Bishops"?

THE DOCTORS:

Drugs is one commodity where the consumer has no choice in selection and where the selector won't pay for its cost. Here the selector is Doctor. Hence the drug companies carefully therew their nets on them by way of glittering promotion and advertisement.

After several years of coming out of Medical Colleges, most of the Doctors, lost touch with the current trends in Drug the Aapy, thus ultimately, Medical Representatives employed by the Drug Companies have developed to the stature of " Pharmacology Professors to the Practising Doctors", Statistics even in UK speak this. Nobody need misunderstand me.

Doctors are systematically lured to prescribe their brands and illusioned about the relative benefits of a Particular brand. It is still astonishing that a belief prevails that " a tonic improves Strength", " B1 B6 B12 is necessary in routine weakness and body pains" " cough syrups are essential "- etc.

The impact of brand cult is so immense on doctors that they feel that their independence of treating patients is curtailed by reducing the number of brands available. Fact is that we want to reduce the number of un-necessary brands but not the number of essential drugs. Hence the independence is not curtailed in fact. Instead the burden is lessened by demanding less on the memory of the Practitioner to remember so many brands for a single drug. Besides at a given moment an average practitioner can recollect 200 names of drugs. If he sincerely feels and makes efforts to

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remember all the 60,000 formulations available in the market, he will be forced to forget the names of his friends, wife, children and ultimately his own name&'.

An established Practitioner by and large might develop the vested interest in prescribing a particular brand because of an inwelcome relationship between him and the drug company. Our experience is same wherever we go, but relentlessly we continue our effort to win them over or atleast neutralise these practitioners when we continue our crusade in the drug action.

But in the fresh graduates and also in the Practioners who are to some extent or other committed to social cause but at the same time ignorant about the intricacies of the drug situation our efforts are breeding good results. And this section of the Practitioners is indeed a strong ally to the people to fight in this cause.

THE PEOPLE:

As the people are the ultimate consumers, they are to be aroused to this cause.
In fact they are in a jungle of problems like poverty, lack of safe drinking water, lack of shelter, sanitation, illiteracy, unemployment for which ultimately the people at the helm of affairs should hold responsibility. They are in fact forced to organise themselves to fight against these maladies. Even the fight for rational picture in drugs, if co-ordinated with their day to day fight for their liveli-hood, alone will become successful ultimately.

WHAT ARE WE DOING?

a) To educate the just thinking doctors, we are addressing the doctor gatherings and IMA General Bodies and requesting them to co-operate by not prescribing non-essential drugs with-holding the use of harm-ful drugs, not accepting samples of drugs which they don't want to prescribe and educating their patients, prescribing, cheaper, good-quality generics. Ultimately we request them to follow the WHO essential drug list till a list is drawn in our country and popularised.

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b) Appeal the intellectuals on these issues and familiarise them about the banned and banable drugs The role of drug multinationals, the role of the Government by way of slide shows, exhibitions, lectures and conventions. We conducted this way to Hyderabad, Kurnool twice, Cuddapah twice, Anantapur twice, Nellore, Ngae and Khamman. We are going to conduct shortly at Vizag, Vijayawada, Guntur, Tirupati, Kajahmundry, Nalgonda and Warangal. We hope to cover all the District Head Quarters of Andhra Pradesh in the near future.

c) The most important section is the rural poor. We are drafting the help of teachers and lecturers, students and youth to go to villages, schools, colleges. We are conducting exhibitions and lectures health and drugs demonstrating the unnecessary, harmful drugs, For this we are currently engaged in training teachers in these aspects in some of the District Head Quarters selecting 10 to 15 people from all the sections mentioned above. We hope the people, intellectuals, voluntary organisations, Druggists Chemists, Scientists, representatives, lawyers, socially committed doctors will all come forward unitedly for the realisation of the just right " Healthy living is everybody's right ".

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 the 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. e.g. **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, Hathi Committee 1975, "Alternative strategy Health for All - ICMR-ICSSR Report 1981" and even the last year "National Health PolicyStatement", all of which emphazise that the health needs of the majority have to take priority over sophisticated, centralised, costly, high technology medical servics meant for the minority with the purchasing power.

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.

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 their drug 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.

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.

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 verymuch from the pre-inde- pendence 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.

The issue of essential drugs focuses 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 their interest.

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

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 Chilean 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.

SHRI LANKA :

In 1971 under the guidance of Seneka 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.

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VOLUNTARY HEALTH ASSOCIATION OF INDIA

C-14 Community Centre
Safdarjung Dev. Area
New Delhi-110016

As Part Of Rational Drug Policy Campaign

CHLORAMPHENICOL WITH STREPTOMYCIN

Brand	Manufacturer
1. Basiplon	Khandewal
2. Bichlorphenin	Medinex
3. Chemistrep	Suprachem
4. CHLOROSTREP SUS.	Parke Davis
5. Chlorocinstrep	Jagson Pal
6. Chlorostrep Kapseals	Parke Davis
7. Chlorostreptoseal	INDC
8. Chlorsoin	Dolphin
9. Cilastrep	Acila
10. Contistrep	Continental
11. Cooperstrep	Cooper
12. Chloramphenicol and	Pharma Indiana
13. Streptomycin	
14. "	Sarvodaya
15. "	H.A.
16. Cyperstrep	Cyper Pharma
17. Diastrep	Sunways
18. Dycos	Dynamic
19. Enterostrep	Deys
20. Glucostrep	Gluconate
21. Glycostrep	Glyco
22. Ifistrep	Unique
23. Intestostrep	East India
24. O. Strep	Optho
25. Paam Strep	Paam
26. Pharmastrep	Pharmakab
27. Phenistrep	Usan
28. Phenistrep	PCI
29. Rheofin	Rallis
30. Ranstrepcol	Ranbaxy
31. Strepcol	Medochem
32. Strep-C	Jilichem
33. Strepto-Chloramphen	Stamac
34. STREPTO-PARAXIN	Boehringer-Knoll
35. Streptophenicol	Mercury
36. Wilstrep	Dadha

2/6/89

USED: for diarrhoea and amoebic dysentry.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED.

Bangladesh, Cyprus, Denmark, Dominican Republic, Italy, Japan, Nepal, Norway, Philippines, Saudi Arabia, Sweden, Venezuela, Sri Lanka, Pakistan, and Malaysia.

Safer alternative: for diarrhoea oral rehydration therapy[21], for amoebic dysentry - oral rehydration therapy and metronidazole.

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21. Oral rehydration solution : To 1 glass of water of about 200 cc add 2 fingers pinch of salt. Taste it. It should not be more salty than tears. If it is, throw it away and make a new mix with less salt. Add a scoop of sugar (2 tea spoonful). Try and give one glass of solution sip by sip after each loose motion.

REASON FOR BANNING: Dangerous : Chloramphenicol can cause fatal agranulocytosis [22] and should therefore be used only when it is specifically indicated (eg. for typhoid). Of all the drugs that may be responsible for pancytopenia chloramphenicol is the most common cause. These reactions may represent an idiosyncratic reaction to the drug. The incidence is not related to dosage, however it seems to occur more commonly in individuals who undergo prolonged therapy and especially in those who are exposed to the drug on more than one occasion.

Goodman Gillman, 7th Edition, pg.1181

Streptomycin is not useful for treating typhoid - it is commonly used for tuberculosis. The combination is therefore not useful at all, and only leads to the unnecessary consumption of either chloramphenicol or streptomycin, so that strains of TB become resistant to the latter, thus rendering the drug useless for TB.

"(Chloramphenicol) should never be employed in diseases readily, safely and effectively treatable with other anti-microbial agents, or in agents, or in undefined situations". [23]

Streptomycin is a drug of choice in the treatment of tuberculosis and should generally be reserved for this use because when used in the treatment of other bacterial infections resistance has been found to develop within 2 to 3 days. [25]

Often serious blood dyscrasias including aplastic anaemias after both short term and prolonged therapy bone marrow suppression. grey baby syndrome in infants G.I. upset optic and peripheral neuritis allergic skin reactions can be caused by chloramphenicol.

Chloramphenicol may interfere with development of immunity and it should not be given during active immunization:

Martindale 1982, 28th Edition, Pg.1139.

"Resistance to chloramphenicol in S.Typhi has become a world-wide problem". [24]

The combination of chloramphenicol with streptomycin was recommended for weeding out by the Subcommittee of drug consultative Consultative Committee in 1980 for following reason : "Fixed dose combinations of chloramphenicol with streptomycin should not be allowed. As chloramphenicol is potentially a toxic drug, its use should be kept restricted to enteric fever only". This combination was excluded from the Banned Drug List by the Drug Technical Advisotry Board in 1982 and by the Gazette Notification of Drug Controller of India, 23rd July, 1983 (seepg.33).

The combination has been recommended for being weeded out again by DCC in 1987.

USED: No rational use, but commonly recommended for diarrhoea and bacterial infections.

EXAMPLE OF COMBINATIONS: Chlorostrep suspension (Parke Davis): Chloramphenicol, Streptomycin. Parke Davis who consider themselves pioneers in sales of this combination for diarrhoea have in view of the increasing medical evidence against its use have voluntarily withdrawn their product.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED :

Egypt, Japan, Philippines.

SAFER ALTERNATIVES: for diarrhoea oral rehydration therapy[26], for bacterial infections - another anti-biotic.

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22. See glossary
23. Goodman & Gillman, The Pharmacologieal Basis of Therapeutics, 7th edition, 1985, pg.1182
24. ibid, page 1183.
25. Martindale: The Extra Pharmacopoea, 28th edition, 1982

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SAFER ALTERNATIVES[25] : For diarrhoea-oral rehydration therapy[26], for bacterial infections - another anti-biotic.

Ref- BANNED & BANNABLE DRUGS LIST
VHAI

FIXED DOSE COMBINATION OF STEROIDS

Examples of fixed dose combination of steroids

Brand	Manufacturer	Contents
1.Docabolin	Infar	Nandrolone phenylpropionate, desoxycorticoslerone phenylpropionate.
2.Betaklor	Vilco	Betamethasone, Chlorpheniramine mal.Tab.
3.Betneton	Glaxo	Betamethasone, Chlorpheniramine mal.Soluble Tab.
4.Cortina	Lupin	Chlorpheniramine mal., dexamethasone Tab.
5.Costophen	Uniloids	Chlorpheniramine mal., dexamethas prednisolone Tab.
6.Mistapred	Wyeth	Prednisolone, Chlorpheniramine mal. Tab.
7.Perideca	Merind	Dexamethasone, Cyproheptadin Tab.

Ref- BANNED & BANNABLE DRUGS LIST
VHAI

2/6/89

FIXED DOSE COMBINATION OF STEROIDS

Reasons for Banning

Fixed dose combinations of steroids should not be allowed because; the adrenal suppression accompanying prolonged steroids therapy leads to symptoms of adrenal insufficiency, if the steroid is abruptly withdrawn. It is difficult to titrate the dose of the steroid when it is present in fixed dose combination with other drugs.

(1) Concurrent administration of corticosteroids will cause excessive loss of potassium, (2).

Also it is impossible to vary the dosage or time schedule of each drug separately and because if adverse effects arise it is difficult to know which drug is responsible for them (3).

Corticosteroids and androgens affect the protein bound iodine (4).

In addition to pituitary-adrenal suppression the principle complications resulting from prolonged steroid therapy are fluid and electrolyte disturbances; hyperglycemia and glycosuria; increased susceptibility to infections including tuberculosis; peptic ulcers, which may bleed or periorate; osteoporosis; a characteristic myopathy; behavioural disturbances; and Cushing's habitus, consisting in "moon face", "buffalo hump", enlargement of supra clavicular fat pads, acne etc. (5).

Unless considered life saving, systemic administration of corticosteroid is contra-indicated in patients with peptic ulcers, osteopprosis.

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1. Drug Consultative Committee Recommendation 1980.
2. Martindale, The Extra pharmacopoeia, 28th ed, 1982,PP.449
3. Parish P., Medicines: A Guide for Everybody 5th Ed. 1984 pp.29
4. Adverse Drug React. Bull, 1972, June, pp.104.
5. Goodman LS and Gillman A; The Pharmacological basis of Therapeutics 7th Edition, 1985.

Double Standard - Steroid Combination

Before & After the ban on Steroid Combinations except for Bronchial asthma

Brand Name	Content	Manufacturer	INDICATIONS	
			MIMS March '82	MIMS October '85
Betaklor	Betamethasone Chlorpheneramine Maleate	Valco	Allergies of all types	Allergic asthma when Bronchodilators alone are ineffective.
Betneton	Betamethazone Chlorpheneramine	Glaxo	Allergy	-do-
Cortina	Dexamethasone Chlorpheneramine	Lupin	Stubborn allergy Food poisoning insect bites.	-do-
Cortophen	Prednisolone Chlorpheneramine	Uniloids	Allergic Disorders	Allergic Asthma.
Histacort	Chlorpheneramine Prednisolone	SIRIS	Allergic Manifestation	-do-
Histapred	Prednisolone Chlorpheneramine	Wyeth	Allergic Manifestation	Allergic Asthma when Bronchodilators alone are ineffective.
Kenamina	Triamcinolone	Sarabhai	Allergic disorders angioneurotic oedema Hay fever, drug and serum reactions, certain cases of bronchial asthma.	-do-
Perideca	Dexamethozone Cyproheptadine	MSD	Allergic disorders	-do-

Please note the steriods combinations were banned by the Gazette notification July 23, 1983; only allowing steriods combinations beforn a ior Bronchial Asthma. The differences in the indications before and after the ban to escape the ban is obvious from the above table.

psychoses, or severe psychoneurosis and they should be used only with great caution in the presence of congestive heart failure in patients with diabetes mellitus infections diseases, chronic renal failure and uraemia, and in elderly persons (6). Empirical use of corticosteroid may mask the symptoms to such an extent that a true diagnosis becomes extremely difficult to make.(6).

Countries where banned, withdrawn or severely restricted:

Bangladesh, Turkey, Denmark, Saudi Arabia, Venzuella, Italy, Australia, Belgium, Greece, Norway, New Zeland, Singapore, Thailand, USA, India, Nepal, etc.,(7).

Safer Alternatives: Single steroid drug whenever needed.

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6. Martindale: The Extra Pharmacopea 1982, pp.450.

7. Consolidated list of products whose consumption and/ or sale have been banned, withdrawn, severely restricted or not approved by the governments. Prepared by the United Nations Secretarial in accordance with General Assembly Resolution 37/137, 1994.

ALL INDIA DRUG ACTION NETWORK
C-14 COMMUNITY CENTRE S. D. A. NEW DELHI 110016

RATIONAL DRUG POLICY - STATEMENT

AIDAN

All India Drug Action Network (AIDAN), is a forum, and coordinating body of organizations, and individuals all over the country working towards the adoption and implementation of a people oriented Rational Drug Policy in India as a part of a Peoples Health Policy. It sets out the following outline for the Drug Policy :

Health Policy and drugs

Majority of the Indians suffer from the diseases of poverty and ignorance, i.e. communicable diseases, diseases due to undernutrition etc. Most of these illnesses are preventable and curable. In addition, distorted pattern of industrialisation and urbanisation has led to the development of so called diseases of industrialisation. What we need most is adequate nutrition, adequate and safe water, universal sanitation, development without damaging environmental balance and primary medical service, available to all.

Role of drugs

Although drugs constitute only a small part of the overall health care, they are most urgent, essential and hence a priority need in the country where incidence of death and disability from diseases is high. So long the basic elements of health care are not made available universally, medical care will continue to be the priority service to reduce death and disability and in this context, drugs understandably assume a vital and priority role.

Present situation

The fact that drugs can save life and relieve sufferings has been exploited by the drug industry, which is oriented mainly to profit making, to push all sorts of irrational drugs onto the consumers. The drug industry and the medical establishment has created a very drug-dependant health culture which eclipses the much-needed sustainable solutions to the real health problems. Doctors and non-doctors alike are made to believe that drugs are "cure all"

for all ills. Health is still regarded as basically an individual or personal responsibility and not a product of social factors.

It is also believed that freedom from diseases could be obtained by better an better and more and more drugs. Such a belief among educated and illiterate alike, has led to a universal craze for drugs and this DRUG CULTURE has come to dominate the society. In this situation it is not surprising that drugs provide an opportunity for unlimited profit-making by the drug industry, since hardly any consumer asks for the necessity, utility, rationality, price-justifiability and harmful effects of a drug. It is not even asked whether a substance sold as Drug is actually a Drug at all. As a result, about 60% of the drugs in the market are unscientific or harmful or substandard; a large number of these are not actually drugs; many drugs are consumed by those who do not need it; people die or are disabled from the effects of harmful drugs; drugs are sold at fantastically high prices; and most serious of all life saving and essential drugs are not available to the majority that need them most.

Even 38 years after independence, multinational corporations continue to dominate the drug industry in India. Further, the majority of their production consists of drug formulations and not bulk drugs. Though, according to UNIDO, India has the capacity to be self sufficient in bulk drugs, we still import 40% of our bulk-drug requirement.

Objectives of the Rational drug policy

We feel that the Rational Drug Policy objectives should include the following :-

A. ASSESSING THE DRUG-NEEDS

1) To identify the drug needs in consonance with the health needs of the people, particularly those required for primary health care; to prepare a graded essential and priority list of drugs for different levels of health expertise inkeeping with actual health needs of the people.

2) To eliminate irrational, useless and hazardous drugs.

B. PRODUCTION, PRICE AND QUALITY CONTROL

1) To make all drugs available at low prices to the people, particularly the essential & priority drugs.

2) To ensure quality control of all drugs.

C. DRUG DISTRIBUTION

To establish a national corporation for the distribution of drugs; retailing of drugs through fair price shops and government's health infrastructures.

D. DRUG INFORMATION AND ETHICAL MARKETING

1) To ensure a drug information system for health personnel and consumers.

2) To ensure ethical marketing.

3) To abolish brand names and introduce generic names for all drugs.

E. SELF - RELIANCE

1) To develop self reliance in drug technology.

2) To foster and encourage the growth of the Indian Sector and to provide a leadership role to the public sector.

3) To aim at quick self sufficiency in the output of drugs with a view to reducing the quantum of imports.

F. RESEARCH AND DEVELOPMENT

To promote research and development for self-reliance and in accordance with the needs of the Indian people.

G. LEGISLATION AND ADMINISTRATION

1) To provide comprehensive drug legislation and administrative support to deal effectively with and implement all the above aims and objectives.

2) To ensure smooth Centre-State relations and inter-departmental coordination for effective and relevant drug production, drug control and drug supply.

H. HUMANPOWER DEVELOPMENT

To fulfill the needs of the above Rational Drug Policy, different type of technical personnel (e.g. druggists, paramedics, etc.) need to be adequately and appropriately trained in adequate numbers.

A. ASSESSING THE DRUG NEEDS

A 1. Identification of Drug needs and Prioritized Essential Drug List

i) The National Drug Formulary should be revised and compiled by an expert multi-disciplinary committee with suitable representation from all the sections of health professionals. This committee should draw up the essential priority drug list, keeping the following criteria in mind -

* Medico-social justification should act as a primary criterion keeping in mind - efficacy, safety, cost, ease of administration, potential for misuse, indigenous production.

* Priority for production has to be given to the drugs required for diseases causing greater mortality (death), greater morbidity (illness), severe sequelae (after effects).

* Drugs used in National Programmes e.g. TB, leprosy, malaria, blindness, goitre control, and immunisation programmes should get priority.

This list should be revised periodically.

ii) Selection of the essential and priority drugs would be followed by preparation of graded drug list for different categories of health personnel and health institutions. These lists should form the basic guidelines for bulk purchase procurement and requisition stocking and dispensing.

An appropriate authority (see section G2) should continuously assess drug needs and drug production and monitor capacity utilisation in the industry, drug utilisation patterns, health needs, changing pattern of diseases, drug requirements, new information on old drugs, introduction of new drugs, efficacy of the existing policy of production, distribution and use of drugs.

A 2. **Withdrawal of hazardous, irrational and therapeutically useless drugs.**

i) All the drugs in the market should be scrutinised to assess their rationality on the basis of standard text books of medicine and pharmacology. All drugs which are not recommended in these text books should be banned. Those drugs which have life-threatening or serious side-effects and for which equally effective alternatives are available should be banned immediately. The rest of these drugs should disappear from the market within one year.

ii) No fixed dose combination forms should be allowed to be manufactured if an alternative single ingredient drug is available for the purpose, which is therapeutically equivalent and more cost effective.

iii) Drug Legislation should be modified to ensure that no stay order is granted in cases pertaining to banning hazardous drugs in the interest of public health.

B. PRODUCTION, PRICE AND QUALITY CONTROL

B 1. **Production and Price Controls**

i) The priority drug list should be a part of much larger essential drug list based on WHO recommendations as well as those of our own National Drugs and Therapeutics Authority. In this essential drug list, life saving drugs and drugs for primary health care shall be put as category I termed as priority drug list and the rest of the list shall be put in category II.

ii) The production of essential drug formulations shall be a minimum 75% of total formulation turnover of each manufacturer now and shall be brought up to 90% in five years. The priority drugs shall constitute 60% of the above essential drugs and shall be raised to 80% of the essential druns in the next 5 years. The above production quota should include all dosage forms of essential and priority drugs.

iii) All companies having equity above 26% shall be identified as foreign companies (as per RBI definition).

iv) All foreign companies shall produce bulk as to formulation ratio of 1:5. For other companies the ratio shall be 1:10.

v) A mechanism should be evolved to provide incentive to those companies which produce more than the required quota of essential/priority drugs and deterrent punishment to those companies which produce less than the required quota as given above.

vi) The priority drugs should be made available at low prices. If required, they may even be subsidized. Before any major revision in the pricing policy is done, as a policy there should be an independent study to assess the cost, profitability as well as availability and price from the point of view of consumers. Profit-making should not be the sole basis of the drug industry. All taxes from priority drugs should be abolished to reduce the prices of such drugs.

vii) The trade commission shall be fixed at 20%. However, this is the total commission which will be paid from the principal manufacturer to the distributors and the intermediaries. While the markup under the head of trade commission will be increased, the markup under the head of sales promotion will be decreased for essential and priority drugs.

viii) All drugs including nutritional supplements, except that produced by small scale sector, shall be under price control.

ix) The small scale sector can be free from price and production controls. However, the small scale sector will be defined as those companies whose turnover is less than 20 lakhs and not linked to large scale and organised sector units through ownership, financial participation or marketing arrangements.

B 2. **Proper Drug Registration and Monitoring**

Registration

1. All pharmaceutical products, both ethical drugs and over-the-counter (OTC) preparations offered for sale should be duly registered by a competent authority.

2. Commercially sold indigenous medicines should also be registered and pharmaceutical products which are not registered should not be allowed to be marketed.

3. Pharmaceutical manufacturers and traders must provide the registration authority with a list of all countries in which the specific product has not been accepted for registration.

4. Pharmaceutical manufacturers and traders should inform the registration authority if a pharmaceutical product already registered in the country has been removed from the register of any other country together with the reason for its removal.

5. Pharmaceutical manufacturers and traders, when applying for registration of a product, must be made to undertake that subsequent to the product's registration, they will provide the registration authority and consumers with all new informations they receive about its effects, adverse reactions and interactions.

6. Central Drug Control authorities should have an up-to-date information about the various drug formulations in the market, their combinations, their date of licensing, drug information being given with them by the producers and the latest international medical views on the products.

7. Drugs which have been banned from sale after being marketed for some time in one country must not be submitted for clinical trial or marketing in India. The onus of proving why such a non-essential drug should be introduced or allowed to continue in the market should be with the manufacturers.

8. Whenever a new drug is tested on healthy human subjects or on patients, the clinical trial must be authorised and monitored by a local "Ethical Committee" and must be carried out only with the full informed consent of the people and patients concerned.

Medical Audit System

It should be introduced to review the medical costs, the prescription practices, patient complaints of negligence or financial exploitation and drug misuse. At least minimal medical/clinical record keeping should be made mandatory. Medical audit systems should be introduced in a systematic manner.

Physicians and pharmacists should be answerable to Rational Therapeutics Committee of Experts. This could be appointed by Medical Council or any other academic neutral body. Medical experts involved in primary, secondary and tertiary medical care, chemists and consumer organisations should be represented.

C. DRUG DISTRIBUTION

i) A National Corporation for distribution of drugs and pharmaceuticals to retail drug outlets, hospitals and dispensaries should be established.

ii) National Drugs and Therapeutics Authority (see section G2) (or its sub-committee) should look into the drug needs of the peripheral health units to identify the bottle-necks and deal with them as a priority and ensure timely drug supply.

iii) This corporation should look into

- requirement estimation of various drugs and their dosage forms;
- purchasing effective, safe and quality drugs at most reasonable costs through bulk purchase and other purchase procedures;
- operating an efficient inventory and stock control system;
- developing an efficient workable system, where drug needs of the peripheral institutions can be a gauged and timely drug supplies ensured.

iv) Adequate drug distribution through the Government's health service infrastructure should be ensured. Essential drugs in adequate quantities and at subsidised rates should be available at PHCs, and their sub-centres.

v) Quality essential drugs should be made available from Government fair-price pharmacy shops. These could be handed over to PHCs and sub-centres.

vi) Education and relevant material on good pharmacy management as produced by WHO should be made available to pharmacy management system.

vii) Trained and qualified pharmacists should dispense drugs.

D. DRUG INFORMATION AND ETHICAL MARKETING

D 1. Drug Information

i) It should be the statutory duty of the drug control authorities to inform health personnel and consumers of the WHO's concept of essential drugs, India's graded essential drug lists, drug policies and their rationale regarding banning of drugs. Rational drug policy as a topic should be included in medical and para-medical education.

ii) Names of the brands banned for manufacture and sales should be widely publicized in medical journals, magazines, national newspapers, giving briefly the explanation and rationale of the ban.

D 2. Ethical Marketing

i) All sales promotion material including package inserts, medical data sheets by the drug units should be screened by a permanent National Drug Information body, which will be part of the National Drugs and Therapeutics Authority. This body should be responsible for screening as well as ensuring availability of unbiased drug information to the health personnel and consumers.

ii) Use of audio-visuals for sales promotion on drugs to doctors in absence of a printed copy (to be kept with the doctor), of the claims made, should not be allowed.

iii) All drug promotional literature should contain balanced and verified scientific information about indication, contra-indications side effects and drug interaction and antidotes.

iv) Inadequate and inaccurate information in medical promotional literature or package insert or worse still of the total commission of the package insert (as is the trend at present) should be considered a punishable offence.

v) Seminars, scientific sessions held by drug companies to present mainly industry sponsored research studies should be closely monitored and if need, be restricted as it is associated with presentation usually only of favourable results and tend to create a sense of obligation in the minds of certain medical personnel towards drug companies for sponsoring their research.

vi) Sponsoring of National Conventions of professional medical and academic societies by drug industry should be discouraged since consumers have to ultimately indirectly foot the bill and such sponsorship inevitably introduces bias in favour of the company and its products. The health ministry should take up the responsibility for making funds available for such seminars.

vii) Advertisement of tonics and food supplements should not be allowed in the lay-press. OTC sales advertisements making false or misleading or inaccurate claims should be banned. Authorities should ensure that adequate consumer caution is provided to the consumer in regional languages.

viii) Labelling should be clear. International non-proprietory names (generic names) should be used. Consumer caution should be in regional languages.

For food supplements, nutrients, tonics in the consumer caution in regional languages it should be added that "This is not a substitute for normal food" and message given pictorially wherever possible.

ix) "The International Code for Ethical Marketing" as drafted by the Health Action International should be adopted by India.

D 3. <u>Drug Nomenclature</u>

International non-proprietary names should be used for sales, labelling and prescription writing. This being so because of several advantages:

i) Generic drug names are used in under-graduate/postgraduate medical and pharmaceutical education.

ii) Generic names are used in medical text books, scientific medical journals and WHO publications.

iii) All purchases of medicines from international tenders and international markets are based on generic names.

iv) Use of generic names also ensure production, sale and dispensing of more rational single ingredient drugs.

v) Generic name assures clarity by giving information of the class of drug and thus avoiding confusion arising out of many dissimilar brand names of one drug.

vi) Drugs of equal quality are usually cheaper when purchased by their non-proprietary names than when bought using brand names.

vii) Use of non-proprietary names is a valuable aid to memory as health workers have to learn and remember each drug by one name only.

E. SELF - RELIANCE

1. Technological self-reliance

i) In view of the high importance of achieving the goal of self-reliance in the drug sector, it is imperative that all technology transfer agreements are made in accordance with the United Nations Council for Trade and Development draft code.

ii) Protective mechanisms should be evolved for process that are being developed in the national laboratories so that technology being developed indigenously does not get aborted as it has happened in the recent past in case of processes developed at NCL and Central Drug Research Institute.

iii) While encouraging in house R&D activity through fiscal incentives, mechanism should be evolved that the R&D effort undertaken by different firms is in accordance with the priority drug needs of the Indian people.

2. Encouragement to Indian Sector

i) Make priority drugs, already produced in the country from basic stage by the public sector and wholly Indian companies, a reserved category for which companies holding foreign equity more than 26% should not be allowed any fresh license.

ii) Stipulate a strict time limit of five years for all foreign companies to start production from basic stage for the existing already licensed production capacities.

iii) Ensure implementation of the time limit of two years stipulated for foreign companies to undertake production from the basic stage for fresh license.

iv) No Carry on Business license or production over the licensed capacity should be allowed for MRTP, FERA and ex-FERA companies.

v) Loan licenses being used by the small scale sector units linked through ownership, financial participation and/or marketing arrangements should be cancelled.

E 3. Reduction of Imports

i) The canalisation of all imports should be streamlined. Open general licence system should be abolished. There should be raw material pool in each State to ensure proper pricing and availability of raw materials.

ii) Import and excise duties should be fixed in such a way that the landed cost of imported raw materials and bulk drugs should not be lower than that of indigenous raw materials and bulk drug production.

F. RESEARCH AND DEVELOPMENT

i) Priorities in research should be guided by the health needs of the people in India. Drugs required in diseases causing greater mortality, morbidity, serious sequelae should get priority. Vaccines should get priority over other drugs.

ii) Even 38 years after the cessation of British Colonial Rule in India, research on non-allopathic drugs continues to get step-motherly treatment. Hence research on these drugs should be encouraged. None of these drugs, however, should be allowed to be produced on commercial scale unless their efficacy and safety has been proved through scientific research.

iii) Research policy on drugs should be reviewed every ten years to respond to changing pattern of diseases in India.

iv) All medical research on human beings must be statutorily required to conform to the 1975 Helsinki (Mark II) Declaration. All research proposal must be approved by a central authority before research is started. This should be strictly adhered to in case of contraceptive research also.

The present policy of giving priority to research on hormonal contraceptives rather than to barrier methods must be reversed.

G. DRUGS LEGISLATION AND ADMINISTRATION

G 1. Drug legislation should provide for the following:

- a system of registration of all medical products (including traditional medicines)
- enforcement of good manufacturing practice
- full control of labelling and advertisement
- control of prices of finished drugs and therapeutic raw materials
- prescription control of toxic/poisonous and habit forming drugs
- summary trial for violations against the drug policy by manufacturers and traders in special drug courts
- heavy penalties including confiscation of equipments and properties for the manufacture and/or selling of spurious and sub-standard drugs.

The legislation should be reviewed, regularly modified and updated in the interest of the public and they should not become bottlenecks for implementation of the national drug policy.

G 2. **National Drug and Therapeutics Authority**

i) The greatest need of the moment is greater public accountability and a greater social control over pharmaceutical industry. For this, setting up an independent machinery such as a National Drug and Therapeutics Authority is imperative, which can scrutinize all the drugs currently marketed in India on an ongoing basis and be held responsible for the nature of drugs in the market. This permanent body should have representatives with medical, pharmacy and management expertise. Representation being from :

1) drug and health authorities from states
2) Ministry of Chemicals and Fertilzers and Ministry of Finance
3) medical professional and medical academic bodies
4) consumer groups and NGOs involved in health work

5) Trade Unions related to drug industry

6) chemists and druggists.

The Government should establish National Drug Authorities (NDA) at the State level also. The Drug Controllers should be accountable to NDAs.

ii) The recommendations of the National Drugs and Therapeutics Authority should be binding on the drug industry.

iii) Appropriate powers be delegated to Central Drug Controller and State Drug Control Authorities for the proper implementation of the recommendations of the Drug and Therapeutics Authority.

iv) Relationship of NDA with centre and state drug and health authorities should be clearly defined. Its constitution, functioning and powers should be aimed at proper implementation of National Drug Policy. Suitable drug legislation support should be given to this authority so that its decisions are not unnecessarily challenged in the court.

v) Drugs should be dealt with by this NDA rather than by Ministry of Chemicals and Fertilizers, to give greater emphasis to the therapeutic relevance rather than industrial profits and Government's revenue.

H. HUMAN POWER DEVELOPMENT

Not merely medical and pharmacology related manpower development is required, but also development of drug managers, drug inspectors, quality control technicians, researchers and scientists willing to do R and D in areas of grater concern to the health of our people. The training and development should include training of legal personnel who will be dealing with Food and Drug Courts.

Exposure and training of policy makers to other dimension of drug issues as experienced by consumers and health personnel in the field is also relevant.

Drug control mechanism has to be developed in keeping with the growth of our drug industry and be proportionate to our drug production and sales.

THE ALL INDIA DRUG ACTION NETWORK (AIDAN) COORDINATION COMMITTEE CONSISTS OF

(1) Arogya Dakshata Mandal, Pune.
(2) Catholic Hospital Association of India, Delhi.
(3) Consumer Education & Research Centre, Ahmedabad.
(4) Consumer Guidance Society of India, Bombay.
(5) Drug Action Forum West Bengal, Calcutta.
(6) Delhi Science Forum, Delhi.
(7) Kerala Sashtra Sahitya Parishad, Kerala.
(8) Locost, Baroda.
(9) Lok Vigyan Sangathana, Bombay.
(10) Medico Friends Circle, Pune.
(11) Voluntary Health Association of India, Delhi.

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AIDAN Coordinator

DR. MIRA SHIVA
c/o VHAI
C-14 Community Centre
S.D.A. New Delhi 110 016.

All India Drug Action Network -AIDAN

OUR DEMANDS

* **availability of essential and life saving drugs** (i.e. adequate production and streamlined distribution to peripheral areas).
* **withdrawal of hazardous and irrational drugs**
* **availability of unbiased drug information** to health personnel and consumers (including updating our National Drug Formulary), and provision of therapeutic guidelines as in British National Formulary; provision for consumer caution in regional languages for problem drugs
* **adequate quality control and drug control** so that every fifth drug in the market is not sub-standard as in at present according to Government's own figures
* **drug legislation reform** to prevent drug companies from misusing legalistic loopholes against the people.

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New Delhi 110 028

ALL INDIA DRUG ACTION NETWORK
C-14 COMMUNITY CENTRE S. D. A. NEW DELHI 110016

Dear Member of Parliament

As you know the Drug Policy of our country is being formulated in this session of the Parliament. Drugs and health are very closely related. It is unfortunate that today, drugs-their prioritization and manufacture are under the Chemical and Industry Ministry. We are concerned that drugs, being what they are, should be looked at from the people's health point of view, and not the industry's health.

The WHO list of eassential drugs says only 200 drugs can cure all illnesses of the world. Today India produces more than 60,000 drugs. Majority of them are useless. Many of them are banned abroad. Some, which are banned here, are still being sold.

The prices we pay for these drugs is very high. Often many of these drugs are substandard. There are also a large number of spurious drugs in the market.

You are the people's chosen representative. They chose you over others to safeguard their interests. Health is one of the people's interest - a very large one. We, the people who have elected you wish you to stand up for us at this crucial juncture.

The new drug policy, which you will shortly be formulating should -

1. Restrict the number of drugs based on the criteria laid down by the World Health Organization and Hathi Committee Report of 1975.

2. The new rational drug policy should be in keeping with Government of India's Health Survey and Development Committee (BHORE COMMITTEE) Report, 1946 and the Health Survey and Planning Committee (MUDALIAR COMMITTEE) Report 1959-61.

3. All Hazardous drugs should be banned or severely restricted.

4. Adequate production and supply of essential drugs should be ensured.

5. Adequate measures should be taken to ensure good quality drugs both with brand names and generic names. Interational nomenclature (generic names) should preferably be used. Marketing in spurious or substandard drugs should be considered on par with trafficking in narcotics and psychotropic drugs.

6. All drugs should contain information on their possible side effects in large print and in local languages.

The following model list of essential drugs is taken from the WHO Technical Report Series 641 (World Health Organisation, Geneva, 1979: "The Selection of Essential Drugs")

MODEL LIST OF ESSENTIAL DRUGS
EXPLANATORY NOTES

I. The numbers preceding the drug groups and sub groups in the model list (e.g., 11; 17.6.2) have been allocated, in accordance with the English alphabetical order, for convenience in referring to the various categories; they have no formal significance.

II. Numbers in parentheses following the drug names indicate:

1) Listed as an example of this therapeutic category: choose cheapest effective drug product acceptable;

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 ;

10) Drugs subject to international control under the Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971).

III. Letters in parentheses following the drug names indicate the reasons for the inclusion of complementary 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.

IV. When the strength is specified in terms of a selected salt or ester, this is mentioned in brackets; when it refers to the active moiety, the name of the salt or ester in brackets is preceded by the word "as".

.....2.

V. All drugs listed in this formulary are itemized by their generic names as an aid to encourage the use of generic names in prescribing and ordering medicines.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths

1. ANAESTHETICS

1.1. General Anaesthetics and Oxygen

ether, anaesthetic (2)		inhalation
halothane (2)		inhalation
nitrous oxide (2)		inhalation
Oxygen		inhalation (medicinal gas)
thiopental (2)		powder for injection, 0.5 g, 1.0 g (sodium salt) in ampoule

1.2 Local Anaesthetics

bupivacaine (1,2,9)		injection, 0.25%, 0.5% (hydrochl ride ride) in vial
Lidocaine (1)		injection, 1%, 2% (hydrochloride) in vial
		injection, 1%, 2% + epinephrine 1:100000 in vial
		topical form 2-4% (hydrochloride)

2. ANALGESICS, ANTIPYRETICS, NONSTEROIDAL ANTIINFLAMMATORY DRUGS AND DRUGS USED TO TREAT GOUT

acetylsalicylic acid		tablet, 100-500 mg
		suppository, 50-150 mg
allopurinol (4)		tablet, 100 mg
ibuprofen (1)		tablet, 200 mg
indometacin		capsule or tablet, 25 mg
paracetamol		tablet, 100-500 mg
		suppository, 100 mg
	colchicine (B.C) (7)	tablet, 0.5 mg
	probenecid (B.C)	tablet, 500 mg

3. ANALGESICS, NARCOTICS AND NARCOTIC ANTAGONISTS

morphine (10)		injection, 10 mg (sulfate or hydrochloride) in 1-ml ampoule
naloxone		injection, 0.4mg (hydrochloride) in 1-ml ampoule
	pethidine (A) (1,4,10)	injection, 50 mg (hydrochloride) in 1-ml ampoule

...3.

Main list	Complementary drugs	Route of administration, Pharmaceutical forms and strengths
	4. ANTIALLERGICS	
	Antihistamines	
Chlorphenamine (1)		tablet, 4 mg (maleate)
	5. ANTIDOTES	
	5.1 General	
Charcoal, activated		powder
ipecacuanha		syrup, containing 0.14% ipecacuanha alkaloids calculated as emetine
	5.2 Specific	
atropine		injection, 1 mg (Sulfate) in 1-ml ampoule
deferoxamine		injection, 500 mg (mesilate) in vial
dimercaprol (2)		injection in oil, 50 mg/ml in 2-ml ampoule
sodium calcium edetate (2)		injection, 200 mg/ml in 5-ml ampoule
Sodium nitrite		injection, 30mg/ml in 10-ml ampoule
Sodium thiosulfate		injection, 250 mg/ml in 50-ml ampoule
	methylthioninium chloride(c) (Synonym: methylene blue)	injection, 10mg/ml in 10-ml ampoule
	penicillamine(c) (2)	Capsule or tablet, 250 mg
	6. ANTIEPILEPTICS	
diazepam		injection, 5 mg/ml in 2-ml ampoule
ethosuximide		capsule or tablet, 250 mg
phenobarbital (10)		tablet, 50 mg, 100 mg
		syrup, 15 mg/5 ml
phenytoin		capsule or tablet, 25 mg, 100 mg (Sodium salt)
		injection, 50 mg (sodium salt)/ml in 5-ml vial
	carbamazepine (B.C)	tablet, 200 mg
	valproic acid (B.C) (2,4,7)	tablet, 200 mg (sodium salt)
	7. ANTIINFECTIVE DRUGS	
	7.1 Amoebicides	
metronidazole		tablet, 200-500 mg
	diloxanide(A)	tablet, 500 mg (furoate)

....4.

Main list	Complementary drugs	Route of administration Pharmaceutical forms and strengths
	emetine (A.B)(1,7)	injection, 60mg (hydrochloride) in 1-ml ampoule
	paromomycin (B)	capsule, 250 mg (as sulfate)
		syrup, 125 mg (as sulfate)/5 ml

7.2 Anthelmintic Drugs

mebendazole		tablet, 100 mg
niclosamide		tablet, 500 mg
piperazine		tablet, 500 mg (citrate or adipate)
		elixir or syrup (as citrate) equivalent to 500 mg hydrate/5 ml
tiabendazole		chewable tablet, 500 mg
	bephenium hydroxynaphthoate (B) (8)	granules, 5 g (equivalent to 2.5 g bephenium)

7.3 Antibacterial Drugs

ampicillin (1,4)	capsule or tablet, 250 mg, 500 mg (anhydrous)
	powder for oral suspension, 125 mg (anhydrous)/5 ml
	powder for injection, 500 mg (as sodium salt) in vial
benzathine benzylpenicillin (5)	injection, 1.44 g benzylpenicillin (=2.4 million IU)/5 ml in vial
benzylpenicillin	powder for injection, 0.6 g (= 1 million IU), 3.0 g. (= 5 million IU) (as sodium or potassium salt) in vial
Chloramphenicol (7)	capsule, 250 mg
	powder for injection, 1 g (as sodium succinate) in vial
Cloxacillin (1)	capsule, 500 mg (as sodium salt)
	powder for injection, 500 mg (as sodium salt) in vial
erythromycin	capsule or tablet, 250 mg (as stearate or ethylsuccinate)
	oral suspension, 125 mg (as stearate or ethylsuccinate)/5ml
	powder for injection, 500 mg (as lactobionate) in vial
gentamicin (4)	injection, 10 mg, 40 mg (as sulfate) /ml in 2-ml vial
metronidazole	tablet, 200-500 mg
phenoxymethylpenicillin	tablet, 250 mg (as potassium salt)

..... 5.

Main list	Complementary drugs	Route of administration pharmaceutical forms and strengths
		powder for oral suspension, 250 mg (as potassium salt)/5 ml
Salazosulfapyridine (2)		tablet 500 mg
Sulfadimidine (1, 4)		tablet 500 mg
	------	oral suspension, 500 mg/5 ml
		injection, 1 g (sodium salt) in 3 ml ampoule
Sulfamethoxazole + trimethoprim (4)		tablet, 100 mg + 20 mg, 400 mg + 80 mg
tetracycline (1, 4)		capsule or tablet, 250 mg (hydrochloride)
	amikacin (B.C)(1,4)	injection, 250 mg(sulfate)/ml in 2-ml ampoule
	doxycycline(P)(5,6)	capsule or tablet, 100 mg (as hydrochloride)
		injection, 100 mg (as hydrochloride)
	nitrofurantoin (A.B.)(4,7)	tablet, 100 mg
	procaine benzylpenicillin (A)(7)	powder for injection, 1 g (=1 million IU) 3 g (=3 million IU)

7.4 Antifilarial Drugs

diethylcarbamazine	------	tablet, 50 mg (citrate)
suramin sodium		injection, 1 g in vial

7.5 Antileprosy Drugs

dapsone		tablet, 100 mg
	clofazimine (B)	capsule, 100 mg
	rifampicin (B)	capsule or tablet, 150 mg, 300 mg

7.6 Antimalarials

chloroquine (1)		tablet, 150 mg (as phosphate or sulfate)
		syrup, 50 mg (as phosphate or sulfate)/ 5 ml
primaquine		tablet, 7.5 mg, 15 mg (as phosphate)
pyrimethamine		tablet, 25 mg
quinine		tablet, 300 mg (as bisulfate or sulfate)
	------	injection, 300 mg (as dihydrochloride)/ml in 2-ml ampoule or 250 mg (as formiate) in 1-ml ampoule
	sulfadoxine + pyrimethamine (B)	tablet, 500 mg + 25 mg

....6.

Main list	Complementary drugs	Route of administration pharmaceutical forms and strengths
7.7 Antischistosomals		
metrifonate		tablet, 100 mg
niridazole (7, 8)		tablet, 100 mg, 500 mg
oxamniquine		capsule, 250 mg
		syrup, 250 mg/5 ml
	antimony sodium tartrate (B)	injection, 60 mg in 1-ml ampoule
	sodium stibocaptate (B)	injection, 500 mg
7.8 Antitrypanosomals		
melarsoprol (5)		injection, 3.6% solution
nifurtimox		tablet, 30 mg, 120 mg, 250 mg
pentamidine (5)		powder for injection, 200 mg (isetionate or mesilate)
suramin sodium		powder for injection, 1 g in vial
7.9 Antituberculosis Drugs		
ethambutol		tablet, 100-500 mg (hydrochloride)
isoniazid		tablet, 100 mg-300 mg
rifampicin		capsule or tablet, 150 mg, 300 mg
streptomycin (4)		injection, 1 g (as sulfate)
7.10 Leishmaniacides		
pentamidine (5)		powder for injection, 200 mg (isetionate or mesilate)
sodium stibogluconate		injection, 33%, equivalent to 10% antimony, in 30-ml vial
7.11 Systemic Antifungal Drugs		
amphotericin B		injection, 50 mg in vial
griseofulvin (8)		tablet or capsule, 125 mg, 250 mg
nystatin		tablet, 5000 000 IU
	flucytosine(B) (1,4,8,	tablet or capsule, 250 mg
8. ANTIMIGRAINE DRUGS		
ergotamine (2,7)		tablet, 2 mg (as tartrate)

.....7.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths
9. ANTINEOPLASTIC AND IMMUNOSUPPRESSIVE DRUGS		
azathioprine (2)		tablet, 50 mg
		powder for injection, 100mg (as sodium salt) in vial
bleomycin (2)		powder for injection, 15 mg (as sulfate) in vial
busulfan (2)		tablet, 2 mg
calcium folinate (2)*		tablet, 15 mg
		injection, 3 mg/ml in 10-ml ampoule
chlorambucil (2)		tablet, 2 mg
cyclophosphamide (2)		tablet, 25 mg
		powder for injection, 500 mg in vial
cytarabine (2)		powder for injection, 100 mg in vial
doxorubicin (1,2)		powder for injection, 10 mg, 50mg (hydrochloride) in vial
fluorouracil (2)		injection, 50 mg/ml in 5-ml ampoule
methotrexate (2)		tablet, 2.5 mg (as sodium salt)
		injection, 50 mg (as sodium salt) in vial
procarbazine (2)		capsule, 50 mg (as hydrochloride)
vincristine (2)		powder for injection, 1 mg, 5 mg (sulfate) in vial
10. ANTIPARKINSONISM DRUGS		
levodopa		tablet or capsule, 250 mg
trihexyphenidyl (1)		tablet, 2 mg, 5 mg (hydrochloride)
	levodopa + Carbidopa (B) (1,5,6)	tablet, 100 mg + 10 mg, 250 mg + 25 mg
11. BLOOD, DRUGS AFFECTING THE		
11.1 Antianaemia Drugs		
ferrous salt (1)		tablet, equivalent to 60 mg iron (as sulfate or fumarate)
folic acid (2)		tablet, 1 mg
		injection, 1 mg in 1-ml ampoule
	iron dextran (B) (1, 5)	injection, equivalent to 50 mg iron/ml in 2-ml ampoule
hydroxocobalamin (1, 2)		injection, 1 mg in 1-ml ampoule

* Drug for "rescue therapy" with methotrexate.

.....8.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths
11.2 Anticoagulants and Antagonists		
heparin (2)		injection, 1000 IU/ml, 25000 IU/ml in 5-ml ampoule
phytomenadione		injection, 10 mg/ml in 5-ml ampoule
protamine sulfate (2)		injection, 10 mg/ml in 5-ml ampoule
warfarin (1,2,6)		tablet, 5 mg (sodium salt)
12. BLOOD PRODUCTS AND BLOOD SUBSTITUTES		
12.1 Plasma Substitute		
dextran 70		injectable solution, 6%
12.2 Plasma Fractions for Specific Uses		
albumin, human normal (2,8)		injectable solution, 25%
	antihaemophilic fraction (C) (2,8) (synonym: factor VIII)	(dried)
	fibrinogen (C) (2,8)	(dried)
	plasma protein (c) (2, 8)	injectable solution, 5%
	factor IX complex (coagulation factors II, VII, IX, X, concentrate)(C)(2,8)	(dried)
13. CARDIOVASCULAR DRUGS		
13.1 Antianginal Drugs		
glyceril trinitrate		tablet (sublingual) 0.5 mg
isosorbide dinitrate (1)		tablet (sublingual) 5 mg
propranolol (1)		tablet, 10 mg, 40 mg (hydrochloride)
		injection, 1 mg (hydrochloride) in 1-ml ampoule.
13.2 Antiarrhythmic Drugs		
lidocaine		injection, 20 mg (hydrochloride) /ml in 5-ml ampoule
procainamide (1)		tablet, 500 mg (hydrochloride)
		injection, 100 mg (hydrochloride)/ml in 10-ml ampoule
propranolol (1)		tablet, 10 mg, 40 mg (hydrochloride)
		injection, 1 mg (hydrochloride) in 1-ml ampoule

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths
	quinidine (A.B)(1)	tablet, 200 mg (sulfate)
	13.3 Antihypertensive Drugs	
hydralazine (1)		tablet, 50 mg (hydrochloride)
hydrochlorothiazide (1)		tablet, 50 mg
propranolol (1)		tablet, 40 mg (hydrochloride)
sodium nitroprusside (1,2,8)		injection, 10 mg/ml in 5-ml vial
	methyldopa(A.B)(7)	tablet, 250 mg
	reserpine (4)(1,7)	tablet, 0.1 mg, 0.25 mg
		injection, 1 mg in 1-ml ampoule
	13.4 Cardiac Glycosides	
digoxin (4)		tablet, 0.0625 mg, 0.25 mg
		oral solution, 0.05 mg/ml
		injection, 0.25 mg/ml in 2-ml ampoule
	digitoxin (B) (6)	tablet, 0.05 mg, 0.1 mg
		oral solution, 1 mg/ml
		injection, 0.2 mg in 1-ml ampoule
	13.5 Drugs Used in Shock or Anaphylaxis	
dopamine (2)		injection, 40 mg (hydrochloride)/ml in 5 ml vial
epinephrine		injection, 1 mg (as bitartrate) in 1-ml ampoule
	isoprenaline (C)	injection, 1 mg (hydrochloride)/ml in 2-ml ampoule
	14. DERMATOLOGICAL DRUGS	
	14.1 Antiinfective Drugs	
neomycin + bacitracin (1)		ointment, 5mg neomycin + 500 IU bacitracin zinc/g
	14.2 Antiinflammatory Drugs	
betamethasone (1,3)		ointment or cream, 0.1% (as valerate)
hydrocortisone (1)		ointment or cream, 1% (acetate)
	14.3 Astringents	
Aluminium acetate		solution 13% for dilution

.....10.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths
	14.4 Fungicides	
benzoic acid + salicylic acid		ointment or cream, 6% + 3%
miconazole (1)		ointment or cream, 2% (nitrate)
nystatin		ointment or cream 100 000 IU/g
	14.5 Keratoplastic Agents	
coal tar		solution, topical 20%
salicylic acid		solution, topical 5%
	14.6 Scabicides and Pediculicides	
benzyl benzoate		lotion, 25%
gamma benzene hexachloride		cream or lotion, 1%
	15. DIAGNOSTIC AGENTS	
edrophonium (2,8)		injection, 10 mg (chloride) in 1-ml ampoule
tuberculin, purified protein derivative (PPD)		injection
	15.1 Ophthalmic	
fluorescein		eye drops, 1% (sodium salt)
	15.2 Radiocontrast Media	
adipiodone meglumine (1)		injection, 25% in 20 ml vial
barium sulfate (1)		powder
iopanoic acid (1)		tablet, 500 mg
meglumine amidotrizoate (1)		injection, 60% in 20-ml ampoule
sodium amidotrizoate (1)		injection, 50% in 20-ml ampoule
	16. DIURETICS	
amiloride (1)		tablet, 5 mg (hydrochloride)
furosemide (1)		tablet, 40 mg
		injection, 10 mg/ml in 2-ml ampoule
hydrochlorothiazide (1)		tablet, 50 mg
mannitol		injectable solution, 10%, 20%
	chlortalidone (B) (6)	tablet, 50 mg.

.....11.

Main list	Complementary drugs	Route of administration pharmaceutical forms and strengths

17. GASTROINTESTINAL DRUGS

17.1 Antacids (nonsystemic)

aluminium hydroxide — tablet, 500 mg

oral suspension, 320 mg/5 ml

magnesium hydroxide — oral suspension, equivalent to 550 mg magnesium oxide/10 ml

calcium carbonate (A.B) tablet, 600 mg

17.2 Antiemetics

promethazine (1) — tablet, 10mg, 25 mg (hydrochloride)

elixir or syrup, 5 mg (hydrochloride) / 5 ml

injection, 25 mg (hydrochloride)/ ml in 2 ml ampoule

17.3 Antihaemorrhoidals

local anaesthetic, astringent and antiinflammatory drug (1) — ointment or suppository

17.4 Antispasmodics

atropine (1) — tablet, 1 mg (sulfate)

injection, 1 mg (sulfate) in 1 ml ampoule

17.5 Cathartics

senna (1) — tablet, 7.5 mg (sennosides)

17.6 Diarrhoea

17.6.1 Antidiarrhoeal

codeine (1,10) — tablet, 30 mg (phosphate)

17.6.2 Replacement Solution

oral rehydration salts (for glucose-salt solution)

For 1 litre of water:	(sachet)	mmol/l
sodium chloride (table salt)	3.5 g, Na^+	90
sodium bicarbonate (baking soda)	2.5g, HCO_3^-	30
potassium chloride	1.5 g K^+	20
glucose (dextrose)	20.0 g, glucose	111

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Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths

18. HORMONES

18.1 Adrenal Hormones and Synthetic Substitutes

dexamethasone (1)		tablet, 0.5 mg, 4 mg
		injection, 4 mg (sodium phosphate) in 1-ml ampoule
hydrocortisone		powder for injection, 100 mg (as sodium succinate) in vial
prednisolone (1)		tablet, 5 mg
	fludrocortisone (c)	tablet, 0.1 mg (acetate)

18.2 Androgens

testosterone (2)		injection, 200 mg (enantate)in 1-ml ampoule
		injection 25 mg (propionate) in 1-ml ampoule

18.3 Estrogens

ethinylestradiol (1)		tablet, 0.05 mg

18.4 Insulins

compound insulin zinc suspension(1)		injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial
insulin injection		injection, 40 IU/ml in 10-ml vial, 80 IU/ml in 10-ml vial

18.5 Oral Contraceptives

ethinylestradiol + levonorgestrel (1)		tablet, 0.03 mg + 0.15 mg, 0.05 mg + 0.25 mg
ethinylestradiol + norethisterone (1)		tablet, 0.05 mg + 1.0 mg
	norethisterone (B)	tablet, 0.35 mg

18.6 Progestogens

norethisterone (1)		tablet, 5 mg

18.7 Thyroid Hormones and Antagonists

levothyroxine		tablet, 0.05mg, 0.1mg (sodium salt)
potassium iodide		tablet, 60 mg
propylthiouracil (1)		tablet, 50 mg

.....13.

Main list	Complementary Drugs	Route of administration, pharmaceutical forms & strengths

18.8 Ovulation Inducer

clomifene (c)(2,8)	tablet, 50 mg (citrate)

19. IMMUNOLOGICALS

19.1 Sera and Immunoglobulins

anti-D immunoglobulin (human)	injection, 0.25 mg/ml
antirabies hyperimmune serum	injection, 1000 IU in 5-ml ampoule
antivenom sera	injection
diphtheria antitoxin	injection, 10000 IU, 20000 IU in vial
immunoglobulin, human normal (2)	injection
tetanus antitoxin	injection, 50 000 IU in vial

19.2 Vaccines

19.2.1 For Universal Immunization

BCG vaccine (dried)	injection	All vaccines should comply with the WHO requirements for Biological substances *
diphtheria-pertussis-tetanus vaccine	injection	
diphtheria-tetanus vaccine	injection	
measles vaccine	injection	
poliomyelitis vaccine (live attenuated)	oral solution	
smallpox vaccine	multiple puncture	
tetanus vaccine	injection	

19.2.2 For Specific Groups of Individuals

influenza vaccine	injection
meningococcal vaccine	injection
rabies vaccine	injection
typhoid vaccine	injection
yellow fever vaccine	

20. MUSCLE RELAXANTS (PERIPHERALLY ACTING) & CHOLINESTERASE INHIBITORS

neostigmine (1)	tablet, 15 mg (bromide)
	injection, 0.5 mg (metilsulfate) in 1-ml ampoule
suxamethonium (2)	injection, 50 mg (chloride)/ml in 2-ml ampoule

* Requirements for specific vaccines and their standards are available in various WHO Technical Reports, available on request from the WHO, Geneva.

....14.

Main list	Complementary drugs	Route of administration pharmaceutical forms and strengths
tubocurarine (1,2)		injection, 10 mg (chloride)/ml in 1.5-ml ampoule
	pyridostigmine (B)(2,8)	tablet, 60 mg (bromide)
		injection, 1 mg (bromide) in 1-ml ampoule
21. OPHTHALMOLOGICAL PREPARATIONS		
21.1 Antiinfective		
silver nitrate		solution (eye drops) 1%
sulfacetamide		eye ointment, 10% (sodium salt)
		solution (eye drops), 10% (sodium salt)
		eye ointment, 1% (hydrochloride)
21.2 Antiinflammatory		
hydrocortisone (2, 7)		eye ointment, 1% (acetate)
21.3 Local Anaesthetics		
tetracaine (1)		solution (eye drops), 0.5% hydrochloride)
21.4 Miotics		
pilocarpine		solution (eye drops), 2%, 4% (hydrochloride or nitrate)
21.5 Mydriatics		
homatropine (1)		solution (eye drops), 2% (hydrobromide)
	epinephrine (A,B)(2)	solution (eye drops),2% [illegible] (as hydrochloride)
21.6 Systemic		
acetazolamide		tablet, 250 mg
22. OXYTOCICS		
ergometrine (1)		tablet, 0.2 mg (maleate)
		injection, 0.2 mg (maleate) in 1-ml ampoule
oxytocin		injection, 10 IU in 1-ml ampoule
23. PERITONEAL DIALYSIS SOLUTION		
intraperitoneal dialysis solution (of appropriate composition)		parenteral solution

.....15.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths

24. PSYCHOTHERAPEUTIC DRUGS

amitriptyline (1)		tablet, 25 mg (hydrochloride)
chlorpromazine (1)		tablet, 100 mg (hydrochloride)
		syrup, 25 mg (hydrochloride)/ 5 ml
		injection, 25 mg (hydrochloride)/ml in 2-ml ampoule
diazepam (1)		tablet, 5 mg
fluphenazine (1, 5)		injection, 25 mg (decanoate or enantate) in 1-ml ampoule
haloperidol (1)		tablet, 2 mg
		injectio, 5 mg in 1-ml ampoule
lithium carbonate (2,4,7)		capsule or tablet, 300 mg

25. RESPIRATORY TRACT, DRUGS ACTING ON THE

25.1 Antiasthmatic Drugs

aminophylline (1)		tablet, 200 mg
		injection, 25 mg/ml in 10-ml ampoule
epinephrine		injection, 1 mg (as hydrochloride) in 1-ml ampoule
salbutamol (1)		tablet, 4 mg (sulfate)
		oral inhalation (aerosol), 0,1 mg (sulfate) per dose
		syrup, 2 mg (sulfate)/ 5 ml
	beclometasone (B) (8)	oral inhalation (aerosol), 0.05 mg (dipropionate) per dose
	cromoglicic acid (B) (2, 8)	oral inhalation (cartridge), 20 mg (sodium salt) per dose
	ephedrine (A)	tablet, 30 mg (as hydrochloride)
		elixir, 15 mg (as hydrochloride)/5 ml
		injection, 50 mg (sulfate) in 1-ml ampoule.

25.2 Antitussives

codeine (10)	tablet, 10 mg (phosphate)

26. SOLUTIONS CORRECTING WATER, ELECTROLYTE AND ACID-BASE DISTURBANCES

26.1 Oral

oral rehydration salts (for glucose-salt solution)	for composition, see 17.6.2 replacement solution
potassium chloride	oral solution

26.2 Parenteral

compound solution of sodium lactate	injectable solution

....16.

Main list	Complementary drugs	Route of administration, pharmaceutical forms and strengths
glucose		injectable solution, 5% isotonic , 50% hypertonic
glucose with sodium chloride		injectable solution, 4% glucose, 0.18% sodium chloride (Na^+ 30 mmol, CL^- 30 mmol/l)
potassium chloride		injectable solution
sodium bicarbonate		injectable solution, 1.4% isotonic (Na^+ 167 mmol/l, HCO_3^- 167 mmol/l)
sodium chloride		injectable solution, 0.9% isotonic (Na^+ 154 mmol/l, CL^- 154 mmol/l)
water for injection		in 2-ml, 5-ml, 10-ml ampoules

27. SURGICAL DISINFECTANTS

chlorhexidine (1)		solution, 5% (gluconate) for dilution
iodine (1)		solution, 2.5%

28. VITAMINS AND MINERALS

ascorbic acid		tablet, 50 mg
ergocalciferol (1)		capsule or tablet, 1.25 mg (50000 IU)
		oral solution, 0.25 mg/ml (10000 IU)
nicotinamide (1)		tablet, 50 mg
pyridoxine		tablet, 25 mg (hydrochloride)
retinol		capsule or tablet, 7.5 mg (25000 IU), 60 mg (200000 IU)*
		oral solution, 15 mg/ml (50000 IU)
riboflavin		tablet, 5 mg
sodium fluoride		tablet, 1.1 mg
thiamine		tablet, 50 mg (hydrochloride)
	calcium gluconate (c) (2,8)	injection, 100 mg/ml in 10-ml ampoule

*For use in the treatment of xerophthalmia with a single dose, not to be repeated before 4 months have elapsed.

.....17.

A handout prepared as guidelines for exploration of the theme with the participants of the Health Care Administration Course at St. John's Medical College Hospital, Bangalore.

A Rational Drug Policy (issues and prospects)

1. "Eternal vigilance is required to ensure that the health care system does not get medicalised, that the doctor-drug producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill-health".

- ICMR/ICSSR Health for All Report, 1981

2. Understanding Irrationalities of the present situation

i. 45000 formulations available in India while WHO says 200 are essential and Hathi Committee in India says 116 are essential.

ii. Twenty percent of drugs are substandard and spurious.

iii. The formulations available include:
- irrational combinations
- hazardous drugs
- banned drugs and bannable drugs
- costly drugs

iv. Inadequate drug legislation and drug control

v. Shortages and non-availability of essential drugs and life saving drugs

vi. Non-availability of unbiassed drug information.

vii. Unethical medical advertising and drug company sponsored mis-information.

viii. Irrational prescribing practices of medical profession induced by doctor-drug producer axis

ix. Tonics, vitamins and enzymes are in excess whereas anti-TB and anti-leprosy drugs and Vit. A are in short supply.

x. Drug policy is an industrial policy not a health policy.

xi. Increasing prices or inadequate price control.

xii. Drugs as a substitute for caring - new medical culture.

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3. Some issues

a. Brand vs. Generic names

b. Drug/business - dumping
transfer pricing
profit orientation
mis-information
corrupting control systems
doctor-drug producer axis

(one of the biggest and most profitable business in the world today)

c. Inadequacies in Medical/Nursing education and health team training

d. Consumer Awareness/consumer protection forums

e. Absence of health personnel's continuing education

f. Floor moppers to Tap turners off
- the increasing role of preventive/promotive health care.

4. Components of a Rational Drug Policy

i. Drug availability/production in consonance with health needs of the people.

ii. Elimination of irrational, useless and hazardous drugs

iii. Low cost drugs in adequate quantities particularly essential/priority drugs.

iv. Adequate quality control and drug control.

v. Availability of unbiassed drug information and ethical marketing of drugs.

vi. Drug legislation reform

vii. Generic prescribing.

viii. Technological self reliance.

ix. Increase drug availability through fair price shops and government health infrastructure.

x. Training of health personnel in Rational therapeutics and rational drug policy.

5. What can Managers of Hospitals do?

i. Educate yourselves on rational drug policy and rational therapeutic issues.

ii. Share and disseminate information to all staff and colleagues in hospital and associated centres.

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iii. Adopt essential drug list using cost, efficacy, safety and quality as criteria. Evolve a hospital formulary and purchase and stock drugs in accordance with this.

iv. Adopt 'generic' concept during purchasing, prescribing and dispensing drugs.

v. Weed out the following types of drugs from the hospital pharmacy:

a. banned and bannable drugs

b. irrational combinations

c. imitative or me-too drugs

d. costly drugs with cosmetic embellishments and elegant packaging.

e. drugs with inadequate evidence of greater value.

vi. Avoid injection and tonic practice.

vii. Avoid drug industry linkages - gifts, sponsorship, unethical trade discounts and other forms of inducement.

viii. Adopt bulk purchasing and or supports co-operative purchasing and production ventures.

ix. Evolve a system of health education on drugs (use, misuse and overuse) for patients and also a continuing education for hospital personnel.

x. Join and participate in groups at local/regional/state/national level who are interested in rational therapeutics/rational drug policy/consumer awareness issues.

xi. Seek information on other forms of treatment. Adopt open policy to rationally tested non-allopathic systems and non-drug therapies and incorporate in work.

xii. Promote 'Health for All' priorities:

a. simple home remedies;

b. health education;

c. community health initiatives;

d. development programme;

e. community organization and awareness pro

6. Suggestions for Reading

1. A Rational Drug Policy (All India Drug Action Network and Voluntary Health Association of India publication, Rs. 20)

2. Banned and Bannable drugs. Health Action Series 2, VHAI publication, Rs.10.

3. Towards a People Oriented Drug Policy (Medical Service, Vol. 41, No. 9, Oct.-Nov. 1984 and Vol. 42, No. 1, January 1985, CHAI)

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4. Drugs-Fact, Fallacy and Fraud, (The Journal of Christian Medical Association of India, Vol. LX, September 1983, No. 9)

5. Getting Essential Drugs to People (CONTACT, No. 63, August 1981)

6. Strengthening & Regulating the Supply, Distribution and Production of Basic Pharmaceutical Products (CONTACT, No. 73, June 1983)

7. The Use of Essential Drugs, WHO Tech Report Series 722 (1988)

8. Tonics, How Much an Economic Waste, Kamala Jaya Rao, Medico Friend circle bulletin, November 1976.

9. The Dangerous Drug List, Claude Alvares, Illustrated Weekly of India, 12 July 1987.

10. Formulary and Therapeutic Guide, Kurji Holy Family Hospital, January 1983.

Items 1, 2, 7, 8, 10 available from VHAI, 40 Institutional Area, South of IIT, New Delhi 110016.

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41st Annual Convention of the Catholic Hospital Association of India

Workshop on: TOWARDS A PEOPLE-ORIENTED DRUG POLICY

23-25 November 1984 : St John's Medical College and Hospital

Objectives

WHAT IS THE PROBLEM

1. To create an awareness of
   a. the health situation in India
   b. the role of drugs in health care
   c. the pattern of drug production in India vis a vis the people's health needs
   d. the dynamics of the drug industry
   e. the patterns of drug distribution/availability in the health system
   f. the national drug policies and laws.
2. To create an awareness of the growing -
   a. irrational use
   b. over use
   c. misuse of drugs by health personnel
3. To look at the above issues within the context of the CHURCH HEALTH SERVICES
4. To try and understand the problem from the people's point of view.

HOW/WHY THE PROBLEM?

5. At the broader level to discover the social, economic, political, cultural and other factors responsible for this problem.
6. At personal level to discover how all of us are part of the problem atthe individual and the institutional levels.

WHAT TO DO TO TACKLE THE PROBLEM?

7. To consider the various responses at the national/international levels by groups/institutions/governments in the areas of -
   a. consumer awareness and people's movements
   b. continuing professional education
   c. pressure groups on policy makers

p.t.o...2

d. search for low cost alternatives
e. individual/group action
f. institutional policy changes

8. To discuss ways and means by which participants can respond to this problem at-

a. individual
b. institutional and
c. regional/national levels

and identify ways and means by which follow up action will be taken in this growing commitment.

PROGRAM — Preparatory Workshop for Faciliation Team

11.00 am — 17th November 1984
St John's Medical College, Bangalore

11.00 am — Introduction of team/theme and details of the programme

11.20 am — Group discussion:

a. What are the different dimensions of the drug policy and prescribing issues in India?

b. What information would we like to have to further understand and analyse this problem?

12.40 p.m. — Plenary session:

Listing out what we would like to know

1.00 plm. — LUNCH

2.00 p.m. — Information check list

3.30 p.m. — Tea

4.00 p.m. — Planning the group discussion and the facilitation

5.00 p.m. — Video presentation on the theme.

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DRUG ISSUES

Information check list

A. Drug Industry

Output	Profits
Type	Pattern of production
Structure	Drug Policy
Prices	Quality control
Research and Development	Consumption of Drugs

B. Drug Policy Issues (Problems)

Plethora of formulations	Mark up
Brand names	Net worth returns
Fixed drug combinations	Transfer pricing
Bio-availability argument	Sales promotion
Dumping	Samples
Me-too drugs	Advertising
Drug controls	

C. Drug Policy Issues (solving Problems)

Essential drug list	Formulary (level of use)
Generic prescribing	Bulk Drug formulation
Price control	Bulk purchasing
Labelling	Quality control
Low cost production	Cooperatives
Herbal gardens	Pharmaceutical code
Physicians code	Counter advertising
[illegible]	Consumer Awareness

D. Drug Laws/Policies/Reports

Drugs and cosmetics Act	Drugs & Magic Remedies Act
The Pharmacy Act	Hathi Committee Report

p.t.o.4

National Drug Policy	Drug Price Control Orders
Health for All Report	Govt. Ban of 22 drugs

E. Irrational Drug use/prescribing types

Types

Extravagant	Overprescribing
Incorrect	Multiple
Under-prescribing	

Causes

Inadequate basic training	Lack of continuing education
Lack of supervision	Inappropriate desire for p prestige
Drug company sales promotion	Drug company misinformation
Heavy patient load	Patient presssure
Panic/fear [illegible] induced prescription	Incorrect generalisations
Lack of patient awareness	Doctor-Drug producer axis

F. Problem Drugs

Specific

Analgin	Amidopyrin
Ancoloxin	Bromides
Chloral hydrate	Cloquinols
Dipyrone	E-P Forte
Ergot	Gripe water
Kaolin	Lomotil
Methapyrilene	Nialamide
Oxyphenbutazone	Phenylbutazone
Phenacetin	Practolol
Penicillin	Quinine
Sulphonamides	Strychnine
Yohembine	

Groups

Antibiotic combinations	Anabolic steroids
Analgesics	Antidiarrhoeals
Enzymes	Fixed dose combinations
Placebos	Steroids
OTC Drugs	Unani/Ayurvedic drugs

G. Church Health Services (context)

Institutional response	New vision/option
Community response	Humanisation
Holistic healing	Issues of social justice

H. People's Point of view

Availability	Accessibility
Cost	Cross-cultural conflicts
Mystique of injections	Communication failures
Self prescribing	Low cost home remedies

I. Initiatives

Meetings and workshops	Newsletters/bulletins
Books/journals	Professional awareness
Continuing education	Consumer awareness
Signature campaign	Memorandum to policy makers
Public interest litigation	Low cost drug production
Bulk/central purchasing	Cooperatives
Herbal gardens	Formularies
--	Codes

J. Case studies

Bangladesh Ban	Vincent's Case
Operation Medicine	Ankuran
VHAI Cell	KSSP
Drug Action Network	Lok Vidnyan Sanghatana
IOCU HAI	LOCOST
Social Audit	Bangarapet Tablet Industry
mfc Rational Drug Policy Cell	Kurji formulary
	State Forum (AP/WB)

Med Service
Nov-84.

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mfc ms

THE DRUG INDUSTRY IN INDIA

What our experts say.

THE INDUSTRY

The total output of the industry increased hundredfold - from Rs.100 million in 1947 to Rs.10,500 million in 1978-79. This was due to expanded production, especially of an ever-increasing number of sophisticated drugs, and rising prices.....

The drug industry has enjoyed a higher man-average profitability so that investment therein has increased substantially from Rs.240 million in 1952 to Rs.4,500 million in 1977.

There are about 125 large and medium factories and nearly 3,000 small scale sector units engaged in this industry which provides employment to about 100,000 workers.

PATTERN OF DRUG PRODUCTION

There is now an overproduction of drugs (often very costly) meant for the rich and the well-to-do while the drugs needed by the poor people (and these must be cheap) are not adequately available. This skewed pattern of drug production is in keeping with our inequitous social structure which stresses the production of luxury goods for the rich at the cost of the basic needs of the poor.

Out of a total production of Rs.700 crores in 1976, 25 percent is taken away by vitamins, tonics, health restoratives and enzyme digestants, mostly consumed by the relatively well-fed urban population. Twenty percent is covered by antibiotics, only 1.3 percent by sulphonamides

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(a very cheap and useful anti-infective) and 1.4 percent by anti-tuberculosis drugs.....

PATTERN OF PRESCRIBING

One of the most distressing aspects of the present health situation in India is the habit of doctors to over-prescribe glamorous and costly drugs with limited medical potential. It is also unfortunate that the drug producers always try to push doctors into using their products by all means--fair or foul. These basic facts are more responsible for distortions in drug production and consumption than anything else.

STRUCTURE OF THE INDUSTRY

The existing drug policy rightly emphasises the attainment of self-sufficiency in the production of drugs, in increasing the share of the Indian producers and in giving a more significant role to public sector.

The foreign companies account for about 40 percent of the total drug production in the country; their share in the production of basic drugs was about 28 percent and that in formulations, 44 percent (1978-79). This is still high.

PRICE CONTROL

The drug prices are high and continue to rise. In some instances, Indian prices are even higher than the international ones.

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....

There may indeed be a glut of applications for the introduction of 'Me-too Drugs' which will not attract new legislation for

another five years in regard to price control.....

Genuine 'breakthrough' research has declined in recent times.

Existing prices of drugs including those of essential drugs of everyday use is highly inflated. For example, the cost of analgin sold over the counter is 30 times the cost of production.

Prices are often inflated by the use of brand names.....

Very often, prolonged controversy over the price of a drug has resulted in stopping its production.

The bill for import of bulk drugs, intermediates, solvents etc., has jumped from Rs.53.77 crores in 1976-77 to about Rs.119 crores in 1979-80.

QUALITY CONTROL

The standards prescribed are unrealistic...are mechanically copied from books.... and not uniformly enforced in all parts of the country.

CONSUMPTION OF DRUGS

At present the supplies of drugs to urban and rural institutions within the health care system is very uneven. In an urban hospital, for instance, the drug cost is Rs.6 per patient per year while in a Primary Health Centre, it is about 40 paise per patient per year.....

AN OVERVIEW

We recognise the value and significance of drugs in the health care system. We fully support the policy that all the essential drugs should be produced in the country, preferably in the Indian sector, and that they should be made available to the people at reasonable prices. To realize these objectives, it is essential to lay down and vigorously implement a national drug policy which will ensure that the pattern of drug production in the country (barring drugs meant for export) should be geared to its actual needs. While the supply of drugs should be adequate, eternal vigilance is required to ensure that the health care system does not get medicalized, that the doctor-drug-producer axis does not exploit the people, and that the 'abundance' of drugs does not become a vested interest in ill-health.

Source:
Health for All - An alternative Strategy :: report of a study group set up jointly by the Indian Council of Social Science Research (ICSSR) and the Indian Council of Medical Research (ICMR).

DRUG COMPANY SPONSORED MISINFORMATION OF DOCTORS.

In countries with less well-organized drug control mechanisms, studies have shown that the same drug manufactured by the same multinational company is sold for more indications

with less contra-indications

less side effects

as compared to the information provided in U.S.A.

The following example of two drugs bears this out only too well.

IFTHERE ARE NO SIDE EFFECTS, THIS MUST BE ARGENTINA

Drug: Tetracycline (Antibiotic used against various infections; Lederle Laboratories)

	Caution Against Use (1)	Adverse reactions publicized (2)
U.S.A.	By infants, children; during pregnancy: Liver or kidney impairement (latter can be fatal) or if overly sensitive to light.	Vomiting, diarrhoea, nausea, stomach upset, rashes, kidney poisoning, can poison fetus.
MEXICO	By infants, children; during pregnancy or if overly sensitive to light.	Vomiting, diarrhoea, nausea, stomach upset.
BRAZIL	By infants, children, during pregnancy.	Vomiting, nausea, stomach upset, rashes.
ARGENTINA	None	None

Drug: Ovulen (birth control pills: GD Searle Co.) in US used for contraception only. In some Latin countries, Searle recommends it also for regulating menstrual cycles, premenstrual tension, menopausal problems.

	Caution against use	Adverse reactions publicized
U.S.A.	If patient has tendency to blood clot, liver dysfunction, abnormal vaginal bleeding, epilepsy, migrain, asthma, heart problem.	Nausea, loss of hair, nervousness, jaundice, high blood pressure, weight change, headaches.
MEXICO	If patient has tendency to blood clot, liver dysfunction.	Nausea, weight change.
BRAZIL	If patient has tendency to blood clot.	None
ARGENTINA	If patient has tendency to blood clot.	None

(Taken from the Mother Jones, Courtesy--Health and Society, also mfc bulletin 73-4, Jan-Feb 1982).

Drug : IMIPRAMINE (Anti-depressant, Ciba Geigy)

In U.S. used for depression only. In some Latin American countries, Ciba Geigy recommends it also for senility, chronic pain and alcoholism

	Caution against use	Adverse reactions publicized
U.S.A	If patient has heart disease, history of urinary retention, history of seizures, manic disorder or is on typhoid medication. Not recommended for children or during pregnancy.	Hypertension, stroke, stumbling, delusions, insomnia numbness, dry mouth, blurred vision, constipation, itching, nausea, vomiting, loss of appetite, diarrhea
MEXICO	During first trimester of pregnancy	Dry mouth, constipation, itching, [redacted] sweating
BRAZIL	If patient has heart disease; not recommended for children or during pregnancy	None
ARGENTINA	May exaggerate response to alcohol	None

(Taken from the Mother Jones, Courtesy--Health and Society, also mfc bulletin 73-4, Jan-Feb 1982.)

What Can We Do?

1. Educate ourselves — We should make an effort to availourselves of all the available materials on drugs. We should purchase some of the books and subscribe to some of the journals and bulletins mentioned in 'widening horizons' to keep ourselves upto date.

2. Share and Disseminate information — We should circulate all the information and resources to all our staff and to other colleagues and centres through all possible channels of communication. We could share our own initiatives and experiences.

3. Adopt essential drug list — We should draw up an essential list for our institution in which cost, efficacy, safety and quality will be important criteria (refer to WHO's suggested list)
We could purchase and stock drugs in accordance with this list.

4. Adopt generic prescribing — We could use/adopt the generic drug concept during purchasing, prescribing or dispensing drugs.

5. Stop Irrational prescribing — Could stop prescribing drugs whose only advertised values are :-
   a. cosmetic embellishments
   b. elegant packing
   c. irrational combinations
   d. imitative drugs

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e. inadequate evidence of greater value

We could weed out 'banned drugs' as well as restricted drugs.

We could stop 'injection and tonic' practice.

6. Avoid Drug Industry Linkages

We could refuse to take gifts and physician samples

We could avoid allowing drug companies to sponsor events/meetings

We could beware of unethical trade discounts or other forms of inducement

7. Adopt Rational Drug Purchase

We could adopt bulk purchasing

Support cooperative purchasing or production endeavours

Produce drugs in your hospitals/dispensaries.

8. Adopt open policy to non-allopathic systems and non-drug therapies

We should be open to other forms of treatment

Seek information and be willing to incorporate it in our work

Share our experience with others

Send our staff for training in these forms of treatment if necessary.

9. Support networks/ organization/ consumer movements taking up drug issues.

Find out about all such groups at local, regional, state level or national level

Support and participate in their activities.

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10. Promote 'Health for all' priorities.

We should actively promote the following in our work:

a. simple home remedies
b. herbal remedies and herbal gardens
c. health education and patient awareness
d. training of village level workers
e. community health initiatives
f. development programmes
g. awareness building.

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often receive no information at all. In Mexico, for example, upto 70% of prescription drugs are sold without prescription. Yet the packaging of these medicines generally contains no information about use, dosage, or risks.

8. Health Workers not adequately informed. In spite of the tremendous amount of self-medication in most countries, many programs still do not teach health workers much about the use - or misuse - of commonly self-prescribed medicines. As a result, many health workers to meet popular demand, secretly purchase and administer a wide range of medicines they know little about.

9. Use of medicine to gain prestige and power. Another reason for medicine overuse is that many professionals use their ability to medicate as a sort of magic to make people grateful and dependent. This way they gain special privilege and power. In the same way, health workers may be tempted to give injections or expensive drugs when home remedies or kindly advice would cost less and do more good.

From Helping Health Workers Learn

- David Werner and Bill Bower

mfc ms

Some reasons for widespread misuse and overuse of medicines.

HEALTH WORKERS SHOULD DISCUSS THESE FACTS
AND HELP MAKE EVERYONE AWARE OF THEM

1. Big business. The production and marketing of modern medicines is one of the biggest, most profitable businesses in the world. Drug companies are continually inventing new products to increase their sales and profits. Some of these medicines are useful. But 1 atleast 90% of medicines on the market today are unnecessary. Doctors prescribe them and people buy them, because the drug companies spend millions on advertising.

2. False advertising. Especially in poor countries, much of the advertising, and even the information published in 'pharmaceutical indexes', is misleading or false. Information on dangerous side effects is often not included. Risky medicines are frequently recommended for illnesses less dangerous than the medicines. (For example chloramphenicol has often been advertised as a treatment for minor diarrhea and respiratory infections).

3. Dumping. Drug companies in wealthy countries sometimes produce medicines that do not sell well in their homelands. Or the use of certain medicines is restricted or prohibited because they have been proved unsafe. It is a common practice for drug companies to 'dump' these medicines on poor countries--often with a great deal of false advertising. For example, several years ago the U.S. government restricted the use of Lincocin (lincomycin) because it proved more dangerous, more costly, and generally less effective than penicillin. The following year, thanks to massive advertising, Lincocin became the best selling drug in Mexico!

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4. Lack of adequate controls. Poor countries, especially, have inadequate laws controlling the production and sale of medicines. As a result, many poor countries sell up to 3 times as many different medicines as rich countries do. Most of these medicines are a waste of money. Many are completely unreasonable combinations of drugs, yet they are widely prescribed by doctors. For example, in both Latin America and Asia, a popular injectable medicine is tetracycline combined with chloramphenicol. This is a senseless combination because the two drugs are 'incompatible' and should never be used together.

5. Bribes and corruption. Drug companies in rich countries pay millions in bribes to officials in poor countries so that governments will buy their products. (A major US pharmaceutical company recently admitted to having spent millions of dollars on bribes to advance its products in poor countries.)

6. Sale of prescription medicines without prescriptions. This is common in many countries (partly because poor people cannot afford doctors' fees). Most people who 'self-medicate' try to use the medicines well, so they follow the patterns set by doctors. Unfortunately, this often leads to incorrect use. For example, in Latin America atleast 95% of doctors' prescriptions for Vitamin B_{12} injections are among the most widely used self-prescribed medicines in Latin America--at a cost of millions to a people too poor to eat well!

7. People not adequately informed. Neither doctors nor the people are adequately informed about the correct use of medicines. Most doctors rely on the information given in misleading 'blurbs' supplied with sample medicines, while villagers who self-prescribe

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IRRATIONAL DRUG ~~USE~~ PRESCRIBING

Type of Irrational Drug Use	Occurs if a drug is prescribed when:
Extravagant Prescribing	* a less expensive drug would provide comparable efficacy and safety * symptomatic treatment of mild conditions diverts funds from treating serious illness * a brand name is used where less expensive equivalents are available
Over-prescribing	* the drug is not needed * the dose is too large * the tr atment period is too long * the quantity dispensed is too great for the current course of treatment
Incorrect prescribing	* the drug is given for an incorrect diagnosis * the wrong drug is selected for the indication * the prescription is prepared improperly * adjustments are not made for co-existing medical, genetic, environmental, or other factors
Multiple Prescribing	* two or more medications are used when one or two would achieve virtually the same effect * several related conditions are treated when treatment of the primary condition will improve or cure the other conditions
Under-prescribing	* needed medications are not prescribed * dosage is inadequate * length of treatment is too brief

From MANAGING DRUG SUPPLY, Management Sciences for Health, Boston, Massachusetts, USA.

IRRATIONAL DRUG USE -- CAUSES

In brief, the main causes identified by those who have studied prescribing behavior are the following:

1. Inadequate training in clinical pharmacology - Despite the daily use of medicines in clinical practice, formal training in drug use is usually brief and often limited to the early part of medical training.

2. Lack of continuing education and supervision - For the medical auxiliary as well as the practicing physician, there is usually little opportunity for regular review of their prescribing habits. In addition, there are few opportunities for them to learn about new drugs from unbiased sources.

3. The practitioner's inappropriate desire for prestige - In some areas a "good doctor" is expected to use many different drugs and prescription of multiple drugs is falsely considered a sign of good care.

4. Promotional activities of drug company representatives - The role of commercial interests in promoting irrational and costly prescribing has been well documented and nn cannot be over-emphasized. Even where the choice of drugs is limited by centralized purchasing, company representatives frequently promote overuse of drugs.

5. Lack of time due to heavy patient load - Medications are often given out to help end a patient visit, or prescribed "just in case", to avoid a return visit.

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6. Pressure from patients - Even in the most remote areas, patients quickly come to expect that every symptom has a medicine to cure it. Because patient education can be slow, time-consuming, and tiring, practitioners often give in to the request for medicines.

7. Fear-induced prescription - Diagnoses are rarely made with absolute certainty and the course of an illness cannot be predicted exactly. Medical practitioners often try to "protect" themselves against this uncertainty by extravagant, multiple, or overprescribing.

8. Incorrect generalization about a drug from limited experience - Unexpectedly favourable results or unfavourable side effects are sometimes seen with the use of a drug. Although these results may be totally unrelated to the drug, practitioners may over-react and, depending on the result, later overprescribe or underprescribe on the basis of this anecdotal information, rather than on the basis of scientific evidence.

From MANAGING DRUG SUPPLY, Management Sciences for Health, Boston, Massachusetts, USA.

Drug Utilisation Survey Report

This survey was conducted by the National Institute of Nutrition (NIN) in cooperation with the Directorate of Drug Control Administration and AP Chemists and Druggists Association, Hyderabad in the twin cities of Hyderabad and Secunderabad covering 10% of the 330 retail pharmaceutical shops.

Some of the findings of the survey are as follows:

- self medication rate was an alarming 46%.
- 27% of the doctors' prescriptions were for 3 to 4 drugs Only 4.3% of prescriptions were for more than 4 drugs.
- the maximum number of prescriptions were for Nutritional Products (tonics, enzymatic preparations and vitamins), then antiinfectives (antibiotics and sulfas) and then analgesics.
- 58% of the self medicated drugs were schedule 'L' and 'H' drugs which cannot be sold without prescription, nor should be consumed without medical supervision, because of the associated major side effects and toxicity.
- amongst self administered drugs analgesics, nutritional products and antibiotics topped the list.

Analgesics, antipyretics and anti-inflammatory drugs:

- 30.2% of the self prescribed analgesics, antipyretics and anti-inflammatory agents were scheduled drugs. These were mainly analgin, phenylbutazone (with or without corticosteroids) and ibuprofen.
- an earlier survey by the CERF (Consumer Education and Research Centre, Ahmedabad) had shown that of 13 over-the-counter brands of these drugs, 11 did not provide any information. The 44 doctors interviewed reported seeing on an average 8 to 10 cases of drug

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drug poisoning per month.

Vitamins and Tonics:

- only 31% persons surveyed had a correct concept regarding nutritional supplements. The majority held the erroneous view that daily consumption of tonics was essential for health. The credit for this false belief goes to advertising pressure as well as doctors' prescription practices.
- 16% of the doctors had prescribed simultaneously more than one vitamin preparation having the same ingredientsin various dosage forms.
- iron deficiency anemia, B2 deficiency, were the commonest deficiencies in the population but sales of B Complex (B1, B2, B6 B12) combinations and other vitamins topped the list of sales figures.

Antibiotics:

- over 30% of the doctors' prescriptions contained antibiotics.
- approximately 12.8% of self-prescribed drugs were antibiotics.
- most antibiotic prescriptions were for sulfa and trimethoprim combinations, tetracyclines and penicillin, in that order.
- tetracycline, sulfa-trimethoprim and penicillin were the most popular self-prescribed drugs.
- 30% of the antibiotics purchased for self medication were for less than a day. Only 18% were purchased for a full course of five days. Only 40% of prescriptions for antibiotics were bought for five days.

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The findings of the NIN and CERC surveys indicate the urgent need for public education where disease and drugs are concerned.

Source: The Drug Action network: Newsletter of the Low Cost Drugs and Rational Therapeutics Cell, VHAI, New Delhi.

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 (funguis 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 diarrhoea. 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

41st ANNUAL CONVENTION

CATHOLIC HOSPITAL ASSOCIATION OF INDIA

23-26 NOVEMBER 1984

WORKSHOP THEME:

towards a people-oriented drug policy

'Eternal vigilance is required to ensure that the health system does not get medicalised, that the doctor-drug producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill-health'.

---ICMR/ICSSR Health for All Report.

Venue: ST JOHN'S MEDICAL COLLEGE, BANGALORE 560034

SIGNIFICANCE OF THE THEME

THE Workshop is to help participants understand the issues relevant to drug prescribing, drug distribution and pharmacy policy in our institutions in the context of the ICMR/ICSSR warning and to challenge them to participate in the growing national response to the problem.

WHAT does the 'abundance of drugs' mean to the millions of the poor in our country who struggle in life to make both ends meet? Can they ever have access to the modern health care system which has become a business today, rather than remaining at the service of humanity at large? Do they have essential and life saving drugs at their reach within a price range they can afford?

IS our drug policy today more profession-oriented, drug industry-oriented rather than patient-oriented? Whose interests are we serving in our institutions?

HOW can we move towards a more people and patient-oriented drug policy?

THESE are some of the QUESTIONS which we shall respond to in our Workshop.

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"Community Health is a process of enabling people to exercise collectively their responsibilities to maintain their health and to demand health as their right. Thus it is beyond mere distribution of medicines, prevention of sickness, and income generating programmes".

--CHAI new vision

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OBJECTIVES

1. TO CREATE AN AWARENESS OF:-

   the health situation in India, the role of drugs in health care, the pattern of drug production in India vis-a-vis the people's health needs, the dynamics of the drug industry, the pattern of drug distribution and availability in the health system, the national drug policies and laws.

2. TO CREATE AN AWARENESS OF:-

   irrational use, over use and misuse of drugs by health personnel.

3. TO DISCOVER

   the social, economic, political, cultural and other factors responsible for this problem.

4. TO DISCOVER

   how all of us are part of the problem at a personal level.

5. TO CONSIDER

   the various responses at national/regional levels in the areas of :-- consumer awareness and people's movements; continuing professional education; pressure group on policy makers; search for low cost alternatives; individual/group action; institutional policy changes.

6. TO DISCOVER

   ways and means by which we can respond to this situation at individual, institutional and regional/national levels.

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PROGRAMME HIGHLIGHTS

Sessions on:

Understanding the problem
Drugs and the healing ministry
Towards rational therapeutics
What to do to tackle the problem
Some initiatives in the country
The people's medicine

Group discussions on:

What/why the problem in our health institutions?
What can we do to tackle this problem?

Liturgy

Reflecting on our calling and the faith dimension of our response

Exhibition on:

Socio-political dimensions of Health and Drugs
Rational Drug Therapy
Home remedies and Herbal medicines

Studies on:

Drugs for a Community Health Center
Understanding the injection/tonic culture
Use/misuse of drugs in surgery
Drug situation in small rurel hospitals
Cost of treatment

Cultural Programme

Understanding the problem from the poor man's point of view.

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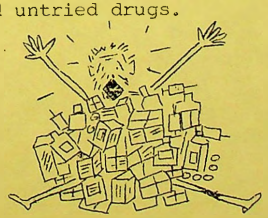
SYNOPSIS OF PAPERS

Drugs for Primary Health Care (C M Francis)

An integral part of our commitment to primary health care is the provision of essential drugs to all those who need them, in adequate quantity and quality and at affordable prices wherever the person is. The various aspects of the drug problem needing our attention include production, what drugs are required, choice of drugs, National Drug Policy, selection of drugs, drug production and procurement, logistics of supply, quality control, regulating the drug trade, drugs for immunization, drugs for cure, drugs for symptomatic relief, search for new drugs, drug information and the need for evaluation of the efficacy of primary health care including drugs.

The Ten Commandments of the Drug Industry (Augustine Veliath)

1. Thou shalt have tens of thousands of drugs
2. Thou shalt not question the price of a drug
3. Thou shalt not tamper with nature's garden
4. Thou shalt respect they doctor more than thyself
5. Thou shalt betray thy people and thy nation for petty rewards
6. Thou shalt not covet, court, or subscribe to any other system of medicine
7. Thou shalt never reveal company secrets
8. Thou shall first seek remedies for fashionable ailments
9. Thou shalt be a dumping ground for banned drugs
10. Thou shalt be a guinea pig for new and untried drugs.



The Ethics of Prescribing (George Lobo, sj)

Discusses reasons for the unfortunate situation related to drugs prevalent today, viz., technological model of health care leading to manipulation of the patient, search and demand for instantaneous cure of symptoms, mystification of medicine, profit motive and 'free enterprise' of the pharmaceutical industry, a deep rooted cultural alienation from the people, exploitation of dependent developing countries, decreasing emphasis being given to preventive medicine and other systems of medicine.

The use of drugs should be regulated by the principles of totality (overall good of the patient) and of double effect (the good effect overriding any harmful effect). It suggests remedies for the development of a person-centred and holistic approach to health care.

Professionals in the Church - an introspection (George Joseph)

Serious questions have been raised about the institutional witness of the church in India, particularly its relevance in the social context of today. In the case of the Healing Ministry there is urgent need to critically look at our priorities and commitment and our style of functioning in the light of the gospel. The role of the professionals have to be reassessed as part of an overall effort to bring back the true spirit of 'Diakonia' into this ministry.

The whole issue regarding the need for evolving a 'rational drug policy' has to be seen in this perspective.

What is Rational Drug Therapy? (Mira Shiva)

Rational drug therapy means practice of socially conscious, relevant, concerned and yet scientifically sound medicine. It recognizes the non-role of drugs in certain conditions, the role of alternative systems of medicine and recognizes the limitations of Western Medicine in our social context.

It emphasises selective use of drugs based on essentiality, efficacy, safety, easy availability, easy administration, quality drugs preferably of indigenous production.

Rational Drug Therapy recognizes the concept of essential drugs and the concept of graded essential drug lists for different levels of health personnel. It recognizes the right of health personnel and consumers to drug information and its effective communication.

It is taking of a conscious decision to boycott certain drugs and use others only when needed. It means prescription with awareness, to avoid as far as possible -- iatrogenesis (drug induced problems, drug interactions, adverse drug reactions and emerging drug resistance).

It is understanding the role of drugs and rational drug therapy in the emerging health movement.

What can be done at a pharmacy level (Alan Cranmer)

(a) Management of Pharmacy Services include involving the users of the service; the Pharmacy Committee - its constitution and functions, viz., implementation of hospital policy, selection of medicines, sources of medicines, cost versus quality, basic drugs and formulations, medicines banned in India and abroad, medicines from other systems; stock control; prescribing discipline and pharmacy discipline.

(b) Good dispensing services involve need for good professional service to patients, proper presentation of patient's medicines, preparation of medicines in the pharmacy compared to purchase, medicines in the pharmacy and at clinic level.

contd.....

(c) Relationships with suppliers, ie., with representatives in the pharmacy and an assessment of products offered and their sources.

(d) Educational requirements - basic courses, legal requirements, course content, continuing education for pharmacists.

(e) Relationships with hospital colleagues.

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INITIATIVES IN THE COUNTRY

(1)

Arogya Dakshata Mandal, Pune has been raising awareness about drug related issues among medical professionals and the lay public since the past 8 years. They publish a monthly--'Pune Journal of Continuing Health Education'--on drug issues and are also bringing out a book 'Rational Drug Therapy' in December 1984.

They launched a movement called 'Operation Medicine' in 1977 against irrational prescription of vitamins, tonics and tinned foods.

(2)

All India Drug Action Network: A number of groups have been working in the field of drug related issues at various levels during the past 3-4 years. They have been in contact with each other and have been working informally together sharing information, putting forward a memorandum (demanding a Rational Drug Policy), participating in campaigns, lobbying with government etc. In August 1984, they felt the need to have a more organized base and have formed the All India Drug Action Network. CHAI is also a member of the Network.

(3)

Lok Vigyan Sanghatana, Maharashtra, or the People's Science Movement have launched campaigns about anaemia and irrational anti-anaemia drug preparations and also about over the counter drugs. They organize jathas, hold district/town seminars, write in the mass media etc.

(4)

Kerala Sastra Sahitya Parishad is a voluntary non-government organization consisting of scientists, doctors, engineers, social scientists, teachers, students, workers, peasants, technicians who are committed to popularising science and channelising it for social revolution. The KSSP has recently decided to take up the Drug issue and initiate a big campaign to expose the anti-people and exploitative tactics of the Multinational Drug Companies. The questions of essential versus non-essential and dangerous drugs, the inadequacy of drug safety control measures, the rising prices of life saving drugs and the non-implementation of the Hathi Committee recommendations are the highlights of the programme.

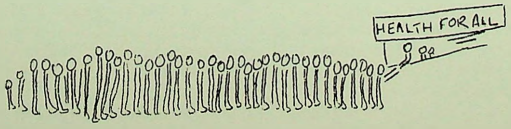
(5)
LOCOST or Low Cost Standard Therapeutics is a collective voluntary enterprise for rational therapeutics. LOCOST aims to promote low cost, scientifically tested medicine under generic names. LOCOST is a response to a growing demand and challenge of the voluntary health sector to meet the needs of the deprived sectors of the society for not only low priced but also good quality medicine. LOCOST includes procurement, quality testing and control, distribution and educational efforts, and is located in Gujarat.

(6)
Bangarapet Mission Tablet Industry in Karnataka is a successful small scale venture providing low cost, good quality formulations to some mission hospitals in the country.

(7)
Low Cost drugs and Rational Therapeutics Cell of the Voluntary Health Association of India, New Delhi, has been instrumental in bringing together various groups in India on the issue of drugs. They have been providing informational backing to these groups, organizing meetings, informally coordinating some actions etc.

(8)
medico friends circle is a group of socially conscious individuals, interested in the health problems of our people. Through their monthly bulletin, they discuss drug issues among others. They have formed a Rational Drug Policy Cell and have launched a campaign on anti-diarrhoeals.

(9)
The Kurji Holy Family Hospital Formulary is the result of the accumulated experience of the hospital over the last 10 years. It gives a comprehensive list of drugs to treat 98% of the hospital admissions. It also gives the generic name, dosage, indications, contra-indications and side effects of these drugs. Information about comparative cost of treatment is also provided.



(10)
State Forums: During the past year drug action forums have been active in Andhra Pradesh and West Bengal. Drug Action forums are also being initiated in Gujarat and Orissa.

(11)
The Pharmacology Department of the Post-Graduate Institute of Medical Education and Research, Chandigarh, provide unbiased technical information on drugs and therapeutics through a monthly publication 'The Drugs Bulletin'.

(12)
Others: The following organizations have also been involved in drug related issues and are part of the All India Drug Action Network:

Consumer guidance Society of India, Bombay
Consumer Education Research Centre, Ahmedabad
Federation of Medical Representatives Association of India
Health Services Association, Calcutta
Delhi Science Forum, New Delhi
People's Participation in Science and Technology, Madras/Bangalore
Centre for Science and Environment, Delhi
Centre of Social Medicine and Community Health, J N University, New Delhi

What we can do ?

-- Support them

-- Join them

-- Keep them informed about what you are doing

.....

RESOURCE MATERIALS

- People, Pills and Prescriptions, column in MEDICAL SERVICE since May-June 1984.
- Objectives of the Workshop, a handout.
- Understanding the Drug situation in our Hospitals, a check list.
- Towards a People-Oriented Drug Policy, Special Convention Issue of MEDICAL SERVICE (October-November 1984) and a supplement to this issue will be distributed during the Workshop.
- Drugs awareness and Action, mfc BULLETIN Special Issue No. 107 November 1984.
- DECCAN HERALD Supplement on the Workshop.

"What people really need, first and foremost is clean drinking water, latrines, school and land, not urban hospitals with their wonder drugs".

-- Planning Commission

AN INSPIRATION

Reading

The story of the sickman
at the pool of Bethsaida

John 5: 1-9

Reflection

The action of Jesus in bypassing the pool is an invitation to us to look more critically at our own health care system. Thanks to our emphasis on curative health care, we have grown accustomed to thinking solely in terms of the health needs of the individual rather than addressing ourselves to the community as a whole. While concentrating on the symptoms, we have failed to take into account the environment and other social factors. Poor sanitation, polluted water supply, the superstitious beliefs and taboos of the community are also related to sickness and disease.

Further, the miraculous pool in its ineffectiveness is a symbol of our own ineffective health care system despite the highly qualified doctors and nurses, well equipped private and public hospitals, medical research centres and multinational drug industry.

The poor man in the gospel story lived very close to the pool, yet he was helpless because of his poverty. In like manner the poor in our midst remain helpless in the shadow of an expensive, curative health care system that is geared exclusively to the service of the rich.

Source: The Bible: Aspirin or Dynamite
by Cedric Rebello s.j.

Integrated Philosophy of Health

Dr. Karan Singh
Minister of Health and Family Planning,
Government of India

Text of the Inaugural Address at the XXIX Session of the WHO Regional Conference for South-East Asia, Srinagar (India), September 14, 1976

It is a genuine pleasure for me to be with you on this occasion, not only because of the very great importance that the Government of India attaches to the work of the World Health Organisation but, in addition, because of the personal reason that this Conference is being held in my home State and, even more, in the very home where I grew up as a boy and spent some of the happiest years of my life. I, therefore, look upon it not only as a professional but as a personal privilege to be with you on this occasion. Kashmir provides an ideal venue for national and international conferences and conventions. The beautiful surroundings have already been referred to in poetic terms by Dr. Gunaratne. My only hope is that the beauty of Kashmir will inspire and not distract the delegates who have gathered here.

The World Health Organisation is a unique organisation. It is perhaps the best example we have of international cooperation for mutual benefit, an example of the way in which the benign uses of science and technology can be harnessed for furthering the welfare of the vast millions of people on this planet. WHO has done remarkable work in many fields; the eradication of smallpox is only one of the more dramatic of these achievements. In a great number of fields of communicable-disease control projects, research, manpower training and so on, WHO is doing continuing service to the world community. The South-East Asia Region, to which we belong, is particularly important. It has almost a billion people now - 950 million by the last count - which is over 23% of the entire population of the world. Therefore, the deliberations of this Regional Committee are of very special importance not only because of the numbers involved but also because it consists of ten developing nations, nations which are grappling with the problem of trying to provide acceptable health services to the people.

I would like at the outset to commend the work of the Regional Director, Dr. Gunaratne, his staff and office. I find that they have brought a good deal of dedication and imagination to bear upon the problems of this Region, to promote and develop expertise within the Region, the setting up of a Regional Advisory Committee on Medical Research and the furthering of inter-country cooperation. I hope that the Regional Committee will continue to strengthen and deepen its efforts in all these fields.

The theme for your conference this year is Nutrition Programmes and Health, and this leads straight to the heart of the new health philosophy that we are moving towards in this country and in other countries. Dr. Mahler, the enlightened and dynamic Director-General of the World Health Organisation, in his message has rightly pointed to the importance of accepting certain social goals, and it is in furtherance of these social goals that the new health philosophy is beginning to develop. I would like to take the opportunity this morning, Mr. Chairman, to say a few words upon what we think are the broad lines on which this philosophy should develop, revolving around the basic concept of integration.

If the philosophy is to be summed up in a single phrase I would call it an integrated philosophy of health; and I would like to spell out, rather briefly, what I mean by this integration. The integration takes place on several levels. First, the very concept of health itself must be widened much more than it has so far. There are three very clear aspects of health. There is the promotive and preventive aspect, there is the curative aspect, and there is the rehabilitative aspect. So far health has been considered to be co-terminus with the curative aspect. When you talk of health, people usually think only of hospitals, in other words of ill-health. It seems to me that ours are more ministries of illness than ministries of health. We have got to move into a larger, broader definition of health. Health is not merely morbidity or its absence. Health is a positive concept which implies the promotive aspect of health, community health, preventive health, the restructuring of medical education in order to give necessary importance to community health. We produce very good specialists but, unless we are able to prevent morbidity, we can convert our whole nation into vast hospitals, and still never be able to meet the health needs of our people.

We have got to fight the enemy on his ground, and this requires a re-orientation of our entire approach. All the plums of health today go to the brilliant clinicians. What about the public health man? What about the person who is working in the villages and slums? He hardly ever gets any recognition. It is important, therefore, that the promotive and preventive aspects of health receive much higher importance and priority than they have done so far; this includes, of course, the whole gamut of health education, starting from the primary school level, the involvement of the community and of the voluntary agencies in the work of health education and promotion and a general national campaign of physical fitness, because unless we are able to build up the bodies of our younger generation it will not be possible for them to develop the resistance to disease that is required.

Along with preventive and promotive health, of course, our massive campaigns against communicable diseases have got to continue with increased vigour, whether it is malaria or filariasis, leprosy, tuberculosis, sexually transmitted diseases or any other. I think we can learn a great deal from the experience of the smallpox eradication campaign, both as far as the methodology is concerned and the general organisational pattern. Therefore, the first aspect is the preventive and promotive side of health.

Then there is the curative aspect and here we are moving towards a three-tier system. The first is the primary health centre downwards. As you know, in our country the primary health centre is our rural hospital, our rural outreach. Each primary health centre has at least two, if not three, M. B. B. S. doctors, and an input of X-ray machine and dentist's chair and various other operative equipment. Each primary

health centre has 6 to 8 sub-centres which will now be manned by a new cadre of Health Assistants which we are developing. Below that, we go to the village level, where we have a national programme now to involve not only the village school teacher, but also the village postman, the traditional village midwife and the gram sewak or the agricultural extension worker. We seek to involve these four categories of functionaries at the village level so that our outreach is able to cover the rural areas where the vast majority of our population lives. I am sure that in each one of the ten countries represented in this South-East Asia Region, the vast majority of population lives in rural areas, and it is only by developing an effective rural outreach that we will be able to cover their problems. The first tier goes upto the primary health centre, beyond that are the 30-bed referral hospitals, the district hospital and the medical college hospitals; and finally on top are the metropolitan hospitals and the super-speciality institutions. This three-tier system of curative health is what we are now trying, with our limited resources, to develop.

Then we come to the rehabilitative aspect, both the mentally and the physically handicapped. So far all we do is to treat them and to send them back to the community without any follow-up, without any way of ensuring that they can go back as useful and creative members of the society. You can cut off a limb, you can cut off an arm or a leg and then you just send the person back, and sometimes he is so badly off after he gets back to the community that one wonders whether it would not have been kinder to let the man die earlier rather than to make him a cripple and to send him into the community with no follow-up. In leprosy, in orthopaedic cases, in various other types of physical and mental handicaps, this is a tremendous lacuna in our system and I think the time has come when we have got to give some thought to the rehabilitative aspects of health.

So the first level of integration is in promotive, curative and rehabilitative health. The second level of integration is the combined package of health, family planning and nutrition that we are attempting to take to the doorstep of every citizen. Health I have already covered. Over-population is one of the major problems in this region, and in fact is very often the cause of low living standards, of morbidity and mortality, particularly of child mortality. Therefore, in countries like ours over-population itself constitutes a major health hazard. In order to meet this we have come out with a remarkably inclusive and integrated National Population Policy which will be circulated at this meeting and could be of some value perhaps to other countries in the development of their policies. This National Population Policy lays special emphasis upon maternal and child health, because child mortality is a direct cause and a direct function of over-population. It is only when we can cut down child mortality and morbidity drastically, that our population rate of growth will also come down.

Then there is nutrition. Nutritional inputs, particularly to pregnant and lactating mothers, to infants and to small children are absolutely essential if their welfare is to be ensured. The first 3-5 years, including the period of pregnancy, are the most critical in the development of the mind and body of the child, and if a child is deprived of adequate nutritional inputs in this period, his body and mind will remain warped for the rest of his life. It is a tragedy and a disgrace to all of us that in our countries millions of children do not get adequate nutritional inputs. How are we going to build the world of our dreams if we cannot ensure to our children at least the minimum inputs that are necessary for the body and the mind to grow? This, therefore, is a problem which has got to receive the highest priority, and I am happy that it has been chosen as the theme of technical discussion at your meeting. This will involve a change of eating habits and cooking methods. A lot of nutritive value is wasted simply because of ignorance and because of wrong methods of preparing foods. There is this question, for example, of white bread. If I had my way I would ban white bread totally and force people to have brown bread, it is so much more delicious and so much more nutritive. And yet we polish the nutrients out of our bread. We polish the nutrients out of our rice and we polish the nutrients out of our sugar. We have some fixation about whiteness which I do not understand. We must have white rice, white sugar and white bread - all three of which are systematically and scientifically deprived of their nutritive value before they are given to our children and to our people. I think we need a revolution here also. We must break away from the mode of behaviour that we have inherited as a result of a long period of colonial exploitation, and begin to develop our own insights into these problems and see that the eating habits and the cooking habits of our people are creatively adapted in order to ensure greater nutritive input.

Then, of course, there are the special feeding programmes that are required because, howsoever well and scientifically we may cook, there are vast number of people who simply do not have the wherewithal to get the minimum nutritional inputs. The UNICEF Representative is here; they are doing valuable work as are various other organisations - UNDP for example and others - but very much more needs to be done. The feeding programme, ideally, should be based upon locally available food. This whole syndrome of elaborately-packaged baby foods also, if I may submit, is something which may suit a developed and an affluent society, but which will never have massive application as far as the countries in our Region are concerned. We have got to develop locally available foods and we have to develop a system whereby these can be given to the most vulnerable sections of our society. Malnutrition is a major cause of morbidity and of mortality, and it is indeed ironic that while there are millions in this world who are under-fed, there are hundreds of thousands who die of over-eating. This once again highlights the unacceptable maldistribution of global resources, particularly in such basic and essential commodities as food and nutritive inputs. This, therefore, is the second level of integration - between health, family planning and nutrition. These have got to be integrated into a package and delivered to the most remote rural areas.

A third level of integration resolves around the modern system of medicine and the traditional systems of medicines. The WHO now is beginning increasingly to appreciate the importance and value of traditional systems of medicine. There was a time when it was thought that the only system of medicine that worked was the so-called allopathic system, but that particular stage of arrogance has now passed. Certainly the achievements of modern medicines have been nothing short of fantastic - the development of antibiotics, the advanced surgical techniques and so on. Nobody wishes to denigrate them, but it is also clear that there are a lot of insights in the traditional systems of medicine. We do not want to move on to an over drug-oriented, over surgery-oriented system. You remember Ivan Illich's thesis on iatrogenic disease, disease caused by doctors. I do not want to go into that particular controversy because there are so many distinguished doctors present this morning, but the fact remains that over-drugging and unnecessary surgery have become increasing features of the affluent society, and in our country we simply cannot afford this. It is, therefore, useful and valuable if we are able to get the insights of the traditional systems of medicine.

In India, for example, we have Ayurveda the science of life, which is a system going back at least to 5000 years, and is incorporated in a number of texts in this country which has some remarkable effects; there is Siddha which is the Tamil version of Ayurveda and which also has got a lot of very interesting approaches; there is the Unani system named after the Greeks but which came to us through the Arab world though, I think it has disappeared from the Arab world.

In India we are still actively encouraging it; we have hospitals and dispensaries for all these systems. There is homoeopathy, which was born in Germany but which was banished from the continent of its birth; that also came to India and today thousands of people are deriving benefit from it. There is naturopathy and there is our new attempt through naturopathy, in coordination with other systems of medicine, to have a combination therapy, and there are several health aspects of yoga. All these constitute a tremendously valuable cultural heritage. I would urge that our Region should take the lead in trying to develop a working relationship between these various systems of medicine; ultimately all systems of medicine must be based around the concept of human welfare, and there is no reason whatsoever why we should give up insights that have been developed in our nations for centuries.

The final element of integration that I would like to talk about is the integrated approach to the human being - the human body, the human mind and, if you like, the human spirit. Man is more than simply a body; there are physical, there are mental and there are spiritual aspects of the human personality. One of the weaknesses of the western approaches so far has been the artificial dichotomy that has been imposed, trying to make a distinction between the body and the mind. I would submit that what is required is a holistic

approach, an integrated approach to the human being. You cannot disassociate the body, the mind and the spirit; you have to deal with the entire human being in his cultural milieu within his intellectual background, with his hopes, his urges and his aspirations. Human beings can no longer simply be looked upon as interesting clinical material. They are more than that. They are human beings, they are people of flesh and blood with fears and hopes and aspirations. Therefore, any system of medicine, and any approach of an enlightened body like the World Health Organisation, has got to realize these dimensions of the human personality. This brings me, in passing, to a subject which is of particular interest to me, and that is this whole field of consciousness research. So far we have assumed that consciousness is static and that everything happens within its own base of a firm screen of consciousness. It is now becoming increasingly realized that consciousness itself is dynamic, is kinetic, and this opens up a totally new field of enquiry into the functioning of the human mind and the spirit. We are on the threshold of exciting developments, as exciting as the latest scientific work in unravelling the mysteries of the cosmos or the structure of the RNA and the DNA molecules. This also is another level upon which our approach has got to be integrated.

These are some of the levels of integration which are essential if we are to have a comprehensive global health policy. In the developing world in particular, Mr. Chairman and friends, in the developing nations in Asia, Africa and South America, we have only one enemy and that enemy is poverty. Malnutrition, disease, ignorance, illiteracy, over-population, unemployment - these are all aspects of poverty, and the time has come when our people are no longer satisfied with remaining within the poverty barrier. This is a battle which has now been joined; it is a battle which has got to be taken to a successful conclusion, not in another 1000 years but in our very lifetimes before the end of the century. It is unacceptable to the millions of people living in the developing countries that they should be deprived ad infinitum of at least the basic essentials of life, and in this tremendous adventure the health input is absolutely crucial. Education is important, clothing is important, shelter is important, but health perhaps is the most important of all; because you can have a beautiful house, you can live in a palace, you can eat 20 different dishes, but you will not be able to enjoy anything without good health. Health ultimately is the parameter of social progress and of the status of any people. And, therefore, the WHO has a very special role to play in this crucial moment in the destiny of the human race. Mankind today is at a crossroad. Science and technology has given man the power, if used wisely, to abolish poverty, want, ignorance, disease and illiteracy from the face of the earth. If the same power is misused it can destroy not only the human race but all life on this planet. We, who are working in the field of health, are privileged because we are on the side of the forces of harmony, the forces of progress. We must have before us a glowing vision of humanity, a human race in which every single child born into this world, regardless of nationality or colour or creed or religion or any other category, is ensured the minimum inputs that are necessary for a healthy development of the body, the mind and the spirit. It is dedicated to this broader vision of the future of humanity that I have greatest pleasure in inaugurating this Conference.

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Uppsala County and the organization for the mentally retarded.

Uppsala County has about 200.000 inhabitants.
It is divided in 5 primary-communes among which the city of Uppsala and its surroundings are the greatest with about 110.000 persons.
The County Council is by a law from 1968 responsible for organization and finances for education, training and care of the mentally retarded. There is in every county a special committee "Omsorgsstyrelsen", though which the County Council has to organize the aktivities for the mentally retarded.

Education and training (special schools).

	Number.
A. Preschool (kindergarten) 4 groups for only mentally retarded children in Uppsala and Enköping (not integrated). In some places there is also a single child who is integrated in groups for normal children.	24
B. Groundspecialschools (7 - 17) In Uppsala and Enköping and two other places. This type of classes is generally integrated in schools for normal children. There are three special-schoolclasses in each normal school..	126
C. Training school (7 - 17) New form of schools in Sweden (from 1968). At present there is only one training school in the county. It is at Rickombergaschool in Uppsala and consists of 6 classes. Many of these pupils live in boarding home during the schoolweeks.	56
D. Individual training (7 - 17) Many of the children at The Childrens Home of Care in Rickomberga (severe mentally retarded children) get	29

Number

Individual training or training in small groups. There are also many children who are living in their parents home and are unable to come and train in the schools. They get training at home.

E. Vocational training schools (18 - 21 year) 77
Are also a compulsory form of school. The vocational training has very varied programmes. Some pupils are able to be rather good in easy manual industrial therapeutics. A part of these pupils lives in group home or at an institution. Most of them live in parents home.

Where the mentally retarded children live.(0 - 21)

A. Children who live at their parents or at another families (20 of them get only individual training) 220

B. Grouphome in Uppsala 10
" in Enköping 5

C. At Rickombergaschool in Uppsala
Boarding home for small children 15
" " belongs to ground-specialschool and trainingschools 40
Hostel for severe mentally retarded children "Childrens Home of Care" 39

D. Pupils from this county in other special-schools. 64

In these varios forms of schools 300 children and youths will be educated and trained in the County. If they are in need of continued help in any way after 21 they will be recorded as adult mentally retarded and the organization for the adults takes over.

Where the mentally retarded adults live (22 -)

Belong to the "open care"	With their parents	121
	Homes of themselves	61
	At homes of other peoples	41
	Group home	45

In institutions	
Hågaby cottages	84
" residential homes	64
Group homes within Hågaby	10
Älby residential homes	51
Special hospitals (mentally retarded + mentally ill + complicated handicapped)	34
Institutions in other counties	36

What do the mentally retarded adults do?

Open market (factories etc)	67
Sheltered workshops	36
Therapeutics within our institutions (inclusive 30 persons who live outside)	131
At present without therapeutics	98
Special hospitals + private institutions	34 + 22

MEDICATION AS A SUBSTITUTE FOR CARING

Perhaps the biggest reason for overuse of medicines, however, is that doctors and health workers often find it easier to hand out medicine than to give the time and personal attention that people need.

About 4 out of 5 illnesses are self-limiting. This mean people' get well whether they take medicine or not. Most health problems can be better managed without any medication. What often will help people most is friendly advice and understanding support.

However, many doctors and health workers get into the habit of giving everyone medicine--for any and every problem they have. The less curable the problem, the more medicines they give!

At the same time, people have come to expect medicine every time they visit a doctor or health worker. They like to believe that "there is a medicine for everything". They are disappointed if the doctor or health worker does not give them any, even when medicines will do no good and the health worker carefully explains why.

So a 'vicious circle' results in which the doctor always gives medicine because the 'patient' always expects (or demands) it, because the doctor always gives it. The prescribing of a medicine becomes both the symbol and the substitute for human caring. This problem is especially common in places where doctors nurses, and health workers are overworked. The result is not only a costly overusedof medicine, but a failure to meet human needs on human terms.

--Helping Health Workers Learn
David Werner and Bill Bower.

Received today 4/4/83

20

Source - CIMS

Trivandrum Vol 14 Sept '82

News & Views

TATA PHARMA MAKING RAPID STRIDES

The new pharmaceutical venture of the house of Tatas—TATA PHARMA—a division of Lakme Limited (see CIMS Volume-11), recently commenced marketing a range of 5 ethical and very modern formulations.

Tata Pharma have already acquired land in Patalganga, a notified backward area in Maharashtra, and are in the process of setting up a bulk drug plant for manufacture of cetrimide, chloroquine diphosphate, ethambutol and some important drug intermediates.

MAY & BAKER DILUTING EQUITY AND EXPANDING

May & Baker India Ltd. has announced an expansion and diversification programme involving additional investment of Rs.120 million to increase production of existing bulk drugs and to introduce their two new drugs—KETOPROFEN (anti-arthritic) and ACEBUTOLOL (anti-hypertensive).

The Chairman of May & Baker India Ltd., Mr. C.C. Chokshi, recently announced that the company would dilute its foreign equity from 60% to 40% under the FERA.

LUPIN LAUNCHING MAJOR EXPANSION AND DIVERSIFICATION

Based on a technology agreement with the International Minerals & Chemical Corporation (USA), Lupin Laboratories have promoted a joint venture with the Gujarat Industrial Investment Corporation (GIIC) for the manufacture of racemic 2-aminobutamol and ethambutol. This Rs.75 million project will be located at Ankleshwar in Gujarat.

Lupin's new and modern Rs.17 million formulations facility at Aurangabad will help raise the company's annual turnover beyond the projected Rs.300 million by 1984-85.

Lupin is already manufacturing and exporting pharmaceutical machinery.

ESTROGEN-PROGESTOGEN FIXED DOSE COMBINATIONS OTHER THAN ORAL CONTRACEPTIVES BANNED

The Office of the Drugs Controller (India) has announced a ban on fixed dose combinations of oestrogens with progestogens, other than those used as oral contraceptives in low doses.

The medical experts in the country taking note of the misuse of these preparations and the action taken in many countries to ban these preparations, recommended their ban in India. The experts have pointed out that there are substitutes available in the country for the management of secondary amenorrhoea and similar gynaecological disorders.

The ban becomes effective on January 1, 1983 for manufacture and July 1, 1983 for marketing these preparations.

18 CATEGORIES OF FIXED DOSE DRUG COMBINATIONS BANNED

The Drugs Controller of India, based on the recommendations of the Drugs Technical Advisory Board, has issued directives for ban of the following:

Fixed dose combinations of:

1. Vitamins with anti-inflammatory agents and tranquillisers.
2. Atropine in analgesics and antipyretics.
3. Strychnine and caffeine in tonics.
4. Yohimbine and strychnine with testosterone and vitamins.
5. Iron with strychnine, arsenic and yohimbine.
6. Sodium bromide and chloral hydrate with other drugs.
7. Ayurvedic, Unani drugs with modern drugs.
8. Anti-histaminics with anti-diarrhoeals.
9. Penicillin with sulphonamides.
10. Vitamins with analgesics.
11. Tetracycline with Vitamin C.
12. Steroids for internal use except those in combination with other drugs for the treatment of asthma.
13. Chloramphenicol except those of chloramphenicol and streptomycin.
14. Hydroxyquinoline group of drugs except those used for diarrhoea and dysentery.
15. Prophylactic vitamins with anti-TB drugs except combination of INH with Vitamin B_6.
16. Amidopyrine.
17. Phenacetin.
18. Ergot except those of ergotamine with caffeine.

The ban takes effect from October 1, 1982 for manufacturing and April 1, 1983 for sale.

MANUFACTURE AND SALE OF CERTAIN FIXED DOSE COMBINATIONS MADE CONDITIONAL

The Drugs Controller, India, has released a statement of certain categories of drug-combination, the manufacture and sale of which will be subject to certain conditions:

1. Combinations of caffeine with anti-spasmodic drugs provided caffeine is in therapeutic dose.
2. Combinations of tetracycline/oxytetracycline in anti-amoebic preparations, provided the quantity of tetracycline is 125mg/dose.
3. Combinations of analgesics, antipyretics and anti-histaminics provided the formulation contains minimum pharmacopoeal dose of each.
4. Combinations of antacids with only those enzymes which are stable in pH over 5 and where both such drugs are compatible in the same pH.
5. Combinations of enzymes containing either only those stable in acid medium or those stable in alkaline medium.
6. Combinations of metronidazole with methylpolysiloxane provided the dose of the latter is not less than 25mg/dose.
7. Combinations of pharmacopoeal drugs if they are already existing and only if they are rational and having minimum official dose, unless evidence of synergism is available, backed by data.

The State Drugs Controllers have been directed to [illegible]

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The new pharmaceutical venture of the house of Tatas—TATA PHARMA—a division of Lakme Limited (see CIMS Volume-11), recently commenced marketing a range of 5 ethical and very modern formulations.

Tata Pharma have already acquired land in Palalganga, a notified backward area in Maharashtra, and are in the process of setting up a bulk drug plant for manufacture of cetrimide, chloroquine diphosphate, ethambutol and some important drug intermediates.

MAY & BAKER DILUTING EQUITY AND EXPANDING

May & Baker India Ltd. has announced an expansion and diversification programme involving additional investment of Rs.120 million to increase production of existing bulk drugs and to introduce their two new drugs—KETOPROFEN (anti-arthritic) and ACEBUTOLOL (anti-hypertensive).

The Chairman of May & Baker India Ltd., Mr. C.C. Chokshi, recently announced that the company would dilute its foreign equity from 60% to 40% under the FERA.

LUPIN LAUNCHING MAJOR EXPANSION AND DIVERSIFICATION

Based on a technology agreement with the International Minerals & Chemical Corporation (USA), Lupin Laboratories have promoted a joint venture with the Gujarat Industrial Investment Corporation (GIIC) for the manufacture of racemic 2-aminobutamol and ethambutol. This Rs.75 million project will be located at Ankleshwar in Gujarat.

Lupin's new and modern Rs.17 million formulations facility at Aurangabad will help raise the company's annual turnover beyond the projected Rs.300 million by 1984-85.

Lupin is already manufacturing and exporting pharmaceutical machinery.

ESTROGEN-PROGESTOGEN FIXED DOSE COMBINATIONS OTHER THAN ORAL CONTRACEPTIVES BANNED

The Office of the Drugs Controller (India) has announced a ban on fixed dose combinations of oestrogens with progestogens, other than those used as oral contraceptives in low doses.

The medical experts in the country taking note of the misuse of these preparations and the action taken in many countries to ban these preparations, recommended their ban in India. The experts have pointed out that there are substitutes available in the country for the management of secondary amenorrhoea and similar gynaecological disorders.

The ban becomes effective on January 1, 1983 for manufacture and July 1, 1983 for marketing these preparations.

18 CATEGORIES OF FIXED DOSE DRUG COMBINATIONS BANNED

The Drugs Controller of India, based on the recommendations of the Drugs Technical Advisory Board, has issued directives for ban of the following:

Fixed dose combinations of:

1. Vitamins with anti-inflammatory agents and tranquillisers.
2. Atropine in analgesics and antipyretics.
3. Strychnine and caffeine in tonics.
4. Yohimbine and strychnine with testosterone and vitamins.
5. Iron with strychnine, arsenic and yohimbine.
6. Sodium bromide and chloral hydrate with other drugs.
7. Ayurvedic, Unani drugs with modern drugs.
8. Anti-histaminics with anti-diarrhoeals.
9. Penicillin with sulphonamides.
10. Vitamins with analgesics.
11. Tetracycline with Vitamin C.
12. Steroids for internal use except those in combination with other drugs for the treatment of asthma.
13. Chloramphenicol except those of chloramphenicol and streptomycin.
14. Hydroxyquinoline group of drugs except those used for diarrhoea and dysentery.
15. Prophylactic vitamins with anti-TB drugs except combination of INH with Vitamin B_6.
16. Amidopyrine.
17. Phenacetin.
18. Ergot except those of ergotamine with caffeine.

The ban takes effect from October 1, 1982 for manufacturing and April 1, 1983 for sale.

MANUFACTURE AND SALE OF CERTAIN FIXED DOSE COMBINATIONS MADE CONDITIONAL

The Drugs Controller, India, has released a statement of certain categories of drug-combination, the manufacture and sale of which will be subject to certain conditions:

1. Combinations of caffeine with anti-spasmodic drugs provided caffeine is in therapeutic dose.
2. Combinations of tetracycline/oxytetracycline in anti-amoebic preparations, provided the quantity of tetracycline is 125mg/dose.
3. Combinations of analgesics, antipyretics and anti-histaminics provided the formulation contains minimum pharmacopoeal dose of each.
4. Combinations of antacids with only those enzymes which are stable in pH over 5 and where both such drugs are compatible in the same pH.
5. Combinations of enzymes containing either only those stable in acid medium or those stable in alkaline medium.
6. Combinations of metronidazole with methylpolysiloxane provided the dose of the latter is not less than 25mg/dose.
7. Combinations of pharmacopoeal drugs if they are already existing and only if they are rational and having minimum official dose, unless evidence of synergism is available, backed by data.

The State Drugs Controllers have been directed to implem...

21

LOCOST

Low Cost Standard Therapeutics Project

(a collective voluntary endeavour for rational therapeutics through promotion of low cost, quality, generic-named medicine)

c/o AMIL PVT. LTD.
G. P. O. Box 7,
BARODA-390 001.

Your Ref No.

Our Ref No. B/20/83

Dear

All of us involved in voluntary health services have felt the need for the introduction of rational theraputics and having low cost standard generic drugs. However, the issue has so far remained a laudable theoretical study and critique. The hard option of practical experiments to make it a reality is still unattended. The present project is planned and started to fill up this gap.

For the last five years VHAI and GVHA (Dr.Doshi and Dr. Ashvin Patel) were toying with the idea of starting a project under voluntary sector to provide low cost quality drugs for rural and deprived mass of the society. You have already received communication regarding LOCOMP project which has finally shaped into LOCOST (Low Cost Standard Theraputics). Bangladesh has taken lead in this field by starting 'Gonoshasthya Kendra' under low cost health care voluntary sector. The unit manufactures and supplies low cost generic rational drugs to the masses.

In India we have sufficient expertise to plan such project but to get involved people and evolve a group with vision of community health, management capabilities, undettered commitment and honesty is extremely difficult. Fortunately the idea has progressed tremendously in last few months. We have now a group of individuals who are committed to make this project a top priority in their activities. We are ready with LOW COST STANDARD THERAPUTICS (LOCOST) Project.

The project proposal is worked out in detail with precision. We are approaching international funding agencies to help this endeavour. We are confident to have sufficient financial aid within six to eight months. In the mean time, it is decided

-2-

to keep the group together and march forward with funds generated in the form of deposits or loans from friends and partners. The initial deposits of Rs.30,000.00 is already arranged and the project has started functioning from 1st August,1983. We plan to supply your ordered drugs from 1st October, 1983. At this stage of project, we plan to procure quality drugs and get them tested at approved standard laboratory, stock these tested drugs at a unit which is committed to work for LOCOST project without any commercial consideration of profits and dispatch them to our valued partners.

Our limitation for first few months will be availability of finance. We request you all partners to come forward with your cooperation in any of the following forms -

1. Interim loan to the LOCOST for six months
2. Donations
3. Advance towards your orders
4. Immediate payment of your ordered goods

In the beginning we shall provide only -21- drugs which we shall gradually increase to -69- total selected drugs. Our LOCOST representative will visit you as soon as possible to explain our work conditions and obtain your cooperation.

Thanking you,

Yours truly,

Ashwin Patel
(Dr. Ashwin Patel)

Fernandes
(Fr. Jerry Fernandes S.J.)
Secretary
GUHA

LOCOST PROJECT

Dear Sir,

We request you to fill in your order for the understated drugs with the time of delivery after 2nd October, 1983

Sr. No.	Name of drug	Form	Qty. ordered	Period of delivery
1.	Ampicillin	Cap.		
2.	Aspirin	Tab.		
3.	Chloremphenicol	Cap.		
4.	Chlorpheneramine meleate	Tab.		
5.	Chlorphromazine	Tab.		
6.	Chloroquin	Tab.		
7.	Co-trimoxazole	Tab.		
8.	Di-iodohydroxy-quinolin	Tab.		
9.	Ephedrine	Tab.		
10.	Ethambutol	Tab.		
11.	Ferrous Sulphate & Folic Acid	Tab.		
12.	Frusemide	Tab.		
13.	Mebendazole	Tab.		
14.	Metronidazole	Tab.		
15.	Nitrafurantoin	Tab.		
16.	Paracetamol	Tab.		
17.	Penicillin V	Tab.		
18.	Sulphadiazine	Tab.		
19.	Tetracycline	Cap.		
20.	Rifamicin	Cap.		
21.	Vit.A	Cap.		

Our Concern About Drugs

Inspite of the green revolution, white revolution, industrialization, modernization and development, the country's increase in GNP (Gross national Profits), most of these things have not touched that man who hangs helplessly below the poverty line. The irony of all our great development is that the number of such people who are becoming destitutes is increasing.

From 27 we can now boast of over 200 medical colleges. According to WHO's recommendations our doctor population ratio is above the requirement. Our Pharmaceutical Industry is amongst the best in the Third World. The state spends Rs. 9 per person per year on health. Why then do we still have such a high incidence of malnutrition? High infant mortality? - Why are there still 10 million TB patients when we have crores being spent on the National TB Programme ? Why do 27 million Indians get Typhoid every year ? 6 out of 100 children are in potential danger of becoming blind with Vit. A deficiency. Why is it that the great majority of our population has no access to basic health care? 80% of our doctors and our health budget cater to the needs of a small minority.

Drugs costs represent 40-60% of the total health care expenditure in the developing countries (compared with 10-20% in the developed ones).

The rural urban disparity when it comes to health man-power allocation, expenses on drugs, vaccines and other health services is in simple words UNJUST. Only a very meagre percentage of Rs. 9 alloted per person for health expenditure reach him, who forms our 'Millions'.

VHAI believes in making health care available to those who need it most. A prescription written with the high medical standards in mind, may be highly inappropriate in a social context where the patient cannot afford to buy the drugs, or where buying these drugs for the family members means being in

and out of debt with money lenders. **Education and awareness as to how to avoid disease and then how to handle it appropriately at the lowest possible cost is the crux of our approach in low cost appropriate health care.**

*DRUGS :

The marketing of most brand named drugs specially by the multinational in the Third World works against the Health of the poor : (1) **Most critically - because Health Care priorities are distorted by pressure to buy expensive inappropriate drugs, which cream off limited resources, and** (2) Drugs freely promoted in the absence of distribution controls can be dangerous.

1) The effect of promoting the expensive, branded drugs for which generic equivalents are available at a fraction of the cost (sometimes as low as 10%), is to drain limited Health Budgets unnecessarily.

Third World countries spend a disproportionate amount on Drugs, often as much as 55% of the total health budget (compared to 11% of NHS budget on drugs in Britain). Bearing in mind the very limited effectiveness of drugs and curative medicine in general in tackling the major health problems - malnutrition, infectious and parasitic diseases - public funds would be far better spent on preventive health measures and the basic Primary Health Care infrastructure. For this, WHO estimate that 200 generic drugs would be more than adequate to meet Health needs.

the promotional practices of drugs companies, aimed-at maximising profits, run directly counter to the health needs of the poorest. Drug company salesmen (Glaxo has 500 in India alone) concentrate their promotion on encouraging doctors to prescribe the most expensive, latest patented drugs, claiming they are great improvements on far cheaper, well-established drugs. When Beecham's and Wellcome's antibiotics and antimalarials are prescribed at public expense, instead of penicillin and chloroquine, the drug budget is rapidly exhausted. Because of existing imbalances in the health services, reinforced by marketing. the brunt

of wasteful spending invariably falls on the poorest, as the rural dispensaries run short of vital life-saving drugs.

- Apart from promotion of unnecessarily **expensive,** but necessary drugs, doctors are also encouraged into wasteful overprescribing of non-essential tranquilisers, symptom-allaying drugs, and tonics. Once again, the indirect effect on the poor, is that Valium being doled out in hospitals on public funds, can mean shortages of first line drugs in the village dispensaries. Where medicines have to be paid for, (particularly when the doctor is remunerated for prescribing rather than consultation) - sales talk may lead him to prescribe unnecessary drugs e.g. several courses of antibiotics and vitamins for a sick child, costing anything up to a months wages.

2) **Drugs freely promoted in the absence of distribution controls can be dangerous**

- The trickle down effects of uncontrolled drug marketing in the absence of an adequate health infrastructure, trained health workers and controls on over-the-counter sales can seriously endanger the health of the poor. They are most vulnerable through ignorance of dangers and the misconception that a medicine - **any** medicine - will do the trick.

- When under attack for unethical marketing practices in the Third World, the drug companies argue that they stick to the letter of the law. Quite true - But, they demonstrate a total lack of social responsibility in promoting potent, potentially dangerous drugs, in countries where they know they will be freely available over-the-counter, prescribed by local practitioners and traders with little knowledge of medicine - let alone sophisticated drugs. (Whilst deaths from adverse drug reaction go unreported in the Third World - in the USA they are estimated at 30,000 per year.)

- the net effect is that the poor are encouraged to buy drugs for totally inappropriate uses and irrational self-

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medication -- particularly of antibiotics -- leading to serious problems of drug resistance. First line antibiotics given to children with diarrhoea could mean they will die later if they get TB, because there will be no way of obtaining or paying for a second line drug.

Other Activities to decrease health care costs :

- Training of different levels of health personnel to be able to handle common problems as effectively and as cheaply as possible.

- Investigate role of health insurance schemes in different parts of India and their feasibility.

- Preparation of recommended reading list of books and material related to low cost appropriate health care.

- Formation of linkages with groups working on the same lines e.g.: MFC, Centre of Science and Environment.

- Collaborating with groups to do scientific field studies on local remedies, their utility value and optimum methods of preparation (Solidarity, SIRTDO, Ranchi).

This background paper is for discussion.

APPENDIX 1

Distribution of Essential drugs in Developing Countries

Drug distribution was identified as a critical factor in health care and the accomplishment of a comprehensive national drug policy at the consultation and WHO Technical Discussion in 1978.

It appeared that the types of distribution systems or patterns depend largely on the political and economic system and the administrative system under which the Govt. is operating. (Effective distribution of resources depends on nation's political will).

Following were the relevant factors to be considered for any system of distribution of drugs :

1. Health Care System, Demography, Health Indiactors
2. Morbidity pattern
3. List of essential drugs and medical equipment
4. Adequate storage facilities
5. Administration, personnel forecasting and inventory control
6. Transportation facilities and maintenance service
7. Packaging material standardization and labelling
8. Quality surveillance and inspection
9. Education and regular training of staff
10. Drug utilization studies.

APPENDIX 2

The Primary purposes of the Pharmacy and Tnerapeutics Committee

a. Advisory

b. Educational

Functions and Scope

The following list, which is not necessarily comprehensive, is often as a guide :

A. To serve in an advisory capacity to the medical staff and hospital administration in all matters pertaining to theuse of drugs.

B. To serve in an advisory capacity to the medical staff and the pharmacist in the selection of choice of drugs meet the most effective therapeutic quality standards.

C. To evaluate objectively clinical data regarding new drugs or agents proposed for use in the hospital

D. to prevent unnecessary duplication of the same basic drug or its combinations.

E. To recommend additions and deletions from the list of drugs accepted for use in the hospital.

F. To develop a basic drug list or formulary of accepted drugs for use in the hospital and to provide for its constant revision.

G. To make recommendations concerning drugs to be stocked in hospital patient units or services.

H. To establish or plan suitable educational programmes for the professional staff on pertinent matters related to drugs and their use.

I. To recommend policies regarding the safe use of drugs in hospital, including a study of such matters as investigational drugs, hazardous drugs, and others.

J. To study problems involved in proper distribution and labelling of medications for inpatients and out patients.

K. To study problems related to the administration of medications.

L. To review reported adverse reactions to drugs administered.

M. to evaluatate periodically medical records in terms of drug therapy.

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VOLUNTARY HEALTH ASSOCIATION OF INDIA

C-14 Community Centre
Safdarjung Dev. Area
New Delhi-110016

As Part Of Rational Drug Policy Campaign

Hazardous, Bannable and Dumped Drugs

The issue of dumped drugs has been in the news for the past few years. The drug companies involved in the manufacture and sales of such drugs have received their due share of condemnation. Foreign governments policies, which provided scope for exports of such hazardous products have been also condemned, e.g., the Clayton Amendment Act and the U.S. Regulation.

It is well known that sales of medical technologies and drugs is a commerical enterprise, the motivation being profit rather than "service" or "welfare work".

Realising all this, the question arises as to how much can we, as citizens of India, expect our drug control authorities to safeguard our interests. The pressure from the drug industry is immense. In spite of knowing this, our expectations from the drug control authorities is high. After all our pharmaceutical industry is the most developed in the Third World. According to UNIDO, it belongs to Category V -- 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, as per WHO's guidelines for Essential Drugs. The drug industry and its supporters allege that the concept of essential drugs is only for struggling, less developed countries of the Third World and not for a country like India, with its well-developed industry and its 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. The lobby claims that consideration of hazards over efficacy is a luxury which we cannot afford.

However, consumers anywhere in the world have the right to expect that irrational and hazardous drugs are not issued licences and that licences of banned drugs should be withdrawn as soon as possible, the ban implemented, and that all drugs in the market are quality - controlled. We have 20 per cent substandard drugs . One out of every five drugs will not be effective. With the incereasing number of spurious drugs floating in the market, the problem is beginning to take on dangerous proportions.

Since 1980 we've been concerned about this issue of dumped and hazardous drugs.

SOME BANNABLE DRUGS -- WHAT IS THE POSITION NOW

Under Section 23 P of the Drugs and Cosmetic Act of 1940, the Central government has the power 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 the power to prohibit manufacture, distribution and sale of drugs by a gazette notification.

The sub-committee of the Drugs Consultative Committee, in its 1980 report, recommended the banning of 23 combinations of drugs, giving their reasons for such banning, 16 categories of these drugs were recommended for immediate weeding and seven of the categories were to be weeded out over a specified time. Over 500 brand drugs would be thus affected. This report was presented to the Durg Consultative Committee at a special meeting on 10.10.81, and later to the Drug Technical Advisory Board (DTAB) and the Ministry of Health and Family Welfare accepted it in 1981.

The DTAB, a Statuatory Body under Section 5 of the Drugs and Cosmetics Act of 1940 recommended banning of 18 fixed dose combinations. These drugs were randomly selected from the Pharmaceutical Guide. Out of the 350 brand names affected, 44 were marketed by the foreign sector, 8 by public sector, and 298 by private sector. Most of these drugs were being produced by national companies According to the authorities, "the purpose was to give time limit to firms who may already have purchased the bulk drugs form manufacturing the formulatios". What compassion and consideration for the drug companies!

SOME BATTLES

Halogenated Hydroxyquinoline

Ban of fixed dose combinations of halogenated hydroxyquinoline

was to be effective from 1.11.82. The date of the ban was extended to 31.3.83 through DO No. X19013/8/81-D dated 13.8.82.

High Doses of EP Drugs

Through another DO. No. 12-48/79 DC dated 26.6.82, the Drug Controller of India directed the State Drug Controllers to ban the manufacture of high dose Estrogen-Progesterone combinations from 31.3.83 and their sales from 30.6.83.

M/s. Unichem Labs, Bombay (OP 2927/82 of writ petion 2928/-82), M/s. Nicholas Labs, Bombay and M/s. Organon (now known as Infac (India) Ltd., Calcutta filed writ petitions in Bombay and Calcutta high courts challenging the ban. Their contention was that the Central Government has no powers to ban the drugs. The High Court of Bombay and the High Court of Calcutta have granted stay orders against the ban. Now these products are available in the market.

Section 10A and 26A of the amended Drugs and Cosmetics Act (April 1982) empower the Central Government to prohibit import, manufacture and sale of any drugs considered harmful/ toxic or irrational, etc. Since the matter was in court during the gazette notification of 23.7.83, this combination of drugs has not been included in it.

What is absolutely objectionable is the fact that -- inspite of the act of the Drug Controller of India's ban of the production and sale of EP drugs, M/s. Organon have managed to obtain extension of licences to manufacture these products for another two years.

Paediatric Tetracycline

Although this drug is banned in its oral liquid from to discontinue its being prescribed for children because of its often serious side-effects, it is being manufactured today as a tablet of 30mg. for children -- an example of how a company can follow the letter of law and yet disobey it without any legal consequences.

Aspirin and Vitamin C

In October 1982, M/s. Nicholas Labs, Bombay filed a writ petition in the Bombay High Court against the decision to ban the fixed dose combinations of Aspirin with Vitamin C. The Court ruled that the State Drug Controller has no power under Section 18 of the Drugs and Cosmetics Act to stop the manufacture and sales of this product. However, it would be open to the respondents as and when the law has been enacted, to pass any fesh order as it is considered necessary in accordance with the law after following procedures prescribed by the Government.

Subsequent to the Drug Amendment Act of 1.2.83, the manufacturers have again gone to court challenging the Central government and Sections 26 A and 10A on the grounds of "lack of objective criterion for such ban".

This has resulted in the FDA -- Maharashtra (which is supposed to be having the best drug control mechanism in India) informing the Drug Controller of India 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 9.6.1984 by the Drug Controller of India to the Voluntary Health Association of India).

Gazette Ambiguities

It is not clear from the DO letter banning 22 drugs, whether some drugs like strychnine and yohimbine, and caffeine are banned only in some combinations, or in all combinations :

- any drug containing yohimbine, or strychinine would be banned (as neither of the two were considered to have any therapeutic value and infact could lead to serious side effects).

- or the ban was applicable to drugs containing both yohimbine and strychnine.

- or to yomhimbine and strychnine with testesterone or vitamins

- or ONLY to drugs which contained all four : yohimbine, strychine, testesterone and vitamins.

Bangladesh banned 1742 drugs in June 1982. The time period given to the drug companies to **withdraw these products from the market, to destroy these products** was three to nine months, depending on the product. **They were strictly prohibited from exporting these products to other countries.** But we failed to ban even a few hundreds, let alone 1742 drugs. The time period given to drug companies was to complete the manufacture of their formulation and sell off their stocks.

WHO IS MORE IMPORANT --- THE DRUG COMPANY OR THE CONSUMER ??

The drug policy is now on the anvil. It is now that we can assume the responsibility for putting people's health before the health of the industry. If Indian people have to become healthy, Indian Drug Policy needs to be rational. The choice is ours -- and we must make a decision now.

Third World Network

87 Cantonment Road, Penang, MALAYSIA.
M-139 Goa Housing Board Colony, Alto-Betim 403 112, INDIA.

Date: 6th November 1985.

Dear Friends

The TWN would like to bring to your attention the following 'Action Alert' from D. Rajeandran, Secretary of Sahabat Alam Malaysia (SAM) and Coordinator of the Asia-Pacific People's Environment Network (APPEN).

APPEN ACTION ALERT: UN CONSOLIDATED LIST OF PRODUCTS

This is in response to an urgent request for support from the Coordinating Committee on Toxics and Drugs in the United States with regard to the United Nations Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or Not Approved By Governments.

On the 10th of April this year, we had circulated an action alert to you all calling for support of this important campaign which concerns all of us. Unfortunately, we had not heard from a number of you, but we hope that this time you will all respond towards this crucial matter in the spirit of solidarity. Remember that it costs us a lot of time and money to circulate more than 1,000 copies around the world. If we ourselves are not concerned, then nobody will be on the fate of the earth and mankind.

Yes, coming back to the Consolidated List, we are sure you all are aware that it contains critical information on regulatory decisions, restrictions and bans taken by national governments on more than 500 hazardous products. It has just been revealed that trade names and manufacturing data will most likely not be part of the 1986 version. The trade name index which is so useful to NGOs will thus disappear.

With reference to the 1986 edition of the Consolidated List, the actual collection, screening and processing of the relevant data will now be carried out by the World Health Organisation for pharmaceuticals while the United Nations Environment Programme will be concerned with pesticides and industrial chemicals. What is interesting to note is that the UN Centre on Transnational Corporations, which was actively involved in the previous two editions of the Consolidated List, is not included in the multi-agency negotiations.

Other substantial changes include the deletion of all pharmaceuticals that have been banned because they are useless. There are other changes as well, most of which we feel appear to cater more to industry's wishes than to address consumer, health and environmental concerns. In pure political terms, the LIST is more vulnerable now as the United States, the primary opponent of the LIST has significantly more control and influence over the multi-agencies.

...2/-

Drug file
RN

Latest Pamphlet and Drug Cell Newsletter sent RN 20/11/85

We need your undivided and continued support for the Consolidated List which may otherwise be considerably weakened.

WHAT YOU CAN DO:

1. Write to the UN Program Planning and Coordination office in support of the LIST, but also to introduce yourself to the new director, Mr Luis Gomez. Ask the office to continue to include trade data as it is mandated to do by the original 1982 UN resolution, "Protection against products harmful to health and the environment." The address is

   Mr Luis Gomez
   Assistant Secretary General
   United Nations
   DIESA - Program Planning and
   Coordination Office
   DC 2, 18th Floor
   New York, NY 10017
   USA

2. Write to the UN Centre on Transnational Corporations to express your support for their efforts. Send any trade data (that you have not sent previously) directly to the UNCTC to assist them in their work. Urge your government officials as well to submit trade data directly to the UNCTC. The address is

   Mr Peter Hansen
   Executive Director
   UN Centre on Transnational Corporations
   DC 2, 12th Floor
   New York, NY 10017
   USA

3. Continue to send all official information on bans and restrictions of pesticides, pharmaceuticals, industrial chemicals and consumer products to the United Nations Program Planning and Coordinating Office in New York. The UN office will then mail your information to the appropriate agency, but we feel that it will be wiser for us as NGOs to continue the practice of going through one central office, to effectively monitor what is being sent. The address is

   Ms Eileen Nic
   Project Coordinator
   Coordinating Committee on Toxics and
   Drugs
   Natural Resources Defence Centre
   122 East 42 St
   New York, NY 10168
   USA

4. As the World Health Organisation and the United Nations Environment Program are playing a new, pivotal role this year with respect to the LIST, we must let them know that NGOs support a readable, comprehensive document. By writing to them to explain that you have been following the work on the CONSOLIDATED LIST and that you will continue to be helpful and supportive, you can make it clear that we are taking our mandate very seriously. The addresses of those agencies are

   Mrs Inger Brugemann
   Director of External Coordination
   World Health Organisation
   20 Avenue Appia
   1211 Geneva 10
   [redacted]ND

Mr Jan Huismans
Director
IRPTC/UNEP
Palais des Nations
1211 Geneva 10
SWITZERLAND

5. Many governments may not know the agreement to delete trade data from the 1986 version of the LIST or that other changes have been made. If possible, speak with or write to government officials to express your concern about the new arrangements. If your country is supportive of the LIST, ask that it make that support known through the UN mission or directly to the Program Planning and Coordination Office and request that it also provide data on bans, withdrawals and severe restrictions to the United Nations.

6. If you know of any case where use of the UN CONSOLIDATED LIST has resulted in new regulations on pesticides, pharmaceuticals or consumer products or has actually saved lives, prevented injury or resulted in some positive change in your country, please let the Coordinating Committee on Toxics and Drugs and the United Nations know about it. The information is needed to counter allegations that the LIST serves no role for governments.

7. As postage by air to all organisations is exorbitant, we will be grateful if you can reproduce this APPEN ACTION ALERT and circulate it to all concerned groups in your country.

8. Finally, do keep us informed of your activities and don't forget to send us copies for our follow-up reference.

We thank you and hope that we can continue to work together in future campaigns of interest.

Note: Please send carbon copies of all your letters and cables to:

THIRD WORLD NETWORK
M-139, Goa Housing Board Colony,
Alto-Betim 403 112, Goa.

for transmission to Malaysia and follow up action. Carbon copies on air-mail (thin) paper preferred.

FEDERATION OF MEDICAL REPRESENTATIVES' ASSOCIATION OF INDIA

372/2, Russa Road (East)
Calcutta - 700033

Note on the Brand List of Banned Drugs

In pursuance of the brand list of banned drugs as prepared and circulated by VHAI following list is prepared after investigation in the market of Eastern India. It was surprisingly observed that most of the companies have either withdrawn their products or changed the formulations without any official information. Active sales promotion of all these products except the steriods have been stopped.

Details of the drugs of Class I is enclosed.

Class II

0/0/4 Tonizal = Caffine has been withdrawn from the drug

Vitahest: Hoechst - is to be added in this group.

13/9/8 - Phenacetinin has been withdrawn from all the drugs enlisted.

15/0/0 - Bistrapen, Bistrapen Forte, Crys- 4, Omnymycin are available. Other drugs are not marketed

7/0/0 - Analgin of all brands and combinations are available.

14/0/0 - Rans-trepcol - withdrawn. A leading brand 'Strepto Parasin' of Boerhringer Knoll is to be included in the list.

- E.P. Drugs, Clioquinols, Phenyl butaone, Oxyphen butazone and Anabolic Steriods are all available.

- Amitava Guha

Sl. No.	Brand / Company	Available	Not marketed	Changed	To be added in the list
2/1/1	Allergin			√	
	Aristopyrin	√			
	Cibalgin		√		
	Dolorindon			√	
	Nee-spasmindon			√	
	Esgipyrin			√	
	Optalidon		√		
	Oripyrin			√	
	Pyrindon			√	
	Spasmindon		√		
	Uni-Spasm			√	
	Spasmo-Cibalgin		√		
	Veganin			√	
	Dolviron		√		
	Codopyrin		√		
	Apidin		√		
	Trevpel		√		
5/2/2	Placidin		√		
	Spasmo-Proxivon	√			
	Sudhinol-M-C	√			
	Tylinol		√		
	Walagesic	√			
	Diligan		√		
	*Duodil				√
	Equagesic			√	
6/3/3	Antispasmin	√			
	Prydonal		√		
	Spasmolysin		√		

The Drug action network

NEWSLETTER OF THE LOW COST DRUGS
AND RATIONAL THERAPEUTICS CELL
VOLUNTARY HEALTH ASSOCIATION OF INDIA C14 COMMUNITY CENTRE SDA NEW DELHI 110016

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NEW DELHI Oct 23 1983

With this issue of what was so far simply the "Drugs Newsletter" we introduce a new, and we hope more attractive format for the humble two page leaflet that served as our forum for exchange of news and views.

We have been painfully aware of the irregularity of its appearance and this is one of the shortcomings that we are determined to overcome. So that at least once in two months there is a review and sharing of the activities of the network.

One of the reasons for giving the newsletter this shape and style is to try and reach more people through the efforts of the existing networkers, who will hopefully circulate it to their friends - in fact we can send extra copies on request or directly to individuals or groups whose names and addresses you send us.

And so for those who have just come into the network, the story so far :

What we have called today, rather tentatively "The Drug Action Network" began for most of us with an informal and exciting three day meeting in Pune in January 1982 where 28 participants representing various interest groups already involved in drugs and health met to pool their efforts in discussing problems and finding solutions to them. The individuals and groups included doctors, pharmacologists, consumer education groups, journalists, documentation centres, management experts and other professionals.

Problem areas were defined and action plans drawn up. It was decided to launch a concerted nationwide campaign against the widely misused high dosage estrogen-progesterone combination drugs on March 8, 1982, International Women's Day. It was in a sense, a test balloon for the network. The campaign was a success both in terms of public awareness as well as the response from the government, which finally banned the drugs. The scene of this battle has now shifted to the courtroom with the drug companies challenging the ban in the High Courts. (See "The Case Against EP Forte")

Drug Workshop I (Pune) was followed by Drug Workshop II at Jaipur in August 1982. The issues selected for the workshop included

- follow up of EP Forte campaign
- misuse of anti-diarrhoeals, anabolic steroids, clioquinol, ped. tetracycline.
- banning of drugs
- need for a code of ethical marketing for the companies
- the events in Bangladesh, the new drug policy, etc.

Various members of the network again assumed responsibility for different facets of the follow up action.

Since then the "Drugs Newsletter" and various cyclostyled papers on different issues from members of the network have been the chief means of communication within the network. We hope that the present attempt will reinforce these efforts.

It has been suggested that the drugs network should be given a proper name by which it can be identified. This would be one way of emphasising the collective character of our action plans, which should not appear to be diffused as the efforts of individual do-gooders.

What do you think of this suggestion? If you agree, what would you suggest for a name? Or is "Drug Action Network" good enough?

Please write in your feedback. Together with news from your point of view.

That's what this newsletter is all about, anyway.

network news

★Aspi Mistry who was formerly with the Centre for Education and Documentation in Bombay and one of its founder-members has joined VHAI since July 1983. He is based in Dehradun with the Low Cost Drugs and Rational Therapeutics Cell and will be working with Mira Shiva from there. For all future correspondence their address is :

105 Rajpur Road
Dehradun
U.P. 248 001

Tel : 23374

★Ms Kapila Hingorani who has been working on some of the legal aspects of health issues has got a group of NSS students from Delhi involved in the drugs issue as part of their project work. Shebani and her friends from Lady Sriram College have been compiling and collating information on the banned drugs.

★Vincent Panikulangara's writ petition in the Supreme Court was due to come up in October for hearing. In this petition (No.3492 of 1983) he had asked for a writ of mandamus directing the govt.

Xth MFC ANNUAL MEET

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As announced in the last issue, the Xth MFC Annual Meet will take place in January-end 1984. The dates and the venue have been finalised-27th to 29th January, 1984 at the Child In Need Institute (CINI) at Calcutta, West Bengal. We are thankful to Dr. Samir Choudhary, the Director of CINI for offering to help organize the MFC Meet at CINI. There are many socially conscious medicos in W. B. But so far we never had an Annual Meet in that region. By arranging the Meet near Calcutta, we hope to contact other socially conscious medicos in West Bengal.

Theme for discussion : The first two days of the meet will be devoted to the discussion on "**Why alternative medical education is necessary ?**" The Third-day will be reserved for the Annual General Body meeting of MFC. There has been a strong feeling among MFC-members and like-minded people that the existing medical education is inappropriate. In fact, one of the founding inspirations of MFC has been the realization of the irrelevence of the medical education to the needs of the rural poor. But we have not so far discussed systematically and in detail, as to what is exactly wrong with the existing medical education, why an alternative is necessary ? The aim of the two days' discussion at the coming Annual Meet would be to build a strong case for an alternative medical education by showing in some depth the inappropriateness of the existing medical education.

As usual, some background material and the discussion-papers would be circulated well in advance. There will be a special double issue of MFC-Bulletin containing 1) Survey of history of evolution of medical education in India during last 150 years, 2) An article pointing out the gap between the health-needs of the people and the health-facilities available-this will lead us to what system of medical care do we need and what should be the role of the doctor in it and accordingly what should be the training he/she should receive. 3) A survey of different experiments done in different countries about alternative medical education.

After the last Annual Meet at Anand, some of us stayed back for one day to discuss alternative medical education. Some MFC members had been invited for a workshop at Dhaka on alternative medical education. The discussion at Anand had been mainly organized as a preparation for the Dhaka Conference. This time, however, the focus will be different—to argue out in the first place, the inappropriateness of medical education.

Travel arrangements etc : As usual, participants will have to pay for their own travel. Since participants outside West Bengal would have to spend considerable amount on travel, attempts are being made to subsidize food. The exact extent of subsidy is yet undecided. Those who cannot afford to pay will be exempted.

Those of you who want to attend this Meet, are requested to write to me so that I can send all further details and also the background—papers...etc. as they get ready.

-Anant Phadke, Convenor, MFC.

(Published as supplement ro the November- 1983 issue.)

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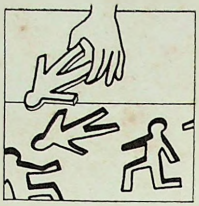

Just released

Management Process in Health Care

S. Srinivasan, (ed.) pages 534, 1982, Rs. 58

This is a book on management of health care institutions. Written by a team of people with training and experience in administration, this book is meant for the manager and those interested in the art of management. This book will interest all who are interested in organising for health—be it in a hospital, a dispensary, a community health programme or a special care home for the handicapped.

The book is meant as a guide. It can be used as a text-book or a reference for basic principles and practices. The book seeks to put together notes, cases and articles and present the Indian experience of health care management. This book focuses more on the process of planning, activating and reviewing. There is less emphasis on the tools and techniques of management. But it would give you an idea of the availability of these tools and techniques, and the situations where they could be appplied.

Edited by S. Srinivasan of the Health Care Management team of VHAI, the book is a beautiful example of the team effort it advocates.
To order (add Rs. 8/- postage), write to VHAI.

* * *

19 going on 19

जहां डॉक्टर न हो ।

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If you still do not have the Hindi version of **Where There is No Doctor**, this is the time to order. Thanks to a well wisher. We are able to offer another 3,000 copies at Rs. 19+ postage Rs. 7 instead of the usual 29/- +postage. Order your copies now. Till stocks last.

* * *

Health Care: Which Way to Go

Abhay Bang and Ashwin Patel
Pages 272 **Rs. 10**

This is the second anthology of the Medico Friend Circle.
Probing articles on
Doctors-Prescriptions-Khesari Camp-Women-Nutrition
Nurses-Curses-Mass Vaccine-Diarrhoea-Rehydration
Health Politics-Liberators-Rural Health-Health Workers
Dais-Directions etc.

Illustrated, humorous, thought provoking.
(To order (add Rs. 3/- Postage) Write to VHAI.

A Letter from a Friend on Drugs

Dear Renu*

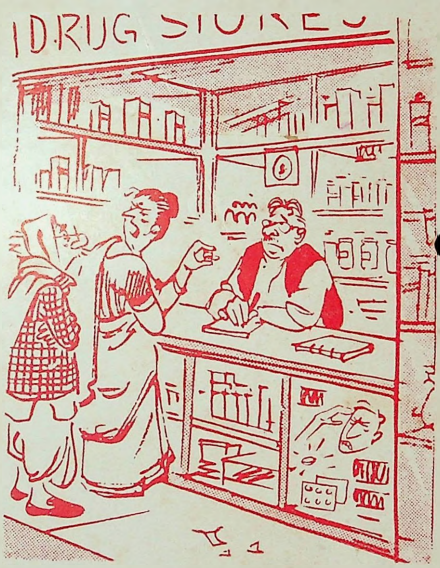
.....The holistic seminar group is still very enthusiastic. I am very happy about it. The latest news is that the medical representatives are a bit worried. They were asking me about the posters that we have put up in the OPD. "Who gave you the ideas", they asked. I handed over to them a Black copy of the drugs issue of *Health for the Millions* and also the article 'Drugging the Indian.' I guess that I was the first woman who challenged them. They did not stay very long in my office after that. I have asked all of them to go and have a chat with VHAI staff. Then, if they feel like coming, they are welcome. Lots to tell you. Love and prayers,

Dated 30-9-82

Sr. Agnes
Administrator,
Holy Family Hospital,
Mandar.

*VHAI staff member

THE VICIOUS CIRCLE THAT LEADS TO THE OVERUSE OF MEDICINE



Expensive, yes, but the doctor says, you have got to take a couple of these pills—we will have to put off paying the house rent, the grocer, the milkman—!

There is very little evidence to substantiate the criticisms made by the industry in either Thailand or Bangladesh. By way of contrast, in Mozambique, a country which has successfully implemented a restricted drugs list based on the WHO model, coupled with competitive bulk buying and an education programme to transform prescribing habits, the evidence shows a positive improvement in health care which meets people's needs.

Drug Prices Are Falling

Drug prices in Mozambique are dropping. Some basic antibiotics and pain killers now cost one-third less than they did three years ago. Useless and dangerous drugs have largely been taken off the market. And for the first time, according to a WHO evaluation report, most rural health posts have enough basic drugs.

One commentator in Mozambique has noted: "Drug imports in Mozambique today cost the same as they did 10 years ago: about US $1 per person. Mozambique is buying a lot more drugs for its money, simply by not wasting money on useless and dangerous drugs, on fancy packets, and on well known trade names."

The Mozambique experience and the efforts of Bangladesh and Thailand are significant initiatives on the part of developing countries to decrease dependence on the transnational pharmaceutical industry. With TNCs looking to developing countries to provide about one-third of their sales turnover by the end of the next decade, the importance of these initiatives becomes apparent.

Bangladesh has given permission to WHO to circulate its new drugs policy to all WHO member states. If this is done, and other countries begin to implement similar measures, the pattern of drug usage may be radically altered in the coming years. We may be witnessing the beginnings of a revolution in drugs therapy—a revolution no less significant than the development of antibiotics a few short decades ago—and a revolution that may have tremendous impact on people's health.

Doctor's Prescription

Before the Ban

Dr. Abdul Khan M.B.B.S.
Dr. Sheela Abdul Khan M.B.B.S.
FATIMA CLINIC
285, Bose Road, Mujeeb Nagar-5
Phone : 47946

Azij Age-2

Cap. Chloros trep † TDS x 3 days
Tab Flagil † TDS x 5 days
Kaopectate † 1 tsf 6h x 3 days
Becosulin † TDS x 3 days
Phosphomine ① bottle

Abdulkhan
29-3-81

FOR EMERGENCY
Please ring up to 674321

After the Ban

Dr. Abdul Khan M.B.B.S.
Dr. Sheela Abdul Khan M.B.B.S.
FATIMA CLINIC
285, Bose Road, Mujeeb Nagar-5
Phone : 47946

Azij - Age 3½

Oral Rehydration Solution
Plenty of fluid

Abdulkhan
10-12-82

FOR EMERGENCY
Please ring up to 674321

ZAFRULLAH & SUSANNE CHOWDHURY

Gonoshasthaya Pharmaceuticals

Gonoshasthaya Kendra (People's Health) Charitable Trust's original objective of establishing a preventive and primary health care service in a rural area of Bangladesh gradually developed into a broader community development programme and not surprisingly, we began to consider how to provide our service area with quality and inexpensive medicine.

A project of the Gonoshasthaya Kendra Charitable Trust, (Gonoshasthaya Pharmaceuticals Ltd.) GPL is designed to supply 15-20% of the present Bangladesh market in essential drugs. It aims to produce high quality, essential and generic drugs only, at the lowest possible price through responsible marketing practices. GPL is registered with the Joint Stock Companies under the Companies Act of 1913 and as such, is subject like any other company, to the usual customs, taxes and other duties. Unlike other companies, however, there are no private shareholders. The entire stock is owned by the Trust which, by its charter, limits profits to 10-15% after payment of duties and bank charges. About 50% of the profits must be ploughed back into the factory and 50% spent for research and charitable purposes.

The Board of directors has nine members—five from GK Trust and the rest representatives from the Ministry of Health, Directorate of Industries, Bangladesh Shilpa (Industrial) Bank and NOVIB, a Dutch non-government organisation. This structure was adopted with the hope that GPL would combine the advantages of private industry with its freedom of decision making for management with the character of a public enterprise oriented to the consumer and avoiding profit motives.

Funding came in good part through foreign voluntary organisation donations directly to the GK Trust for this (GPL) project. A break-down is shown at the end of the second column.

Technical expertise was provided by the International Dispensary Association (Holland) who helped to organise additional training for managers and procured machinery and raw materials. Professor J. Polderman, Expert Committee Chairman of the European Pharmacopeia has been sponsored by NOVIB as our Production Advisor. All managers of the factory are Bangladeshi.

Establishment of GPL, needless to say, met with problem areas. The first of these was infrastructure. Any attempt to establish a high technology project in an underdeveloped country will suffer from lack of infrastructure and problems arising from having to import much of the necessary equipment. Our main problems here were in the lines of architecture, electrical supply and assembling and maintenance of machines/equipment.

The second area of concern was personnel. Skilled workers in all categories, but especially maintenance technicians are extremely difficult to hold in Bangladesh due to migration to the Middle East where wages are much higher. Unskilled labourers, we were determined to recruit from among the really needy, maintaining the emphasis of the whole of Gonoshasthaya Kendra on developing women's skills. Since this was our objective, a good deal of basic functional education was necessary before the women could begin working in the factory. For most of our recruits, it meant functional literacy classes as well as learning pharmaceutical terminology and familiarisation with the machinery they would be using.

NOVIB (Holland)	US dollars	2.62	million
OXFAM (U.K.)	,, ,,	0.33	,,
CHRISTIAN AID (U.K.)	,, ,,	0.22	,,
COMMUNITY AID ABROAD (Australia)	,, ,,	0.05	,,
EUROPEAN ECONOMIC COMMUNITY (through Novib)	,, ,,	0.20	,,
Bangladesh Shilpa Bank, GK Trust and Others (this is strictly a loan to GPL)	,, ,,	1.50	,,
	US dollars	4.92	million

The social and political climate cannot be ignored either, when beginning a new industry in a country like Bangladesh. The government's policy is to encourage industrial development, especially in such a thing as essential drugs. However, anyone who intends to produce or market in Bangladesh has to cope with the corrupt practices which pervade the industrial and commercial life of the country. For those who have 'been in the business,' GPL's conditions for doing business come as a surprise which they often cannot fully understand, since everyone knows bribery is part and parcel of the way of life in this country.

Then of course, there is the problem of moving into an already well-established market. Considering that our aim is to supply quality drugs at the lowest possible price, we knew trouble would be waiting—just how much trouble has only come in bits and pieces, but it has come, especially in the field of pricing and marketing.

We believe that for the proper information of the consumer, all pharmaceuticals should be obliged to give details of their pricing policy. The table "Contrast in Drugs Prices" though not a break-down in details of pricing, compares some of GPL's prices with those of similar products being manufactured and marketed in Bangladesh.

It should be noted that as a new company, as well as due to our insistence on very high quality control and social benefits for our workers, our overheads are very high. Older companies whose machines are fully depreciated will have much lower overheads. We intentionally make higher profits on drugs we consider less

CONTRAST IN DRUGS PRICES

Company Name	*Product's Name*	*Capsule/Tablet Price*	*Syrup/Liquid Price*
1. Ampicillin			
Fisons	Penbritin	Tk. 1.69/cap*	Tk. 23.80/60mls
Hoechst	Amblosin	1.80	23.80
Square	Ampicin	1.70	21.00
K.D.H.	Amplin	1.70	23.80
Pioneer	Ampicil	1.70	21.00
Albert David	Aldapen	1.30	
G.P.L.	G-Ampicillin	1.00	24.00/100mls
2. Amoxicillin			
Fison	Amoxil	3.00/cap	32.00/60mls
K.D.H.	Amolin	2.47	25.00
G.P.L.	G-Amoxicillin	2.25	
3. Tetracycline/Oxytetracycline			
Pioneer	Teracin	0.90/cap	
Pharmadesh	Oxalin	0.97	
Hoechst	Hostacycline	0.90	
Albert David	Aldacycline	1.00	
Squibb	Sumycin	0.98	
I.C.I.	Imperacin	1.05	
G.P.L.	G-Tetracycline	0.50	
4. Sulphamethoxazole & Trimethoprim			
Burrough Wellcome	Septrin	2.30/tab	26.00/60mls
Square	Cotrim	1.98	22.00
Therapeutics	Theratrim	1.80	22.00
Opsonin	Chemotrim	1.75	16.00
Pioneer	Sephtazol	1.90	
G.P.L.	G-Cotrimexazole	1.25	21.00/100mls
5. Paracetamol			
BPI (May & Baker)	Paracetamol	0.25/tab	
Square	Cetamol	0.25	
Hoechst	Pyralgin	0.27	
Fisons	Fitamol	0.25	
Nicholas	Paratan	0.25	
G.P.L.	G-Paracetamol	0.15	
6. Metronidazol			
BPI (May & Baker)	Flagyl	Tk.0.78/tab	
Square	Amodis	0.70	
Pioneer	Metazol	0.60	
Opsonin	Metril	0.50	
G.P.L.	G-Metronidazole	0.40	
7. Aspirin (300mg)			
K.D.H.	Aspirin	0.12/tab	
Fisons	Genasprin	0.10	
G.P.L.	G-Aspirin	0.75	
8. Diazepam (5 mg)			
Square	Sedil	0.30/tab	
Opsonin	Easium	0.25	
Peoples	Sudex	0.20	
K.D.H.	Sedalin	0.30	
G.P.L.	G-Diazepam	0.125	
9. Antacid			
I.C.I.	Aviocid	0.45	Tk.23.00/225mls
Squibb	Antacil	0.25	15.20/228mls
K.D.H.	Nutracil	0.20	16.00/228mls
G.P.L.	G-Antacid	0.20	14.00/200mls

* 2 Bangladesh Taka = Approximately One Indian Rupee.

10. Frusemide (40 mg)

Hoechst	Lasix	1.30/tab
G.P.L.	G-Frusemide	0.60

11 Oral Rehydration Salt Sachet (27.5 gm)

Pioneer	Oralite-D	10.00
G.P.L.	Labon Jafer Sarbat (O.R.S.)	2.50

12. Ferrous Fumerate with Folic Acid

Fisons	Folte Tab	0.06
G.P.L.	G-Iron with Focid Acid	0.05

important or whose use we wish to discourage. For example we make a 6.57% profit on ampicillin and 3.2% on paracetamol (which are below our overall profit margin of 10-15%) and make it up with a 36.6% profit on diazepam and 85.6% on frusemide.

GPL hopes to market about 60-70% of its production to government, government agencies and charitable health services in bulk supply. This is deemed the safest, quickest way to channel the benefits of cheap drugs to people most in need. The remaining 30-40% will be sold on the open market but this involves a system of education (most, including doctors, believe the higher the cost, the better the drug) and distribution. It is difficult for even doctors to come by unbiased drug information since there is no Bangladesh National Formulary and often the product information leaflets are very different in content in third world countries than they are in first. The only way then for doctors to keep abreast of pharmaceutical developments is through foreign medical journals, etc. and most don't have access to the foreign currency necessary for purchase of these.

In this respect, we have used our Bengali language health bulletin 'Monthly Gonoshasthaya' to disseminate various information in relation to the baby food issue, abuse and exploitation in the drug market and other vital health-related topics.

Bid for Government Tender

Each year, the government calls for a large tender for medicines for rural health centres. In 1978-79, the government after proper calculation, put pressure on the government-owned Albert David company to sell them their ampicillin at a price of 95 paisa/capsule. In 1979-80, Albert David management contended that due to rising costs they couldn't supply lower than 99 paisa. In 1981, GPL bid for the tender of 10 million ampicillin capsule at 93 paisa, basing our calculation on the raw materials price cited by one of the leading trading houses and considering our high overheads. The day after submitting the bid, we were informed by the Trading Company that they could now quote a better raw material price. The previous one had been 95-120 US dollars per kg, the new one was 89-100 US dollars. This cheaper price would have resulted in a lowering of 5-17 paisa per capsule. We later learned that the Trading House in question is owned by the wives of the Managing Directors of three large pharmaceutical companies, one multinational and two national. Still later, we learned that some multinational and top-selling national companies had a meeting before the tender. We did not win the tender. It went to a national company which had bid at 80 paisa per capsule. The retail price of the same company's ampicillin is 159 paisa. For the government, this was the cheapest ampicillin they had ever purchased and giving credit where credit is due, some officials thanked us, requesting us to keep up the good work.

Role of UNICEF and WHO

UNICEF is the main supplier of drugs for primary health care in the rural health centres of Bangladesh, largely through their 'Drug and Diet Supplement' (D & DS) kits. The drugs are purchased through a general tender, mainly from East and West European countries, packaged in Copenhagen and then shipped to the recipient countries. We are pleased to say that UNICEF is now considering GPL as a supplier for the Bangladesh rural health scene.

Since one of our aims is to encourage the sale of generic drugs, we thought the translation, publication

An Indian Low Cost Drugs Project

A meeting of Abhay Bhang and Ashwin Patel of Medico Friend Circle, Dilip Desai of Sewa-Rural (Jhagaria, Gujarat) and S. Srinivasan of VHAI, took place on October 20, 1982 at Delhi. The purpose of the meeting was to finalise action plans for a low cost drugs project. The project involves ensuring a rigid quality control check on the products of low cost drug manufacturers. Initially, partners (user institutions, groups) for this project are being sought in Gujarat and Maharashtra only. The drugs envisaged for distribution will be generic formulations along the lines of the WHO essential drugs list and the Hathi Committee list. For details, contact : Dr. Dilip Desai, SEWA-RURAL, Jhagadia—393110, District Bharuch, Gujarat.

Manila Declaration

Stepped-up activities and more organized action to promote breastfeeding in Asia are in the offing. This is a direct result of a seminar held in Manila from September 27-30, 1982.

The Asian regional seminar for the promotion of breastfeeding, organised by IOCU with support from UNICEF, was attended by representatives of consumer groups, women's and health organizations, and key social action groups from 12 countries.

The local host was the National Coalition for the Promotion of Breastfeeding.

During the highly successful seminar, a number of workshops, evaluative and planning sessions were held. The framework for a regional programme of action was drawn up. At the end of the four days of lively and stimulating discussions, participants unanimously adopted a declaration calling on all governments, health professionals and consumers to promote breastfeeding.

Noting that milk companies continued to violate the provisions of the WHO/UNICEF Code, they stressed the need to formulate national codes of marketing to restrict excessive promotion of artificial baby milks. Consumer groups and other people's organizations were urged to expose such violations.

Augustine Veliath who represented NANI and India, ended his country report with the following prayer :

Lord's Prayer a la Amul

Amul Father who art in Anand give us this day
Amulspray (or Balamul if you prefer)
but before that
Give us clean, running water constantly and fuel
to boil that water so that we may follow the instructions on your tin.
Give us a fridge to keep the feed safe
and above all
Give us lands and jobs so that
we may pay for Amulspray.
Forgive us our poverty but do not lead us
into the temptation of diluting your formula.
May the WHO/UNICEF Code be always with you
Utterly, butterly Amen.

Anwar and Alternative Nobel

The president of IOCU, Anwar Fazal, has been awarded the 1982 Alternative Nobel Prize by the Right to Livelihood Foundation for founding Consumer Interpol. He shares the US $ 50,000 prize with : Petra Kelly, leader of the West German "GREENS", the rapidly growing environmental and peace movement which has transformed the German political scene; Sir George Trevelyan, a pioneer of adult education in Britain and founder of the Wrekin Trust, which brings together scientists and mystics, doctors and healers etc., in order to bring about "an evolutionary leap in human consciousness"; and the Participatory Institute for Development Alternative (PIDA), a group working to multiply grass root self-reliant development in rural Asia.

The annual prize was started three years ago by a Swedish stamp dealer, Jakob von Uexkull, to "support those working on practical solutions to the real problems in the world today". Von Uexkull believes that Nobel Prizes today reward "the wrong kind of knowledge which is often irrevelant and irresponsible". The new 'Alternative Nobel' award is presented in Stockholm on the day before the official Nobel Prize ceremony. The Right to Livelihood Award winners are chosen by an international panel which includes Robert Muller, Assistant Secretary General of the United Nations.

Anwar Fazal in the early 1970s was to Malaysia what Ralph Nader was to the US. His decision to become a fulltime consumer activist (which required him to give up his Nos. 2 position in the city government) came about when he led a group of citizens to oppose the building of a bridge that was to have connected his native Penang to the mainland for ecological and socio-economic reasons. "There was conflict of interests" was how the 41 year-old Fazal explained his decision. After nearly a decade of being in the forefront of his country's consumer action movement, Fazal was elected president of the International Organization of Consumers Union (IOCU)—the first from a Third World country to assume the position.

Health Workers' Convention

—D. Rayanna reports from Hyderabad.

The first ever Andhra Pradesh State VHWs convention was concluded at V R O, Pedakakari, Guntur on October 25, 1982. The three day convention was organised by A.P. Voluntary Health Association. 200 delegates from 20 districts participated in this convention.

The whole programme was geared to the VHWs themselves through groups sessions for sharing of their experiences and through opportunities for discussion.

On the first day at the inauguration of the convention, the lighting of the lamp was done by a VHW, the inaugural address was given by Dr. C. Savithri, principal, Guntur Medical College, and the Presidential Address by Dr. Lakshman Rao, Superintendent, Govt. General Hospital, Guntur.

Another highlight of the convention was the participants' programmes where health themes were presented in various media (skits, dramas, songs dances, Burakhatha etc.)

David Werner, the author of WHERE THERE IS NO DOCTOR, then on a visit to India, was the centre of attraction on the second day. He was welcomed by the VHWs and happily shared the morning session with them as they discussed the problems in working and living in the villages.

In the afternoon, Werner presented his personal experiences in Piaxtla, a rural health project in Mexico, through an excellent slide show emphasising traditional medicine as they have discovered and utilised in Mexico. That presentation was followed by a discussion period.

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On the concluding day, Amruthavani presented health related skits. This was followed by a group discussion on these themes by VHWs. Various health songs were compiled by the VHWs and were either written down or tape-recorded.

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* * *

The Ban is Coming

The Government proposes a total ban on advertisements of baby milk powder as a substitute to breast-feeding and restriction on advertisements of weaning foods for infants up to the age of 18 months, reports *patriot*.

A legislation, which is in an advanced stage, is expected to go before the Cabinet shortly, Social Welfare Secretary, Mir Nasrullah told newsmen in Delhi on November 9, 1982.

The proposed legislation is intended to promote breast-feeding. It will also discourage doctors from prescribing these foods as a substitute for breast-feeding and put restrictions on physician's samples. Mr. Nasrullh, however said that a total ban on the sale of baby milk foods may not be possible for various reasons.

While there were no problems in the rural areas where mothers had no alternative to breastfeeding, most working mothers in metropolitan and other cities turned to tinned food which was to be discouraged.

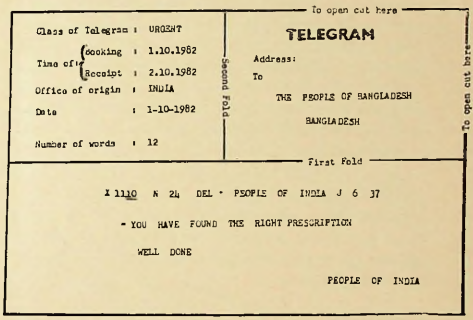
Mr. Nasrullah said his ministry was trying to create greater awareness among the people in a big way by propagating that "investment in child is an investment in future,"

Critique of Amendment

Basically the Bangladesh government cannot be criticised for its final report. The items reinstated under Schedule I can easily be taken care of at the time of renewal of licence (if the policy survives). Oddities, discrepancies begin to appear in Schedule II. Heptuna-plus, manufactured by Pfizer, USA, was 'lobbied' for by the country's gynaecologists (headed by Professor Feroza Begum, President of the Bangladesh Medical Association and a shareholder and member of the Board of Directors of Pfizer). This capsule, containing Iron, folic acid, multi-vitamins and minerals was claimed a necessary ante-natal drug, pleading the general under-nourished, anaemic condition of so many pregnant women in the country. The problem now is—other companies,' products of similar formulation remain banned. Naturally they have appealed to the Drug Controller and if the government succumbs, the door is wide open for further manipulation. No time beyond the previous six months limit was necessary for companies to submit their reformulation recipes. Extending this limit to 12 months merely prolongs the hope that change can still come.

The major coup for withdrawal/banning under Schedule III was, of course, allowing third party/ under licence products to continue to be manufactured until expiry of the present contracts, thus 'honouring international agreements, or the more aptly phrased, succumbing to international blackmailing by imperialist countries'. However, in this respect the government has not lost entirely in that. It also allows no further import of raw materials for these items. A definite conflict is now arising in this area,. The Drug Controller (who is the actual authority in this matter) is an honest, but weak person directly under the Secretary of Health who is a very clever individual, said to have connections with a number of multinationals. Ten companies have already applied for excipients (most products contain 1-2 active ingredients and 3-5 excipients) to be imported to use up on-hand, active ingredients. Squibb on the other hand, has all the excipients but has applied for two tonnes of alum hydroxide gel (active ingredient) for antacid manufacture. Organon has two milion capsules and some vials for their hormonal preparation decadurbolin and they want to import a few kilos of the active ingredient for this product. Herein lies the danger—the Drug Controller has rejected application for active ingredients but has become soft about allowing excipients. If one item is allowed, the cycle will continue with no hope of effective control and actual implementation of the new policy regulations. These applications are all naturally in the name of 'saving foreign exchange, by allowing the items on hand for manufacture to be used up rather than destroyed.

Support/Lack of Support



To open out here

Class of Telegram : URGENT

Time of filing: (booking : 1.10.1982; Receipt : 2.10.1982)

Office of origin : INDIA

Date : 1-10-1982

Number of words : 12

Second Fold

TELEGRAM

Address:

To

THE PEOPLE OF BANGLADESH

BANGLADESH

To open out here

First Fold

I 1110 N 24 DEL • PEOPLE OF INDIA J 6 37

- YOU HAVE FOUND THE RIGHT PRESCRIPTION

WELL DONE

PEOPLE OF INDIA

Those concerned with the survival of the new drug policy have been tremendously encouraged by the support the policy has received world over through various nongovernmental, voluntary organizations; scientists, academics, journalists, etc. Their cables to the Chief Martial Law Administrator and Health Minister, their news media exposes and anti-pressure, and questioning of various governments' (especially USA) interference has most certainly played a major role in keeping the policy alive. It cannot be questioned that Bangladesh or any other third world country is in need of this support system if they are to implement any policy of this nature for the good of their countries.

Conspicuous has been the lack of support, (Please also see page 6,—Ed, Hfm) from the campaigners of 'Health for all by 2000) the World Health Organization (WHO). One wonders how directly this is tied to the fact that 25% of WHO funds come from the USA. Dr. Halfden Mahler, Director General of WHO, in Dacca mid-September for meetings, lauded the advancement being made in health services in the country (where actually under 10% receive adequate health care) and assured his co-operation in this

matter. Asked specifically whether he appreciated the national drug policy, he avoided a direct reply saying, "governments announce policies for people." Dr. Cohen, also of WHO, when questioned on the subject by *South* magazine is reported to have replied, "How would you like WHO to ask the government of Bangladesh to make comments on your magazine ?".

Multinationals have done their utmost to discredit voluntary agencies supporting various health/pharmaceutical/consumer education works in Bangladesh. Some supporting agencies have written to various presses in protest, others have been weak in this fight. Little of this protest has appeared in print and the time seems appropriate for the maligned agencies to take their comments to the Bangladesh Press Council and demand hearing via the printed media.

Similarly, when local multinational opposition has gone to the press with their advertisements, these have been refused by all the larger papers. If a newspaper won't take money for advertising, the natural assumption is, that they are being paid by someone else NOT to take it.

Conclusion

The Bangladesh Government has taken a major step to curb exploitation of their people by multinational and national drug companies/manufacturers, but the battle is far from over. The policy still has to be implemented in the face of continuing opposition and pressure. A vigorous doctor/consumer education campaign needs to continue in the country to counteract the deliberately planned confusion which has been created in respect of the drug policy. We therefore need the continued support of concerned groups and individuals outside bringing this matter to the attention of the people of their own countries. We also need the continued support of pharmacologists, pharmacists, medical professors, etc. to feed our medical knowledge so our people will be the recipients of quality, low-cost medicines which meet their specific needs.

APPEAL

Dr. Zafrullah Chowdhury
Gonoshasthaya Kendra
P.O. Nayarhat, Via Dharmrai
District Dacca
Bangladesh.

Dear Readers,

I kindly appeal to you to send for our information, any newspaper/magazine clippings which you may come across

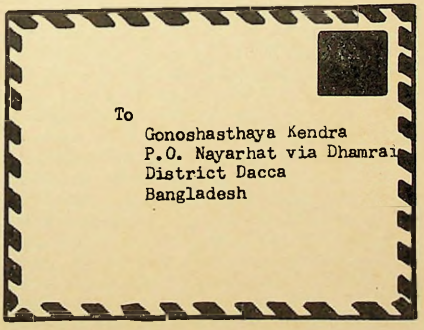
dealing with new drugs,
ban of drugs in any country,
the Bangladesh drug policy and
any other information of a similar nature.

I would also be pleased to receive any articles on the subject which you may personally write.

Thank you for your kind cooperation.

Yours sincerely,

Dr. Zafrullah Chowdhury
Project Coordinator



Course in Community Health and Development

The International Nursing Services Association will conduct 10-week course in Community Health and Development for medical and para-medical workers involved in community health and interested in training village health workers.

Courses begin on January 13, 1983 and June 13, 1983. (Applications due for the second Course—April 10, 1983), Contact Programme Director, INSA/INDIA, Rural Health and Development Programme, 2 Benson Town, Bangalore 560 046.

ZAFRULLAH & SUSANNE CHOWDHURY

Gonoshasthaya Pharmaceuticals

Gonoshasthaya Kendra (People's Health) Charitable Trust's original objective of establishing a preventive and primary health care service in a rural area of Bangladesh gradually developed into a broader community development programme and not surprisingly, we began to consider how to provide our service area with quality and inexpensive medicine.

A project of the Gonoshasthaya Kendra Charitable Trust, (Gonoshasthaya Pharmaceuticals Ltd.) GPL is designed to supply 15-20% of the present Bangladesh market in essential drugs. It aims to produce high quality, essential and generic drugs only, at the lowest possible price through responsible marketing practices. GPL is registered with the Joint Stock Companies under the Companies Act of 1913 and as such, is subject like any other company, to the usual customs, taxes and other duties. Unlike other companies, however, there are no private shareholders. The entire stock is owned by the Trust which, by its charter, limits profits to 10-15% after payment of duties and bank charges. About 50% of the profits must be ploughed back into the factory and 50% spent for research and charitable purposes.

The Board of directors has nine members—five from GK Trust and the rest representatives from the Ministry of Health, Directorate of Industries, Bangladesh Shilpa (Industrial) Bank and NOVIB, a Dutch non-government organisation. This structure was adopted with the hope that GPL would combine the advantages of private industry with its freedom of decision making for management with the character of a public enterprise oriented to the consumer and avoiding profit motives.

Funding came in good part through foreign voluntary organisation donations directly to the GK Trust for this (GPL) project. A break-down is shown at the end of the second column.

Technical expertise was provided by the International Dispensary Association (Holland) who helped to organise additional training for managers and procured machinery and raw materials. Professor J. Polderman, Expert Committee Chairman of the European Pharmacopeia has been sponsored by NOVIB as our Production Advisor. All managers of the factory are Bangladeshi.

Establishment of GPL, needless to say, met with problem areas. The first of these was infrastructure. Any attempt to establish a high technology project in an underdeveloped country will suffer from lack of infrastructure and problems arising from having to import much of the necessary equipment. Our main problems here were in the lines of architecture, electrical supply and assembling and maintenance of machines/equipment.

The second area of concern was personnel. Skilled workers in all categories, but especially maintenance technicians are extremely difficult to hold in Bangladesh due to migration to the Middle East where wages are much higher. Unskilled labourers, we were determined to recruit from among the really needy, maintaining the emphasis of the whole of Gonoshasthaya Kendra on developing women's skills. Since this was our objective, a good deal of basic functional education was necessary before the women could begin working in the factory. For most of our recruits, it meant functional literacy classes as well as learning pharmaceutical terminology and familiarisation with the machinery they would be using.

NOVIB (Holland)	US dollars	2.62	million
OXFAM (U.K.)	,, ,,	0.33	,,
CHRISTIAN AID (U.K.)	,, ,,	0.22	,,
COMMUNITY AID ABROAD (Australia)	,, ,,	0.05	,,
EUROPEAN ECONOMIC COMMUNITY (through Novib)	,, ,,	0.20	,,
Bangladesh Shilpa Bank, GK Trust and Others (this is strictly a loan to GPL)	,, ,,	1.50	,,
	US dollars	4.92	million

The social and political climate cannot be ignored either, when beginning a new industry in a country like Bangladesh. The government's policy is to encourage industrial development, especially in such a thing as essential drugs. However, anyone who intends to produce or market in Bangladesh has to cope with the corrupt practices which pervade the industrial and commercial life of the country. For those who have 'been in the business,' GPL's conditions for doing business come as a surprise which they often cannot fully understand, since everyone knows bribery is part and parcel of the way of life in this country.

Then of course, there is the problem of moving into an already well-established market. Considering that our aim is to supply quality drugs at the lowest possible price, we knew trouble would be waiting—just how much trouble has only come in bits and pieces, but it has come, especially in the field of pricing and marketing.

We believe that for the proper information of the consumer, all pharmaceuticals should be obliged to give details of their pricing policy. The table "Contrast in Drugs Prices" though not a break-down in details of pricing, compares some of GPL's prices with those of similar products being manufactured and marketed in Bangladesh.

It should be noted that as a new company, as well as due to our insistence on very high quality control and social benefits for our workers, our overheads are very high. Older companies whose machines are fully depreciated will have much lower overheads. We intentionally make higher profits on drugs we consider less

CONTRAST IN DRUGS PRICES

Company Name	*Product's Name*	*Capsule/Tablet Price*	*Syrup/Liquid Price*
1. Ampicillin			
Fisons	Penbritin	Tk. 1.69/cap*	Tk. 23.80/60mls
Hoechst	Amblosin	1.80	23.80
Square	Ampicin	1.70	21.00
K.D.H.	Amplin	1.70	23.80
Pioneer	Ampicil	1.70	21.00
Albert David	Aldapen	1.30	
G.P.L.	G-Ampicillin	1.00	24.00/100mls
2. Amoxicillin			
Fison	Amoxil	3.00/cap	32.00/60mls
K.D.H.	Amolin	2.47	25.00
G.P.L.	G-Amoxicillin	2.25	
3. Tetracycline/Oxytetracycline			
Pioneer	Teracin	0.90/cap	
Pharmadesh	Oxalin	0.97	
Hoechst	Hostacycline	0.90	
Albert David	Aldacycline	1.00	
Squibb	Sumycin	0.98	
I.C.I.	Imperacin	1.05	
G.P.L.	G-Tetracycline	0.50	
4. Sulphamethoxazole & Trimethoprim			
Burrough Wellcome	Septrin	2.30/tab	26.00/60mls
Square	Cotrim	1.98	22.00
Therapeutics	Theratrim	1.80	22.00
Opsonin	Chemotrim	1.75	16.00
Pioneer	Sephtazol	1.90	
G.P.L.	G-Cotrimexazole	1.25	21.00/100mls
5. Paracetamol			
BPI (May & Baker)	Paracetamol	0.25/tab	
Square	Cetamol	0.25	
Hoechst	Pyralgin	0.27	
Fisons	Fitamol	0.25	
Nicholas	Paratan	0.25	
G.P.L.	G-Paracetamol	0.15	
6. Metronidazol			
BPI (May & Baker)	Flagyl	Tk.0.78/tab	
Square	Amodis	0.70	
Pioneer	Metazol	0.60	
Opsonin	Metril	0.50	
G.P.L.	G-Metronidazole	0.40	
7. Aspirin (300mg)			
K.D.H.	Aspirin	0.12/tab	
Fisons	Genasprin	0.10	
G.P.L.	G-Aspirin	0.75	
8. Diazepam (5 mg)			
Square	Sedil	0.30/tab	
Opsonin	Easium	0.25	
Peoples	Sudex	0.20	
K.D.H.	Sedalin	0.30	
G.P.L.	G-Diazepam	0.125	
9. Antacid			
I.C.I.	Aviocid	0.45	Tk.23.00/225mls
Squibb	Antacil	0.25	15.20/228mls
K.D.H.	Nutracil	0.20	16.00/228mls
G.P.L.	G-Antacid	0.20	14.00/200mls

* 2 Bangladesh Taka = Approximately One Indian Rupee.

10. Frusemide (40 mg)

Hoechst	Lasix	1.30/tab
G.P.L.	G-Frusemide	0.60

11. Oral Rehydration Salt Sachet (27.5 gm)

Pioneer	Oralite-D	10.00
G.P.L.	Labon Jaler Sarbat (O.R.S.)	2.50

12. Ferrous Fumerate with Folic Acid

Fisons	Folte Tab	0.06
G.P.L.	G-Iron with Focid Acid	0.05

important or whose use we wish to discourage. For example we make a 6.57% profit on ampicillin and 3.2% on paracetamol (which are below our overall profit margin of 10-15%) and make it up with a 36.6% profit on diazepam and 85.6% on frusemide.

GPL hopes to market about 60-70% of its production to government, government agencies and charitable health services in bulk supply. This is deemed the safest, quickest way to channel the benefits of cheap drugs to people most in need. The remaining 30-40% will be sold on the open market but this involves a system of education (most, including doctors, believe the higher the cost, the better the drug) and distribution. It is difficult for even doctors to come by unbiased drug information since there is no Bangladesh National Formulary and often the product information leaflets are very different in content in third world countries than they are in first. The only way then for doctors to keep abreast of pharmaceutical developments is through foreign medical journals, etc. and most don't have access to the foreign currency necessary for purchase of these.

In this respect, we have used our Bengali language health bulletin 'Monthly Gonoshasthaya' to disseminate various information in relation to the baby food issue, abuse and exploitation in the drug market and other vital health-related topics.

Bid for Government Tender

Each year, the government calls for a large tender for medicines for rural health centres. In 1978-79, the government after proper calculation, put pressure on the government-owned Albert David company to sell them their ampicillin at a price of 95 paisa/capsule. In 1979-80, Albert David management contended that due to rising costs they couldn't supply lower than 99 paisa. In 1981, GPL bid for the tender of 10 million ampicillin capsule at 93 paisa, basing our calculation on the raw materials price cited by one of the leading trading houses and considering our high overheads. The day after submitting the bid, we were informed by the Trading Company that they could now quote a better raw material price. The previous one had been 95-120 US dollars per kg, the new one was 89-100 US dollars. This cheaper price would have resulted in a lowering of 5-17 paisa per capsule. We later learned that the Trading House in question is owned by the wives of the Managing Directors of three large pharmaceutical companies, one multinational and two national. Still later, we learned that some multinational and top-selling national companies had a meeting before the tender. We did not win the tender. It went to a national company which had bid at 80 paisa per capsule. The retail price of the same company's ampicillin is 159 paisa. For the government, this was the cheapest ampicillin they had ever purchased and giving credit where credit is due, some officials thanked us, requesting us to keep up the good work.

Role of UNICEF and WHO

UNICEF is the main supplier of drugs for primary health care in the rural health centres of Bangladesh, largely through their 'Drug and Diet Supplement' (D & DS) kits. The drugs are purchased through a general tender, mainly from East and West European countries, packaged in Copenhagen and then shipped to the recipient countries. We are pleased to say that UNICEF is now considering GPL as a supplier for the Bangladesh rural health scene.

Since one of our aims is to encourage the sale of generic drugs, we thought the translation, publication

An Indian Low Cost Drugs Project

A meeting of Abhay Bhang and Ashwin Patel of Medico Friend Circle, Dilip Desai of Sewa-Rural (Jhagaria, Gujarat) and S. Srinivasan of VHAI, took place on October 20, 1982 at Delhi. The purpose of the meeting was to finalise action plans for a low cost drugs project. The project involves ensuring a rigid quality control check on the products of low cost drug manufacturers. Initially, partners (user institutions, groups) for this project are being sought in Gujarat and Maharashtra only. The drugs envisaged for distribution will be generic formulations along the lines of the WHO essential drugs list and the Hathi Committee list. For details, contact: Dr. Dilip Desai, SEWA-RURAL, Jhagadia—393110, District Bharuch, Gujarat.

Manila Declaration

Stepped-up activities and more organized action to promote breastfeeding in Asia are in the offing. This is a direct result of a seminar held in Manila from September 27-30, 1982.

The Asian regional seminar for the promotion of breastfeeding, organised by IOCU with support from UNICEF, was attended by representatives of consumer groups, women's and health organizations, and key social action groups from 12 countries.

The local host was the National Coalition for the Promotion of Breastfeeding.

During the highly successful seminar, a number of workshops, evaluative and planning sessions were held. The framework for a regional programme of action was drawn up. At the end of the four days of lively and stimulating discussions, participants unanimously adopted a declaration calling on all governments, health professionals and consumers to promote breastfeeding.

Noting that milk companies continued to violate the provisions of the WHO/UNICEF Code, they stressed the need to formulate national codes of marketing to restrict excessive promotion of artificial baby milks. Consumer groups and other people's organizations were urged to expose such violations.

Augustine Veliath who represented NANI and India, ended his country report with the following prayer :

Lord's Prayer a la Amul

Amul Father who art in Anand give us this day
Amulspray (or Balamul if you prefer)
but before that
Give us clean, running water constantly and fuel
to boil that water so that we may follow the instructions on your tin.
Give us a fridge to keep the feed safe
and above all
Give us lands and jobs so that
we may pay for Amulspray.
Forgive us our poverty but do not lead us
into the temptation of diluting your formula.
May the WHO/UNICEF Code be always with you
Utterly, butterly Amen.

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Reading list on drug issues

Bangladesh situation	Source/Available at
1. Gonoshasthaya Kendra - a program report	LINK Vol.1, No.1, May-June 1981 (Asian Community Health Action Network Newsletter)
2. Gonoshasthaya Kendra - a progress report (Aug, 1980)	Handout available from VHAI, New Delhi
3. Bangladesh finds the right prescription	Health for the Millions (VHAI Bimonthly) Vol.VIII, No.6, December 1982 SPECIAL ISSUE.
4. Drugs in Bangladesh	LINK Vol.2, No.3, Aug-Sept 1982 (Asian Community Health Action Network Newsletter)
5. In Support of Bangladesh Drug Policy	Handout of VHAI Cell on Low Cost Drugs and Rational Therapeutics.
6. The War against Bangladesh - Claude Alvares	A Rustic/VHAI publication
7. Bitter Pills--Medicine and the Third World Poor - Dianna Melrose	OXFAM publication 1982.

Indian situation	
1. Report of Committee on Drugs & Pharmaceuticals Industry (Hathi Report)	Ministry of Petroleum and Chemicals, Government of India, April 1975.
2. Medicine-as if people mattered	Special Issue of Health for the Millions, VHAI, New Delhi, April-June 1981.
3. Aspects of Drug Industry in India - Mukaram Bhagat	Center for Education and Development, Bombay
4. Insult or Injury - Charles Medawar	Social Audit, England, 1979

PMA argued that blocking the flow of drugs from its member companies could open the market in Bangladesh to uncertified and potentially impure drugs from their sources.

Approximately 60 percent of Bangladesh's health budget is devoted to the purchase of drugs compared to less than 10 percent in the USA. Because of that Bangladesh is eager to bring its drug outlays under control and to begin to produce some of the less complex drugs immediately.

The Bangladesh committee acknowledged "with appreciation" the role of the transnationals but urged them to devote their "machinery and technical know-how" to producing important and innovative drugs and leave the production of simple and cheap drugs to the domestic companies.

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source: INDIAN EXPRESS of 21.8.82

I

GONOSHASTHAYA KENDRA
(PEOPLE'S HEALTH CENTRE)
DACCA, BANGLADESH

OBJECTIVES

1. To provide adequate health service in the rural area of Savarthana

2. to increase the independence and bargaining power of women, and

3. to bring about a change in the infrastructure and thereby allow for the economic and social development of poor villagers, i.e., 90 percent of the population of Bangladesh.

ACTIVITIES

1. A health programme which encompasses

   a. training of paramedical workers, basic health workers, medical students and doctors in rural health care delivery,

   b. curative care through a system of sub-centres which are staffed by paramedical workers and backed by a main centre which is staffed by doctors, technicians and paramedics, and which offers OT, sick-room, pathology, x-ray, and dental care facilities,

   c. preventive care including immunization programmes, mother/child clinics, pre-, and post-natal care, nutrition, hygiene, and basic health education carried out through regular programme of village visiting,

   d. family planning which provides contraceptives (pills and injection), sterilizations, and abortions, while carrying out a programme of motivation and follow-up,

   e. an insurance scheme for users of the health care services,

   f. pharmaceutical plant which manufactures drugs under their generic names (this is in the initial stages of operation), and

   g. publication and distribution of literature to assist medical practitioners in effective health care delivery in rural areas.

2. A vocational training programme for villagers in which both men and women are instructed and employed in all of the following areas:

   a. agriculture,
   b. jute handicraft manufacture for export,
   c. shoe manufacture and sale,

.../2

d. metal work including welding, etc.,
e. woodworking and finishing, and
f. management of canteen which caters to a sizable public clientele.

3. Education

a. classes in literacy and conscience-raising for village women and staff members, and

b. experimental school for children of landless combining practical training with formal study.

4. Credit unions providing loans for marginal and landless farmers.

CRITICAL ANALYSIS

1. Health Programme. "Some success of the primary service have been ascertained by surveys of sample villages and also by more random observation of disease incidence. Thus, there has been a dramatic fall in incidence of serious diarrhoea with dehydration. This is probably due to our intensive teaching of oral fluid therapy to mothers of small children, who now give the 'shortbut' to their infants as soon as they notice the first symptoms of diarrhoea. Since diarrhoea in children is still the commonest cause of death in Bangladesh as a whole, our success with preventing serious cases may well account for the lower overall death rate in our area which has been established by a sample survey (12/1,000 as opposed to the national average of 17/1,000). There has also been a marked decrease in scabies and other forms of skin diseases. Care of at-risk pregnancies, especially of women with symptoms of pre-eclampsia, has resulted in nil maternity deaths for the last year in the area fully covered by our service."

2. Women. "Out of a total project staff (including subcentres) of 114, forty six are female; and on the health side, women outnumber men. Apart from nightguard duty, there is no single task which women have not been engaged in on equal terms and on equal pay with their male colleagues, it the daily agricultural labour, health work, welding in the technical workshop, teaching, or office work. In the vocational training programme women are taught blacksmithing, carpentry, whitewashing, and varnishing ....

"A much talked-about event occurred on May 1, 1977, when 23 women from the project cycled all the way to Dacca to demonstrate solidarity with women's movement all over the world ....

"While behavioral changes and increased self-confidence made possible by economic independence and experience of work outside the home is most striking in the women closely connected with the project, there has also been a discernible change in the attitudes of women in our area in general. Burkas (veils) have almost vanished from sight among patients both at

~~10.1~~ ALPHABETICAL LIST OF ESSENTIAL DRUGS

(Fourth Revision)

WHO Technical Report Series 722

A

acetazolamide
acetylsalicylic acid
albumin, human
allopurinol
aluminium acetate
aluminium hydroxide
□amiloride
□aminophylline
□amitriptyline
amodiaquine
amphotericin B
□ampicillin
anti-D immunoglobulin (human)
antihaemophilic fraction (see factor VIII concentrate)
antihaemorrhoidal preparation: local anaesthetic, astringent and antiinflammatory drug
antirabies hyperimmune serum
antiscorpion sera
antivenom sera
ascorbic acid
□atropine 16.
□azathioprine

B

□bacitracin + □neomycin
barium sulfate
BCG vaccine (dried)
beclometasone
benzathine benzylpenicillin
benzoic acid + salicylic acid
benzyl benzoate
benzylpenicillin
□betamethasone
□biperiden
bleomycin
□bupivacaine

C

□calamine lotion
calcium carbonate
calcium folinate
calcium gluconate
carbamazepine
□carbidopa + levodopa
charcoal, activated
□chloramphenicol
□chlorhexidine
□chloroquine
□chlorphenamine
□chlorpromazine
chlortalidone
□cimetidine
cisplatin
clofazimine
clomifene
□cloxacillin
coal tar
□codeine
colchicine
cromoglicic acid
cyclophosphamide
cytarabine

D

dactinomycin
dapsone
deferoxamine
dehydroemetine
depot medroxyprogesterone acetate
□dexamethasone
□dextran 70
□diazepam
diethylcarbamazine
digitoxin
digoxin
diloxanide
dimercaprol
diphtheria antitoxin
diphtheria-pertussis-tetanus vaccine
diphtheria-tetanus vaccine
dopamine
□doxorubicin
doxycycline

E

ephedrine
epinephrine 16, 23, 29,
□ergocalciferol
□ergometrine
ergotamine
erythromycin
ethambutol
ether, anaesthetic
□ethinylestradiol
□ethinylestradiol + □levonorgestrel
□ethinylestradiol + □norethisterone
ethionamide
ethosuximide
etoposide

F

factor VIII concentrate
factor IX complex (coagulation factors II, VII, IX, X) concentrate
ferrous salt
ferrous salt + folic acid
flucytosine
fludrocortisone
fluorescein
fluorouracil
□fluphenazine
folic acid
folic acid + □ferrous salt
□furosemide

G

□gallamine
gentian violet[1]
□gentamicin
□glibenclamide
glucose
glucose with sodium chloride
glyceryl trinitrate
griseofulvin

H

□haloperidol
halothane
heparin
□homatropine
□hydralazine
□hydrochlorothiazide
□hydrocortisone 24,
□hydroxocobalamin

I

□ibuprofen
imipramine
immunoglobulin, human normal
indometacin
influenza vaccine
insulin injection, solution
insulin, intermediate acting
intraperitoneal dialysis solution
□iodine
□iohexal
iotroxate
□iopanoic acid
ipecacuanha
□iron dextran
isoniazid
isoniazid + thioacetazone
isoprenaline
□isosorbide dinitrate

[1] Also known as crystal violet (International Nonproprietary Name: methylrosanilinium chloride).

K

ketamine

L

levodopa
levodopa + □carbidopa
□levonorgestrel + □ethinylestradiol
levothyroxine
□lidocaine 15.
lindane
lithium carbonate

M

magnesium hydroxide
magnesium sulfate
mannitol
measles vaccine
□mebendazole
meglumine amidotrizoate
melarsoprol
meningococcal vaccine
mercaptopurine
methotrexate
methyldopa
methylthioninium chloride
metoclopramide
metrifonate
□metronidazole 17.
□miconazole
□morphine

N

naloxone
□neomycin + □bacitracin
□neostigmine
□nicotinamide
niclosamide
□nifurtimox
nitrofurantoin
nitrous oxide
□norethisterone 26.
norethisterone enantate
norethisterone + □ethinylestradiol
nystatin 19

O

oral rehydration salts (for glucose salt solution) 26
oxamniquine
oxygen
oxytocin

P

paracetamol
penicillamine
pentamidine 19.
□pethidine
phenobarbital
phenoxymethylpenicillin
phenytoin
phytomenadione
pilocarpine
piperazine
podophylline
poliomyelitis vaccine
potassium chloride, oral solution 26.
potassium chloride, parenteral
potassium iodide
praziquantel 17.
□prednisolone 16, 21.
primaquine
probenecid
□procainamide
procaine benzylpenicillin
procarbazine
□promethazine
□propranolol 22.
propyliodone
□propylthiouracil
protamine sulfate
protionamide
pyrantel
pyrazinamide
pyridostigmine
pyridoxine
pyrimethamine + sulfadoxine

Q

□quinidine
quinine

R

rabies vaccine
□reserpine
retinol
riboflavin
rifampicin

S

salazosulfapyridine
□salbutamol
salicylic acid
salicylic acid + benzoic acid
□senna
silver nitrate
sodium amidotrizoate
sodium bicarbonate
sodium calcium edetate
sodium chloride
sodium chloride with glucose
sodium fluoride
□sodium lactate, compound solution
sodium nitrite
□sodium nitroprusside
□sodium stibogluconate
sodium thiosulfate
spectinomycin
spironolactone
streptomycin
sulfacetamide
□sulfadimidine
sulfadoxine + pyrimethamine
□sulfamethoxazole + trimethopri
suramin sodium
suxamethonium

T

tamoxifen
testosterone
tetanus antitoxin
tetanus antitoxin, human
tetanus vaccine
□tetracaine
□tetracycline 18.
thiamine
thioacetazone + isoniazid
thiopental
tiabendazole
□timolol
trimethoprim + □sulfamethoxazole
trisodium citrate dihydrate
tuberculin, purified protein derivative (PPD)
typhoid vaccine

V

valproic acid
□verapamil
vinblastine
vincristine

W

□warfarin
water for injection

Y

yellow fever vaccine

Reproduced from The Use of Essential Drugs, Second Report of the WHO Expert Committee, WHO Technical Series 722, WHO, Geneva, 1985

A

acetazolamide
acetylsalicylic acid
albumin, human
allopurinol
aluminium acetate
aluminium hydroxide
□amiloride
□aminophylline
□amitriptyline
amodiaquine
amphotericin B
□ampicillin
anti-D immunoglobulin (human)
antihaemophilic fraction (see factor VIII concentrate)
antihaemorrhoidal preparation: local anaesthetic, astringent and antiinflammatory drug
antirabies hyperimmune serum
antiscorpion sera
antivenom sera
ascorbic acid
□atropine 16.
□azathioprine

B

□bacitracin + □neomycin
barium sulfate
BCG vaccine (dried)
beclometasone
benzathine benzylpenicillin
benzoic acid + salicylic acid
benzyl benzoate
benzylpenicillin
□betamethasone
□biperiden
bleomycin
□bupivacaine

C

□calamine lotion
calcium carbonate
calcium folinate
calcium gluconate
carbamazepine
□carbidopa + levodopa
charcoal, activated
□chloramphenicol
□chlorhexidine
□chloroquine
□chlorphenamine
□chlorpromazine
chlortalidone
□cimetidine
cisplatin
clofazimine
clomifene
□cloxacillin
coal tar
□codeine
colchicine
cromoglicic acid
cyclophosphamide
cytarabine

D

dactinomycin
dapsone
deferoxamine
dehydroemetine
depot medroxyprogesterone acetate
□dexamethasone
□dextran 70
□diazepam
diethylcarbamazine
digitoxin
digoxin
diloxanide
dimercaprol
diphtheria antitoxin
diphtheria-pertussis-tetanus vaccine
diphtheria-tetanus vaccine
dopamine
□doxorubicin
doxycycline

E

ephedrine
epinephrine 16, 23, 29,
□ergocalciferol
□ergometrine
ergotamine
erythromycin
ethambutol
ether, anaesthetic
□ethinylestradiol
□ethinylestradiol + □levonorgestrel
□ethinylestradiol + □norethisterone
ethionamide
ethosuximide
etoposide

F

factor VIII concentrate
factor IX complex (coagulation factors II, VII, IX, X) concentrate
ferrous salt
ferrous salt + folic acid
flucytosine
fludrocortisone
fluorescein
fluorouracil
□fluphenazine
folic acid
folic acid + □ferrous salt
□furosemide

G

□gallamine
gentian violet[1]
□gentamicin
□glibenclamide
glucose
glucose with sodium chloride
glyceryl trinitrate
griseofulvin

H

□haloperidol
halothane
heparin
□homatropine
□hydralazine
□hydrochlorothiazide
□hydrocortisone 24,
□hydroxocobalamin

I

□ibuprofen
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insulin injection, solution
insulin, intermediate acting
intraperitoneal dialysis solution
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□iohexal
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isoniazid
isoniazid + thioacetazone
isoprenaline
□isosorbide dinitrate

[1] Also known as crystal violet (International Nonproprietary Name: methylrosanilinium chloride).

K

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L

levodopa
levodopa + □carbidopa
□levonorgestrel + □ethinylestradiol
levothyroxine
□lidocaine 15.
lindane
lithium carbonate

M

magnesium hydroxide
magnesium sulfate
mannitol
measles vaccine
□mebendazole
meglumine amidotrizoate
melarsoprol
meningococcal vaccine
mercaptopurine
methotrexate
methyldopa
methylthioninium chloride
metoclopramide
metrifonate
□metronidazole 17.
□miconazole
□morphine

N

naloxone
□neomycin + □bacitracin
□neostigmine
□nicotinamide
niclosamide
□nifurtimox
nitrofurantoin
nitrous oxide
□norethisterone 26.
norethisterone enantate
norethisterone + □ethinylestradiol
nystatin 19

O

oral rehydration salts (for glucose salt solution) 26
oxamniquine
oxygen
oxytocin

P

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protamine sulfate
protionamide
pyrantel
pyrazinamide
pyridostigmine
pyridoxine
pyrimethamine + sulfadoxine

Q

□quinidine
quinine

R

rabies vaccine
□reserpine
retinol
riboflavin
rifampicin

S

salazosulfapyridine
□salbutamol
salicylic acid
salicylic acid + benzoic acid
□senna
silver nitrate
sodium amidotrizoate
sodium bicarbonate
sodium calcium edetate
sodium chloride
sodium chloride with glucose
sodium fluoride
□sodium lactate, compound solution
sodium nitrite
□sodium nitroprusside
□sodium stibogluconate
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sulfadoxine + pyrimethamine
□sulfamethoxazole + trimethopri
suramin sodium
suxamethonium

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tetanus antitoxin, human
tetanus vaccine
□tetracaine
□tetracycline 18,
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G

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gentian violet[1]
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□glibenclamide
glucose
glucose with sodium chloride
glyceryl trinitrate
griseofulvin

H

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□hydrochlorothiazide
□hydrocortisone 24,
□hydroxocobalamin

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imipramine
immunoglobulin, human normal
indometacin
influenza vaccine
insulin injection, solution
insulin, intermediate acting
intraperitoneal dialysis solution
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□iohexal
iotroxate
□iopanoic acid
ipecacuanha
□iron dextran
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isoniazid + thioacetazone
isoprenaline
□isosorbide dinitrate

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levothyroxine
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magnesium sulfate
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meglumine amidotrizoate
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meningococcal vaccine
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pyridoxine
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rifampicin

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salazosulfapyridine
□salbutamol
salicylic acid
salicylic acid + benzoic acid
□senna
silver nitrate
sodium amidotrizoate
sodium bicarbonate
sodium calcium edetate
sodium chloride
sodium chloride with glucose
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streptomycin
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sulfadoxine + pyrimethamine
□sulfamethoxazole + trimethopri
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suxamethonium

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tamoxifen
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tetanus antitoxin, human
tetanus vaccine
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□tetracycline 18,
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thiopental
tiabendazole
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trimethoprim + □sulfamethoxazole
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(Fourth Revision)

WHO Technical Report Series 722

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□cloxacillin
coal tar
□codeine
colchicine
cromoglicic acid
cyclophosphamide
cytarabine

D

dactinomycin
dapsone
deferoxamine
dehydroemetine
depot medroxyprogesterone acetate
□dexamethasone
□dextran 70
□diazepam
diethylcarbamazine
digitoxin
digoxin
diloxanide
dimercaprol
diphtheria antitoxin
diphtheria-pertussis-tetanus vaccine
diphtheria-tetanus vaccine
dopamine
□doxorubicin
doxycycline

E

ephedrine
epinephrine 16, 23, 29,
□ergocalciferol
□ergometrine
ergotamine
erythromycin
ethambutol
ether, anaesthetic
□ethinylestradiol
□ethinylestradiol + □levonorgestrel
□ethinylestradiol + □norethisterone
ethionamide
ethosuximide
etoposide

F

factor VIII concentrate
factor IX complex (coagulation factors II, VII, IX, X) concentrate
ferrous salt
ferrous salt + folic acid
flucytosine
fludrocortisone
fluorescein
fluorouracil
□fluphenazine
folic acid
folic acid + □ferrous salt
□furosemide

G

□gallamine
gentian violet[1]
□gentamicin
□glibenclamide
glucose
glucose with sodium chloride
glyceryl trinitrate
griseofulvin

H

□haloperidol
halothane
heparin
□homatropine
□hydralazine
□hydrochlorothiazide
□hydrocortisone 24,
□hydroxocobalamin

I

□ibuprofen
imipramine
immunoglobulin, human normal
indometacin
influenza vaccine
insulin injection, solution
insulin, intermediate acting
intraperitoneal dialysis solution
□iodine
□iohexal
iotroxate
□iopanoic acid
ipecacuanha
□iron dextran
isoniazid
isoniazid + thioacetazone
isoprenaline
□isosorbide dinitrate

[1] Also known as crystal violet (International Nonproprietary Name: methylrosanilinium chloride).

K

ketamine

L

levodopa
levodopa + □carbidopa
□levonorgestrel + □ethinylestradiol
levothyroxine
□lidocaine 15.
lindane
lithium carbonate

M

magnesium hydroxide
magnesium sulfate
mannitol
measles vaccine
□mebendazole
meglumine amidotrizoate
melarsoprol
meningococcal vaccine
mercaptopurine
methotrexate
methyldopa
methylthioninium chloride
metoclopramide
metrifonate
□metronidazole 17.
□miconazole
□morphine

N

naloxone
□neomycin + □bacitracin
□neostigmine
□nicotinamide
niclosamide
□nifurtimox
nitrofurantoin
nitrous oxide
□norethisterone 26,
norethisterone enantate
norethisterone + □ethinylestradiol
nystatin 19

O

oral rehydration salts (for glucose salt solution) 26
oxamniquine
oxygen
oxytocin

P

paracetamol
penicillamine
pentamidine 19.
□pethidine
phenobarbital
phenoxymethylpenicillin
phenytoin
phytomenadione
pilocarpine
piperazine
podophylline
poliomyelitis vaccine
potassium chloride, oral solution 26,
potassium chloride, parenteral
potassium iodide
praziquantel 17.
□prednisolone 16, 21,
primaquine
probenecid
□procainamide
procaine benzylpenicillin
procarbazine
□promethazine
□propranolol 22,
propyliodone
□propylthiouracil
protamine sulfate
protionamide
pyrantel
pyrazinamide
pyridostigmine
pyridoxine
pyrimethamine + sulfadoxine

Q

□quinidine
quinine

R

rabies vaccine
□reserpine
retinol
riboflavin
rifampicin

S

salazosulfapyridine
□salbutamol
salicylic acid
salicylic acid + benzoic acid
□senna
silver nitrate
sodium amidotrizoate
sodium bicarbonate
sodium calcium edetate
sodium chloride
sodium chloride with glucose
sodium fluoride
□sodium lactate, compound solution
sodium nitrite
□sodium nitroprusside
□sodium stibogluconate
sodium thiosulfate
spectinomycin
spironolactone
streptomycin
sulfacetamide
□sulfadimidine
sulfadoxine + pyrimethamine
□sulfamethoxazole + trimethopri
suramin sodium
suxamethonium

T

tamoxifen
testosterone
tetanus antitoxin
tetanus antitoxin, human
tetanus vaccine
□tetracaine
□tetracycline 18,
thiamine
thioacetazone + isoniazid
thiopental
tiabendazole
□timolol
trimethoprim + □sulfamethoxazole
trisodium citrate dihydrate
tuberculin, purified protein derivative (PPD)
typhoid vaccine

V

valproic acid
□verapamil
vinblastine
vincristine

W

□warfarin
water for injection

Y

yellow fever vaccine

Reproduced from The Use of Essential Drugs, Second Report of the WHO Expert Committee, WHO Technical Series 722, WHO, Geneva, 1985

(See 23)

Hazardous, Bannable and Dumped Drugs

The issue of dumped drugs has been in the news for the past few years. The drug companies involved in the manufacture and sales of such drugs have received their due share of condemnation. Foreign governments policies, which provided scope for exports of such hazardous products have been also condemned, e.g., the Clayton Amendment Act and the U.S. Regulation.

It is well known that sales of medical technologies and drugs is a commerical enterprise, the motivation being profit rather than "service" or "welfare work".

Realising all this, the question arises as to how much can we, as citizens of India, expect our drug control authorities to safeguard our interests. The pressure from the drug industry is immense. In spite of knowing this, our expectations from the drug control authorities is high. After all our pharmaceutical industry is the most developed in the Third World. According to UNIDO, it belongs to Category V -- 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, as per WHO's guidelines for Essential Drugs. The drug industry and its supporters allege that the concept of essential drugs is only for struggling, less developed countries of the Third World and not for a country like India, with its well-developed industry and its 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. The lobby claims that consideration of hazards over efficacy is a luxury which we cannot afford.

However, consumers anywhere in the world have the right to expect that irrational and hazardous drugs are not issued licences and that licences of banned drugs should be withdrawn as soon as possible, the ban implemented, and that all drugs in the market are quality - controlled. We have 20 per cent substandard drugs . One out of every five drugs will not be effective. With the incereasing number of spurious drugs floating in the market, the problem is beginning to take on dangerous proportions.

Since 1980 we've been concerned about this issue of dumped and hazardous drugs.

SOME BANNABLE DRUGS -- WHAT IS THE POSITION NOW

> Under Section 23 P of the Drugs and Cosmetic Act of 1940, the Central government has the power 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 the power to prohibit manufacture, distribution and sale of drugs by a gazette notification.

The sub-committee of the Drugs Consultative Committee, in its 1980 report, recommended the banning of 23 combinations of drugs, giving their reasons for such banning, 16 categories of these drugs were recommended for immediate weeding and seven of the categories were to be weeded out over a specified time. Over 500 brand drugs would be thus affected. This report was presented to the Durg Consultative Committee at a special meeting on 10.10.81, and later to the Drug Technical Advisory Board (DTAB) and the Ministry of Health and Family Welfare accepted it in 1981.

The DTAB, a Statuatory Body under Section 5 of the Drugs and Cosmetics Act of 1940 recommended banning of 18 fixed dose combinations. These drugs were randomly selected from the Pharmaceutical Guide. Out of the 350 brand names affected, 44 were marketed by the foreign sector, 8 by public sector, and 298 by private sector. Most of these drugs were being produced by national companies According to the authorities, "the purpose was to give time limit to firms who may already have purchased the bulk drugs form manufacturing the formulatios". What compassion and consideration for the drug companies!

SOME BATTLES

Halogenated Hydroxyquinoline

Ban of fixed dose combinations of halogenated hydroxyquinoline

was to be effective from 1.11.82. The date of the ban was extended to 31.3.83 through DO No. X19013/8/81-D dated 13.8.82.

High Doses of EP Drugs

Through another DO. No. 12-48/79 DC dated 26.6.82, the Drug Controller of India directed the State Drug Controllers to ban the manufacture of high dose Estrogen-Progesterone combinations from 31.3.83 and their sales from 30.6.83.

M/s. Unichem Labs, Bombay (OP 2927/82 of writ petion 2928/-82), M/s. Nicholas Labs, Bombay and M/s. Organon (now known as Infac (India) Ltd., Calcutta filed writ petitions in Bombay and Calcutta high courts challenging the ban. Their contention was that the Central Government has no powers to ban the drugs. The High Court of Bombay and the High Court of Calcutta have granted stay orders against the ban. Now these products are available in the market.

Section 10A and 26A of the amended Drugs and Cosmetics Act (April 1982) empower the Central Government to prohibit import, manufacture and sale of any drugs considered harmful/ toxic or irrational, etc. Since the matter was in court during the gazette notification of 23.7.83, this combination of drugs has not been included in it.

What is absolutely objectionable is the fact that -- inspite of the act of the Drug Controller of India's ban of the production and sale of EP drugs, M/s. Organon have managed to obtain extension of licences to manufacture these products for another two years.

Paediatric Tetracycline

Although this drug is banned in its oral liquid from to discontinue its being prescribed for children because of its often serious side-effects, it is being manufactured today as a tablet of 30mg. for children -- an example of how a company can follow the letter of law and yet disobey it without any legal consequences.

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VOLUNTARY HEALTH ASSOCIATION OF INDIA
40, Institutional Area, South of I.I.T.
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As Part of Rational Drug
Policy Campaign

RESOURCES

HAI Clearinghouse
Resource Sheet #3
March 1982

This list covers articles on drugs published since 1975 in a major consumer magazine.

DRUGS AND DRUG INDUSTRY

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Pharmaceutical Industries View of Drug Control Ordinance 1982.

A. K. M. SHAHIDULLAH,
Secretary General, Bangladesh Aushad Shilpa Samity.

There is perhaps no denial of the fact that the Drug Control Ordinance 1982, came as a big jolt for the entire industry. Changing an entire industrial sector from their existing direction to a new direction overnight, demanded a great deal of the industry's capability and flexibility to adjust to such changes. The initial despair and frustration was the result of this adjustment-crisis.

What the ordinance proposed and obviously accomplished to a large extent today, would have perhaps evolved naturally, incourse of a long time, as a result of the growing public and industry conscience in favour of such change in direction.

What was a probability in future was made by the ordinance into a reality over night. Perhaps every such revolutionary change has a cost which initially makes its potential benefits less obvious. Needless to mention that the pharmaceutical industry of the country paid that cost in terms of substantial loss of turnover, lower growth or even negative growth in some instances in the years following the ordinance, wastage of resources, and finally in redundancies of man power. Nevertheless, despite this initial experience, today, four years after the ordinance came into effect many of its beneficial aspects have become vivid, some of which are worth the initial negative consequences.

CONCEPT OF ESSENTIAL DRUGS:

The single most important benefit of the Drug Control Ordinance was its emphasis on the concept of essential Drugs. The concept emanated from the realisation that although every 'drug' is essential for people who may require it, some drugs are required more often and by many. Survey of the disease prevalence in our country would show that about 150 drugs can cover almost all major ailments affecting the general mass. Pharmaceutical Industry's approach to the market did not overlook this fact totally since, it is obvious that the industry being basically business enterprises can not ignore products which have mass demands. However, government emphasis on the essential drugs as enumerated in the Drug Control Ordinance 1982, was a powerful motivating force for the industry to treat the essential drugs in higher order of priority than before.

The result is well evident, today the industry commits 64% of its total production capacity to the essential drugs, compared to 30% in 1981. This does not only help people, as larger output of these much needed products results into the deeper penetration of the same into the rural market, but also the industry. It is easy to appreciate that the industry is based on much stronger foundation than before as they thrive on products needed by the mass and such need is only likely to grow and not diminish for any reason whatsoever, be it commercial or regulatory.

REDUCED DEPENDANCE ON IMPORTED PRODUCTS:

One of the fundamental objectives of the ordinance was to encourage local production of import-substitute. Clearly, before the promulgation of the ordinance there were fixed ideas in the minds of all concerned that there were many products which were beyond the abilities of the local industry to formulate. That this was a myth, became obvious by successful formulation of many of the import-substitutes by local industries during the four years period following the ordinance.

Before the ordinance, it required years of efforts by local industries to secure protection for their locally formulated import substitute. Import substitutes received no priority treatments in registration.

Today, import substitutes are prioritised over other products in registration, they receive preferential considerations in price fixation. Sometimes, the licencing authority even takes the initiative to recommend to the manufacturers to take up production of certain high volume import-substitutes. Industry does not have to move for tariff protection any more. They are consulted before formulation of the import policy and their recommendations on import restriction of products are viewed more seriously than before.

All these were possible because of the serious re-biasing of the attitude of all concerned which includes of course the regulatory authorities.

The result is obvious from the reduction in the quantum of imported products since 1981. By value the imported products share of the total drug consumption came down from 15% in 1981 to 10% in 1985. If we take into account the depreciation of Taka against the various currencies it will appear that the imported product share of the total pharmaceutical market by unit, is perhaps as low as 5-7% today.

INCREASED AWARENESS OF THE GENERAL PEOPLE:

Before the ordinance, Drug was a subject which did not concern the general population. The wide-spread impact of the ordinance on the general people stimulated their overall interest on this subject which they realised was vitally connected to their overall welfare. The ordinance greatly boosted the realisation of the mass that their health care needs are as vital as other needs of their life, such as food, clothing and housing. This increased their health consciousness and resulted into expension of the pharmaceutical market, as more people sought medical attention than ever before. This is a welcome sign for the industry as well as for the country in general.

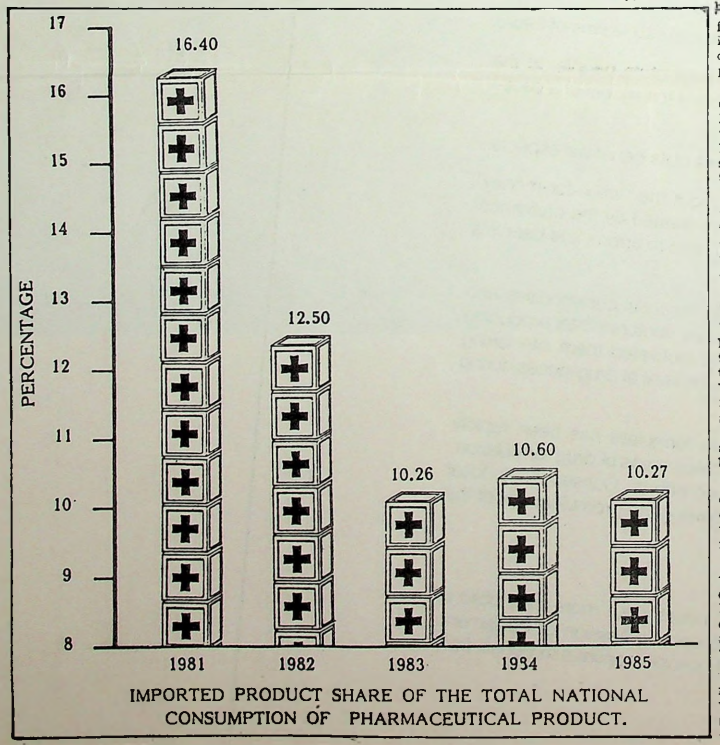
QUALITY CONTROL MUST FOR SUCCESSFUL IMPLEMENTATION OF ORDINANCE

It would be wise to sound a note of caution that while achieving greater production of essential drugs at lower prices is the main objective, at no cost standard of quality be compromised. A certain section who would deliberately like to foil this objective are diverting attention from this vital aspect of drug manufacture. Emphasis must be given by the Government and the Regulatory Authorities on maintaining the highest quality of products regardless of the size or capability of the manufacturer. Also at the time of import of raw materials due consideration to origin and quality must be made. Lastly but most important, testing facilities must be further strengthened so that this extremely important function can be and is properly discharged on a nation-wide basis.

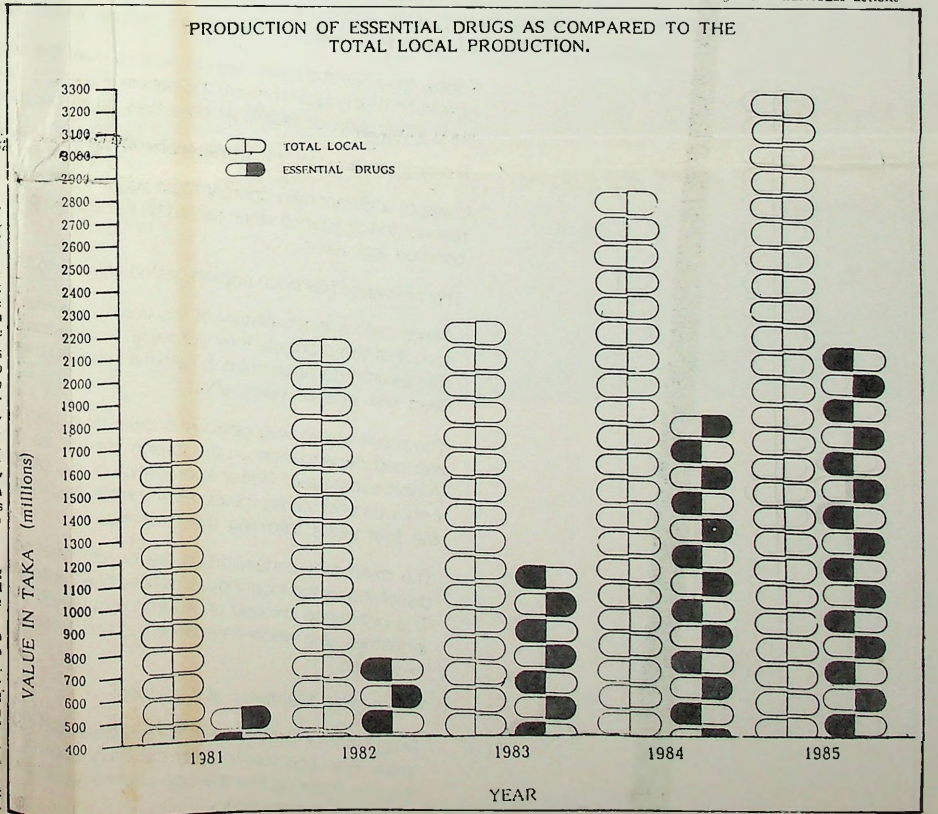
CONCLUSION:

As the history will testify many revolutionary efforts were foiled, due to the euphoria of its immediate gains in which its main objectives got lost. While all of us feel quite satisfied of the achievements, we must be careful of not losing sight of the main objectives of the ordinance, which were to make available, quality products, in enough quantities, at reasonable prices. While working with these objectives it has to be ensured that the quality of pharmaceutical product is the most important fundamental requirement and the same can not be compromised for quantity or for price.

The nation's efforts to achieve health for all by the year 2000, will have a better chance of success, if all concerned keep the main essence of the ordinance in mind while taking their individual actions



IMPORTED PRODUCT SHARE OF THE TOTAL NATIONAL CONSUMPTION OF PHARMACEUTICAL PRODUCT.



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Text of new drug policy

The following is the text of the new drug policy.

WITH a view to ensuring abundant availability of drugs and pharmaceuticals at reasonable prices, the Government has taken some measures for rationalisation, quality control and growth of pharmaceutical industry. The Hathi Committee which is a milestone in the development of drug and pharmaceutical industry in the country gave its recommendations in 1975 on the basis of which a Drug Policy was announced in 1978.

There has been a considerable change in the situation in the pharmaceutical sector in the country since the announcement of the policy of 1978 and it was considered necessary that the new thrust and direction should be given in the policy frame to subserve the objective of growth of pharmaceutical industry in the desired areas. The Government expects that new measures which are being announced would help in the growth of the industry in conformity with the health needs of the country. These measures also cover other important areas like quality control, rationalisation of use of drugs, standardisation of packaging, banning of non-essential and harmful drugs etc. In short, new measures aim at

(a) ensuring abundant availability, at reasonable prices of essential life-saving and prophylactic medicines of good quality;

(b) strengthening the system of quality control over drug production and promoting the rational use of drugs in the country;

(c) creating an environment conducive to channelising new investment into the pharmaceutical industry, to encouraging cost-effective production with economic sizes and to introducing new technologies and new drugs, and

(d) strengthening the indigenous capability for production of drugs.

The salient features of the new measures are:

1. A National Drug & Pharmaceutical Authority will be created. This authority will be an apex body which will have representation from all the concerned agencies including those from the industry. This authority would function as an advisory body on matters of development of pharmaceutical industry. Among other things, it would go into the question of rationalisation of existing formulations in the market including the banning of formulations of harmful nature and better control over introduction of new drugs. The authority will have a permanent secretariat. It is expected that the authority would be set up within a period of three months.

2. Quality control: It is proposed to give statutory effect to the good manufacturing practices and also to introduce a certification system under which recognised institutions with proven expertise and testing facilities would certify the adoption by formulators of good manufacturing practices and the quality of formulations manufactured.

3. Pricing: In order to increase production which will lead to ultimate lowering of prices of drugs, it is proposed to reduce the existing span of price control over drugs and pharmaceuticals. However, a very strong monitoring system will be evolved. As against the existing three categories of drugs and pharmaceuticals hereafter, there will be two categories The first category will consist of drugs necessary for the national health programme and the second category that of other essential drugs. Formulations of the first category would have a MAPE (Maximum Allowable Post Manufacturing Expenses) of 75 per cent and those of the second category that of 100 per cent.

A High-Level Expert Committee would draw up a list of drugs to be included in the second category. However, the existing Drug Price Control Order (DPCO) will continue to be in force till a new one has been announced after the finalisation of drugs in these two categories.

The Government would retain the right to bring within the ambit of control any drug in the decontrolled category whenever considered necessary. Prices of drugs in the decontrolled category would be constantly and closely monitored and an effective monitoring system developed for these.

Drug prices Equalisation Account would be anolished; but all accruals that have taken place to the account or are likely to take place as a result of action in the past would be protected. Protection to indigenous industry would be provided where necessary through the tariff mechanism.

LICENSING

The system of delicensing would be progressively extended subject to the following criteria:

(a) Bulk drugs whose imports are allowed on Open General Licence;

(b) Bulk drugs, whose production is limited to three producers or less in the organised sector;

(c) Bulk drugs whose formulations are of essential and mass consumption nature; and

(d) Formulations and drug intermediates related to bulk drugs which are delicensed.

The scheme of delicensing would be available to non-FERA and non-MRTP companies only. However, a phased manufacturing programme would be prescribed for all companies in order to encourage indigenisation. To encourage introduction of new drugs, it is proposed to bring all new bulk drugs and related formulations developed in the country under the scheme of delicensing. To give a fillip to R&D activities within the country, this scheme would be available to all companies.

To further encourage production and availability of drugs, it is proposed to extend the scheme of broad-banding to 31 groups of bulk drugs and formulations.

Over the course of the last decade, Penicillin has come to be an essential drug intermediate going into the production of such life-saving and essential broad spectrum antibiotics like ampicillin, amoxycillin, cephalexin etc. Its production has been stagnating and imports have increased. To increase production, to curtail imports and to save foreign exchange, it is proposed to allow all non-FERA pharmaceutical companies in the country to produce penicillin. The same facility is being extended in respect of Polio Vaccine also.

To encourage export production, all companies would have total flexibility to produce any products within their existing facilities.

The existing ratio parameters between the value of production of bulk drugs and formulations are proposed to be revised as under:

(a) For FERA companies, ratio parameters would now be 1:4 in place of the present 1:5 in respect of value of production of bulk drugs to formulations.

(b) The ratio parameters for companies other than the FERA companies have been proposed on a graded basis depending upon the turnover; upto Rs 10 crores the ratio will be 1:10; for production in excess of Rs 10 crores and upto Rs 25 crores, the ratio would be 1:7; and for production in excess of Rs 25 crores, the ratio would be 1:5.

To provide effective co-ordination between the Health, Industry and other related Ministries, a Committee would be set up in the Department of Chemicals and Petrochemicals with Secretary, Chemicals and Petrochemicals as Chairman and consisting of Secretary, Ministry of Health and other officials of Health and other concerned Ministries as members to co-ordinate the proposed measures and to monitor the progress.

'Drug policy anti-people'

ıustan Times Correspondent

DELHI, Dec. 19 — Medical …ners, political parties and con… …ıave expressed grave concern …pected price rise of essential …nder the new drug policy …ed here yesterday.

…ndian Medical Association …e prices of medicines would …as much as 60 to 300 per cent …implementation of the poli… …statement, it characterised …as "pro-industry and anti- …the national drug industry and the public sector.

Lok Dal general secretary Sharad Yadav said in a statement that the higher price mark up allowed for life saving drugs would encourage the survival of the capitalist at the expense of the patient. He questioned the wisdom of dereserving penicillin from the public sector list. He said that the increase in import of penicillin was not due to lack of domestic production but high demand for downstream and derivate products from it.

…ıging the Government's con…

The policy also ignored the Hathi Committee recommendation to prom…

Centre of Indian Trade Unions (CITU) flayed the refusal of the Government to nationalise the multinational drug companies despite the recommendation of the Hathi Committee in its favour. It called the policy a "surrender" to the Organisation of Pharmaceutical Producers of india the …tional company dominated …

Financial Express, Wednesday, Decer…

'Drug policy favours manufacturers'

Financial Express Bureau

MADRAS, Dec 23 — The recently-announced drug policy is at best "manufacture-oriented" inasmuch as it does not make it compulsory on the industry to produce essential drugs needed by the common man, according to the President, All-India Organisation of Chemists and Druggists, Mr C. L. Mehta.

…ment that the the vital issue of shortage of experienced licencees to man the growing number of retail outlets.

There are, however, some plus points like a reduction in categories, phased delicensing, abolition of the drug equalisation account, relaxation in the ratio between bulk drugs and formulations, and the scheme the broad-band certain drugs.

New Drug Policy

Times of India, 8.1.87

Health takes a back seat

The New Drug Policy appears to be a policy that caters to the immediate needs of the drug industry rather than the health needs of the people. The policy revolves around pricing and licensing alone and marks a shift from self-reliance

New drug policy is 'anti-people'

NEW DELHI, Dec. 20

The Indian Medical Association (IMA) has described the new drug policy as "pro-industry and anti-people".

"The prices of medicines will go up from 60 per cent to 300 per cent wih the implementation of this policy," Dr. J. J. Sood, General Secretary, IMA, told PTI.

This policy would not ensure abundant availability of essential and useful drugs at reasonable prices, he said and added that this would help the drug formulators.

The CPI in a press statement condemned the decision to decontrol non-essential drugs and progressively delicense the drug industry and said "This is nothing but an extension of the policy of so-called liberalisation and privatisation of the drug industry."

The CITU and the Delhi Science Forum, a body of scientists and science students said the policy sought to appease the pharmaceuticals industry and multinational companies.

The CITU president, Mr. B. T. Ranadive called the policy as a "bonanza for "multinationals", which control an estimated 78 per cent of the Indian drug industry. Some 16 per cent is under the monopoly private sector and only six per cent with the public sector.

The drug industry in Bombay has welcomed the hike in maximum allowable post-manufacturing expenses (MAPE) for essential drugs and the reduction in the number of drugs under price control. —PTI

'Gift for multinationals'

NEW DELHI, Dec. 20

The All India Indian Drgus and Pharmaceuticals Ltd. Kamgar Federation today described the new drug policy announced by the Government on Friday as a 'gift for multinationals' that will further erode the role of the public sector in the drug industry and threatened to launch an agitation if the same was not withdrawn.

In a statement issued here the federation said …

Drug policy criticised

NEW DELHI, Dec 20 (UNI) — The Delhi Science Forum of Scientists and Science Students, on Friday condemned the new drug policy, saying it sought to appease the pharmaceuticals industry at the cost of the nation's health.

The forum, whose President Mr P. N. Haksar, said in a statement here that the two principal formulations of policy — one reducing the number of price-controlled drugs from three to and the other expanding the scheme of delicensing — would have "disastrous consequences".

It said the decision to cut down the categories of price-controlled drugs with mark-up of 75 per cent and 100 per cent — against 50 per cent earlier — will shoot up drug prices much more than the 12 to 15 per cent the Government envisages.

"Given a situation where only 20 per cent of the people in India can afford to buy drugs, the new policy would lead to even less people being able to afford modern drugs", the forum said.

The scientists also criticised the decision to expand the delicensing scheme and to make licensing arrangements for MRTP and FERA companies to produce high-technology drugs.

The first decision, the forum said, would allow the foreign sector to enter the market more aggressively.

The second decision, coupled with the fact that no proper list has been drawn up to define high-technology drugs, and given the record of foreign companies in not bringing any new technology, meant "virtually opening the doors for entry of foreign capital into the market."

The forum said the Government had "totally capituated to the unreasonable demands of the pharmaceuticals industry".

The policy had been announced just a week after the end of the winter session of Parliament and called this "a clear attempt to bypass the people's representatives."

It expressed surprise that while concessions had been made to the industry by "rushing through the … policy" aspects related to the effects of drugs had been ignored.

Besides the forum, many drugs specialists and scientists contend that there are many more drug formulations in the country. It is estimated that about 20,000 formulations are marketed in the country. And scientists say most of them are "irrational" and marketed only for industrial profit.

Mr Sharad Yadav' MP and General Secretary, Lok Dal has dubbed the new drug policy as "pro-capitalist and against the poor ailing consumer".

Mr Yadav said the 35 per cent increase in life-saving drugs will "crucify the public sector."

The Telegraph

MONDAY 22 DECEMBER 1986 VOL. V NO. 163

A half-baked policy?

There is hardly anything new for the people in the "new" drug policy announced last week by the Union government. Except the multinationals, the policy may not please many. It talks loftily of giving a new thrust and direction to the pharmaceutical industry, and striving for the fulfilment of the objectives of ensuring abundant availability of drugs at reasonable prices, rationalisation, quality control and growth. But there is so much of confusion, lack of focus and haziness that all that the new policy may achieve is a precipitate increase in the prices of drugs. The policy is not even a comprehensively thought out action plan. The once much-talked about ideal of ushering in an era of generic drugs appears to have been given a quiet burial. There is also no talk of reducing the number of unnecessary formulations, numbering some 40,000. However, the number of categories has been reduced from four to two. Category one comprises the 40 essential drugs needed to keep the national health scheme going; the second category will contain what has been described as other essential drugs.

In line with the recent efforts of the government in other areas, the drug policy too seeks to reduce controls. But even after working on the new policy for four years now, the government has not been able to come out with a new drug prices control order that will replace the 1978 order. This order, which will regulate the prices, would eventually prove how the policy would translate into actual practice. The policy seeks to ease the pressure of price regulation through higher mark-ups to allow for post-manufacturing expenses. The mark-ups will range between 75 and 100 per cent. One consequence of this could be a better availability of essential drugs, admittedly at prices which could be up by 13 to 43 per cent. At present, no more than a fifth of the population is able to afford drugs. If drug prices go up, the number of those who cannot buy drugs is likely to increase. Reduction in controls in the form of expansion of delicensing may not solve the problem because the pharmaceutical market is known to be subject to the monopolistic behaviour of the bigger companies. The new policy also talks of a national drug and pharmaceutical authority that would monitor the industry. But it will only be an advisory body and, therefore, will have little clout. The inadequate homework done by those who framed the policy also shows up in the fact that a high level expert committee is yet to be set up to prepare a list of drugs to be included in the second category. And last, but not the least, if the list is not ready, if the new drug prices control order is not ready, what was the hurry to come out with a half-baked policy? Again, critics of the government are bound to make some capital out of the fact that although the policy has a bearing on the vital public issue of health, the government chose to announce it so soon after the recent session of Parliament was over.

Drug prices will rise alarmingly

by Kuldeep Kumar and Nirupama Subramanian

NEW DELHI, Dec. 20: A sharp escalation in the prices of essential drugs is feared following the announcement of the new drug policy on Thursday.

It will also reduce the level of self reliance already achieved in the production of drugs and give rise to intense lobbying by drug manufacturers to keep their products out of the price-controlled category.

Delhi Science Forum, an organisation of young scientists led by P. N. Haksar, apprehends that the cost of therapy will shoot up by 50 to 300 per cent.

Investigations by *The Sunday Observer* revealed that a tablet strip of ET-800, a brand of ethambutol manufactured by Wockhardt costs Rs 15.08 now. After the hike, most probably in February, it will be priced between Rs 18 and Rs 26. ET-800 is an anti-tuberculosis drug. The price of streptomycin, another drug used in treating tuberculosis, will shoot up to Rs 6 for a one gramme vial.

Also threatening to cross the Rs 20 mark are medicines used in the treatment of leprosy. One particular brand, Arzide manufactured by Albert David, may cost Rs 24 if the prices rise to the maximum allowed mark up of 75 per cent for essential drugs, as specified in the policy.

The minimum prescribed treatment period for tuberculosis is one year and for those who just …

Strike move against new drug policy

From Our Staff Reporter

NEW DELHI, Jan. 9

A …ational convention representing virtually the entire spectrum of the … held … the MNCs outbid the Ind… technologies which will be up… world …

Drug policy a big disappointment

By Dr. Anant Phadke

The much-awaited drug policy finally announced on December 18, has been criticised by Dr. J.J. Sood, General Secretary of the Indian Medical Association (IMA) "pro-industry and anti-people".

The policy is quite a disappointment. Since discussions were going on for the last three years and since announcement had been postponed so often, it was thought the new policy would settle issues pending for long.

Surprisingly, it is silent on most … issues directly affecting common people.

The policy does not specify production quotas for essential drugs so that there is no shortage. Studies have shown that multinational drug companies, (many deceptively categorized as Indian thanks to FERA) exploit the Indian people by artificially jacking up prices (by as much as 40 per cent on an average) … materials imported from their … the West. The … own admission by a range of 12 to 25 per cent. According to I.M.A., the price-rise would be from 60 to 320 per cent. The price-rise among decontrolled drugs is anybody's guess!

Unnecessary price rise

Some analysts have argued that the earlier profit-rates of 40 per cent, 55 per cent were "unremunerative" and hence the present hike in profit-rates and prices is justified. But this argument is misleading for two reasons.

Firstly, according to the Lavrakumar Committee, the sales promotion, administrative and overhead expenses of multinationals, which dominate the Indian drug industry was very high at about 33 per cent of the total costs. The manufacturing profit can be increased by reducing this unnecessary spending. Similarly, stockists who eat up a substantial part of the profits could …

No Drug Policy

The new drug policy is certain to disappoint all those who expected a balanced and rational policy orientation to emerge after four long years of vacillation on the issue in New Delhi. Not only consumers, but even large numbers of indigenous producers of drugs, will feel let down by the new package. It has only one feature that may seem somewhat positive: the raising of the mark-up (the difference between the cost of production and final selling price) on a small number of essential drugs from the rather unattractive levels to a profitable 75 to 100 per cent. Looked at in isolation, this measure could improve the availability of some essential drugs, albeit at a higher cost — anything from 13 to 43 per cent above current prices. The policy package also involves price decontrol for the overwhelming majority of formulations on the market. Hopefully prices of drugs should not skyrocket. But the drugs market is marked by powerful marketing monopolies and free competition may not stabilise prices at least in the near future.

The new policy also discourages the development of indigenous manufacturing capabilities. First, it allows for the delicensing of bulk drug production even in areas where Indian-owned companies have established their capabilities. And secondly, it abolishes the drug price equalisation fund, which has offered a degree of necessary protection to domestic producers. Infirmities in the drafting of the policy are evident elsewhere also. The package specifies parameters for the ratio of bulk drugs to formulations produced by a company; it also provides for a mechanism to monitor drug prices. But such ratios and mechanisms have never worked and cannot be legally enforced. And as for the critical question of weeding out harmful or useless drugs and of promoting the rational use of essential drugs, the policy has delegated the task to a proposed national drugs and pharmaceuticals authority. Such an authority will, however, only have an advisory role. Even worse, since it will include representatives from all interest groups and is likely to be dominated by the industry, it can safely be expected to be ineffectual and incoherent, much as the national drugs and pharmaceutical development council proved to be. The problem of regulating the use of drugs has never been solved in this way anywhere. The new policy simply evades the vital issue as it does the much-debated issue of the use of brand names. Finally, it is surprising that yet another committee should have been set-up to finalise the second list of essential drugs. In the light of past experience it is wholly unrealistic to expect it to complete its job in three months.

MARKET WATCH

Indian Express, 22.[illegible]

Policy injects new vigour in drug shares

By Deven Malkan

The waiting is over. The long-awaited drug policy, which had remained elusive for over a year even after its reported formulation, has finally arrived. And the Indian ... as well as investors of pharmaceutical com... not have expected a ... than what h... the progress... and prod...

drug policy announced

Essential drugs to be dearer

...ress News Service

... DELHI, Dec. 18. ...three categories of ...ceuticals have ... the revised ... the Gov...

...cent and those of the second category ... 100 per cent. Earlier, category I and ... 11 drugs were allowed mark-ups of 40 ... and 50 per cent respectively, and category III 100 per cent. Mr. Jaichandra Singh said despite the higher mark-up allowed, the rise of essential drugs was expected to be only between 12 and 25 per cent ... said a higher ma... ...llowed as it...

'Drug policy unhealthy'

BOMBAY, Jan 9 (UNI)—The All-India Drug Action Network (AIDAN) has described the new drug policy statement released by the centre as 'anti-health, anti-people and pro-industry' and said that it defeats the Government's aim of achieving health for all by 2,000 A.D.

At a news conference organised here on Thursday by the Association for Consumers Action on Safety and Health (ACASH), an AIDAN member, eminent doctor expressed concern over the fact that the policy statement had been formulated without public debate and discussion with consumer and health professionals.

The de-licensing and broad-banding of drugs as announced in the statement would only increase the stranglehold of multinational and big Indian pharmaceutical companies on the ... ity health, said the drug policy was aimed at promoting the interests of the profit-based pharmaceutical industry and not the health of people. "It is an unfortunate imbalance that there is a short supply of essential drugs for malaria and tuberculosis in the country but a plethora of tonics and vitamins which are consumed mainly by the rich," he said.

Dr Antia said although the World Health Organisation (WHO) list of essential drugs of 1985 had said that a total of 258 drugs covered all the needs of all the people in the world, "we have somewhere in the region of 40,000-60,000 formulations". Even a medically advanced country like Norway had only 2,000 formulations, he said. Complications due to drug reactions in India were phenomenal, he ...

Dr Zafrullah Chowdhury, who played a major role in drafting a consumer-oriented drug policy in Bangladesh in 1982, said since the ban on the manufacture of non-essential drugs by multinationals in that country, the quality of drugs had greatly improved and the total production of essential drugs had gone up and become available at cheap prices.

Bangladesh's national drug policy stipulates the manufacture of only single incredient drugs, a ban on addictive drugs except in restricted formulations reduction of alcohol content from 40 to five per cent and refusal of loan incence to companies which did not have a factory in the country.

It also bans multinationals from producing antacids and vitamins which are most profitable to them and least useful for the people, he said.

"Bangladesh is the only country where the monopoly cartel of the multinationals is not in operation. The nine multinationals who used to control 84 per cent of the market can now no longer divide the market among themselves and have to compete with one another", he said. Only 10 per cent of drugs in the market were sub-standard today, he added.

Drug policy faulted for bloated list

The Times of India News Service

JAIPUR, Janunary 5.

THE recently-announced drug policy is under fire for omitting measures to prune the list of about 60,000 drugs, being marketed in the country. More than three-fourths of these are stated to be non-essential and useless.

A former member of the national drug technical advisory board, Dr. P. C. Dandiya, who has also been president of the Indian pharmaceutical congress and the pharmacy council of India, said in an interview here today that the overwhelming majority of drugs and their formulations should be banned. These were not only "superfluous", but harmful too. Only seven of these combinations, added to the list of "single compound drugs" were sufficient for the national health, the WHO has said.

Worse still, the total number of drugs manufactured in the country also poses a problem to the medical practitioner. No Doctor can be said to have memorised the names and components of the 60,000 drugs, available in the country.

Dr. Dandiya, wrote to the Prime Minister, Mr. Rajiv Gandhi, about one-and-a-half months before the new drug policy was announced. He said in order to pharmaceutically analyse all drugs for quality control, the country would require an infrastructure worth Rs. 500 crores. At present, the country does not spend more than Rs. 10 crores in this regard.

The 1979 drugs (price control) order identified 181 drugs and their formulations as "essential," bringing them under the purview of the order. It placed them in the first two of the four categories of drugs. Following price control order, the multinationl (FERA) companies shifted their priority from production of essential drugs to the non-essential drugs, which promised them huge profits, as they fixed the price arbitrarily.

According to some estimates, non-essential drug prices are as much as 30 times the cost of production.

The new drug policy involves decontrol of all drugs except those necessary for the national health programme and the essential drugs. According to the Union minister of state for chemicals and fertilisers, Mr. Joychandra Singh, this would ensure "abundant availability of drugs", and would help the country meet the rather difficult target of production of medicines worth Rs. 16,000 crores by 2001.

INDIAN EXPRESS

SATURDAY DEC 20, 1986

No surprises

THE new drug policy, formulated after long deliberations in the Government and hectic lobbying by the giant (and so-giant) drug companies, has no surprises. Given the ...ad economic philosophy of the latter, it was inevitable there would be an attempt at reducing controls on the ...istry. This has taken two forms. First, the number of ...gories in which formulation (tablets, compounds and the ...) were divided have been reduced from four to two. On

Call to reduce drug formulations

BOMBAY, January 9 (PTI): The All India Drug Action Network (AIDAN), has demanded reduction of drug formulations in the country from the present over 1,600 to 250, as recommended by the World Health Organisation (WHO).

Doctors and action group volunteers at a meeting in Bombay on Thursday said the new drug policy instead of reducing non-essential drugs only aided the growth of these and other irrational formulations. It treated the pharmaceutical industry as another chemical industry, where profits and not health was the main concern.

All leading health action groups felt the new drug policy was heavily tilted in favour of multinationals under the Organisation of Pharmaceutical Products of India (OPPI), who sold 50 per cent of the drugs in the Indian market.

Steep hike in drug prices

New policy seeks to lessen controls

Our Special Correspondent

Prices of all drugs needed for the National Health Programme will register a steep hike of 12 to 25 per cent under the new drug policy announced by the Government on Thursday.

The much-awaited policy seeks to lessen controls, allow market forces a ... because of this that the prices are likely to go up further. However, Mr Jai Chandra Singh assured newsmen that the Government would evolve a very strong monitoring system.

Referring to the salient features of the policy, the Minister said the existing three categories of drugs and pharmaceuticals were being henceforth be-

Ranadive: New policy helps MNCs

Our Staff Reporter

The new drug policy was characterised as a 'bonanza for multinationals' and a setback to the small and medium sector by CITU president B T Ranadive in the Capital on Friday.

In a statement, the CITU denounced the Government for allowing a steep-hike in the prices of drugs, both essential and formulations beyond the reach of the common people. The Government had surrendered to the "demands of the Organisation of Pharmaceutical Producers (OPPI), an association of the multinational drug companies", and thereby the Government had not only increased the prices of the drugs but had also resorted to further decontrol, delicensi... and broad-ba... he said.

According t... subserve the ... multinationals, ... monopoly collab... ernment had no... FERA and MR... produce a form... the prior permis... ernment it has, ... lowed furth... liberalisation und...

Mr Ranadive noted that so far ... medium Indian se... major contribution ... the essential ...

MEDIA

OPPI Experiments with Untruth

VIMAL BALASUBRAHMANYAN

AROUND mid-November last year, the Organisation of Pharmaceutical Producers of India (OPPI) ran a series of large misleading advertisements in the major national and financial dailies, claiming to be in 'public interest'. The ads were timed to appear just before the Government was scheduled to announce its long-awaited new drug policy. It is well-known that the last 12 months have seen intensive campaigning by activist health groups all over the country for a rational drugs policy, and OPPI's disinformation campaign was undoubtedly a response to the efforts of health activists to generate public awareness on the issue of health and essential drugs ...

WHO's recommendat... known, active, usef... in the Scandinavian ... India

MAINSTREAM January 17, 19[illegible]

National Drug Policy : Basic Desiderata

AVERTHANUS L. D'SOUZA

IT is a clear indication of the thinking of the Government of India that the pharmaceutical and drugs industry in the country comes within the purview of the Department of Chemicals in the Ministry of Industry. The manufacture, import pricing control

single TB patient who is untreated or wrongly treate... can infect from 8 to 12 other people in a period ... two years. About 500,000 patients die annualy. ... spite of the existence of the 8,000 manufacturi... units, including the giant multinationals, essenti...

DR. OLLE HANSSON'S DAY - BAN HAZARDOUS DRUGS DAY

It was on 23rd May 1985 that Dr. Olle Hansson passed away in a hospital in Stockholm. He was just 49. For almost 2½ decades this paediatric neurologist by profession had faught a long lonely battle against the multinational giant Ciba Geigy. He was instrumental in getting Ciba to withdraw its products mexaform and entrovioform from the world market.

Not merely did he contribute to the Academic world by being the first to show the association of optic neuritis (blindness) with consumption of this drug way back in 1965 but he also challenged the incorrect facts promoted by the manufacturer that the drug was not absorbed from the gut. Through various tests conducted by him he showed that the drug was absorbed, metabolized, in the body and its metabolites excreted in the urine. This information was critical in being able to associate the neurological side effects with the consumption of the drug.

It was due to his extensive research, writing and work on clioquinols that led the Japanese SMON victims to invite him as an expert on their behalf, in their fight for compensation. (SMON i.e. sub acute myelo optic neuropathy left over 11000 people crippled, blinded or with loss of Bladder control over the discharge of urine and stools.

For eight years in Tokyo High Court a legal battle for compensation was faught by the victims themselves with the help of socially conscious lawyers, doctors, and experts like Dr. Olle Hansson, and ultimately won. A major international conference on Drug induced suffering was organised later at Kyoto at which Dr. Olle Hansson spoke emphatically about the consumers 'Right to Information'. The clioquinol tragedy next to the Thalidomide disaster was the second major drug induced tragedy. Even though the

2/6/89

manufacturers faught tooth and nail in trying to prove that SMON was caused by virus and had some genetic etiology, it was only due to a concerted effort on part of the victims and the professionals this case could be faught and won.

Dr. Olle Hansson was not satisfied just seeing the victims compensated, he continued his fight to see that such a thing did not recur in any other country where the drug was being consumed in large amounts by the uninformed public.

In 1976 he initiated a boycott which in Sweden was joined by over 2000 doctors who refused to prescribe any Ciba Geigy product till it withdrew these potentially hazards and therapeutic doubtful drugs from the world market, and the company lost 75 million kroners in Sweden i.e. their entire turnover in 1980. Doctors from Norway, Finland, and Denmark joined the Boycott. By November 1982 the sales of Ciba Geigy fell by 1/3 rd and it was this which forced Ciba Geigy to withdraw mexaform and Enterovioform from the world market proving once again that the only argu ment that seems to make sense to the industrial houses is with economic argument linked/ Today a number of western /with loss/ countries as well as Bangladesh, Pakisthan, Nepal, Sri Lanka, Malaysia have banned the clioquinols in their markets. In India over 150 brands are freely available.

Stricken with Cancer from his hospital bed he faught for withdrawl of yet another hazardous drug Ciba Geigy's Tandril, (Oxyphenbutazone). This was following receipt of incriminating internal documents, where over 1036 deaths due to the drug had been documented - while only 200 had been reported to the drug regulatory authorities. The product while allowed in India only for acute gouty arthritis and cervical spondylosis continues to be used extensively for prolonged periods for diverse indication from arthritis, dental pain, post operatively. It is given to the elderly and the

of Oxyphenbutazone
children. Hundreds of combination with analgin exist and are widely consumed. These are sold without warning and if any warning is given it is in a medical jargon - no consumer caution is given. Ciba Geigy subsidiary Suhrid Geigy continued to sell oxyphenbutazone product suganril stating that it was an Indian company and the marketing policies of the International Head Quarters did not bind them. In India over 100 brands of oxyphenbutazone and Phenylbutazone are freely sold.

Dr. Olle Hansson continued his work right till his death. He had all the elements of a great health campaigner scientifically sound facts, persistence, perseverance, honesty, integrity coupled with humility. The moral support and inspiration that he provided to the drug activists across the globe is unimaginable. On this day he is remembered with respect, love and gratitude for all his selfless efforts, for being such a inspiring teacher, a role model and a dependable friend. There can be no greater tribute that we can pay than for us to be able to continue fighting the battles for safeguarding peoples health against profit oriented vested interest more effectively against.

Like every year the health and drug activists commemorate Dr. Olle Hanssons death anniversary as "Ban Hazardous Drugs Day". For the past two years the focus was on high dose EP combination because of the EP case. This year the two drugs in question are the fixed dose combinations of chloramphenicol streptomycin and of steroids.

Way back in 1980 the Drug Consultative Committee had recommended their IMMEDIATE withdrawl. It was only on 3rd November 1988 that the fixed dose combinations of the above therapeutic category was banned after the matter was reviewed by the Drug Technical Advisory Board. (PLease see Gazette Notification attached). It is with a sense of dismay that it was

found out that the manufacturers have as in the EP case appealed for a stayorder against the ban and a stay has been granted.

Chloramphenicol-Streptomycin is a combination of two antimicrobial agents greatly misused in diarrhoea, when over 60% of the diarrhoeas are viral in origin, not requiring any antibiotic.

Chloramphenicol while considered, useful in Typhoid is not recommended for simple diarrhoea because of the association of serious almost fatal toxicity of the drug leading to Agranulocytosis fall of white cell count which are required for fighting infection and sometimes total bone marrow shut down.

Extensive misuse of antibiotics like chloramphenicol has led to emergence of drug resistance as was evident in Mexico when over 3000 people died of Typhoid before emergence of resistance to chloramphenicol was detected. Emergence of drug resistance to Typhoid has been reported from different parts of the country.

Furthermore, the use of Streptomycin in a combination for diarrhoea when adequate amount its single ingredient preparation for TB is not available is unwarranted. This is specially so when its therapeutic role is marginal and when better antimicrobials for specific conditions eg. Shigella dysentry, amoebiasis, giardiasis, and anti helminthics for worms. Gross over use of a potentially hazardous combination for non specific diarrhoea is not just a matter of misuse it is bad medicine. Unfortunately in India as in many other developing countries these drugs have been promoted for precisely such trivial condition.

AIDAN and its member organisations call for implementation of the ban (It had taken over 7 years in the case of high

dose EP). Academic Bodies eg. IAP, IMA have also made their stand on the above drug adequately clear and called for their removal. Increasing medical evidence against the combination and pressure for medical professionals eg. medical lobby against unethical marketing has led to a company like Parke Davis to withdrawing its popular Chloramphenicol Streptomycin combination, Chloro Strep, from the world market. A large number of other manufacturers continue to produce and sell these products (List attached).

Having been deeply involved with the entire EP case AIDAN feels that the ban orders will continue to be flaunted and stay orders continue to be granted unless drug legislation reforms are brought about, specially ensuring that the onus of proof of safety lying on the manufacturers, other than the onus of providing lack of safety lying on the drug control authorities.

It is a shame that with the New Drug Policy of 1986 which after 4 years of "policy formulation" was presented to the nation as "measures" for Rationalization for the Growth of the Pharmaceutical Industry", except for the increase in drug prices, no other measures eg. ensuring availability of essential life saving drugs of good quality, with adequate information was ensured.

Of the three combinations, (1) High Dose EP (2) Chloramphenicol & Streptomycin (3) Steroid combination, drugs banned - stay orders were granted to all three drugs.

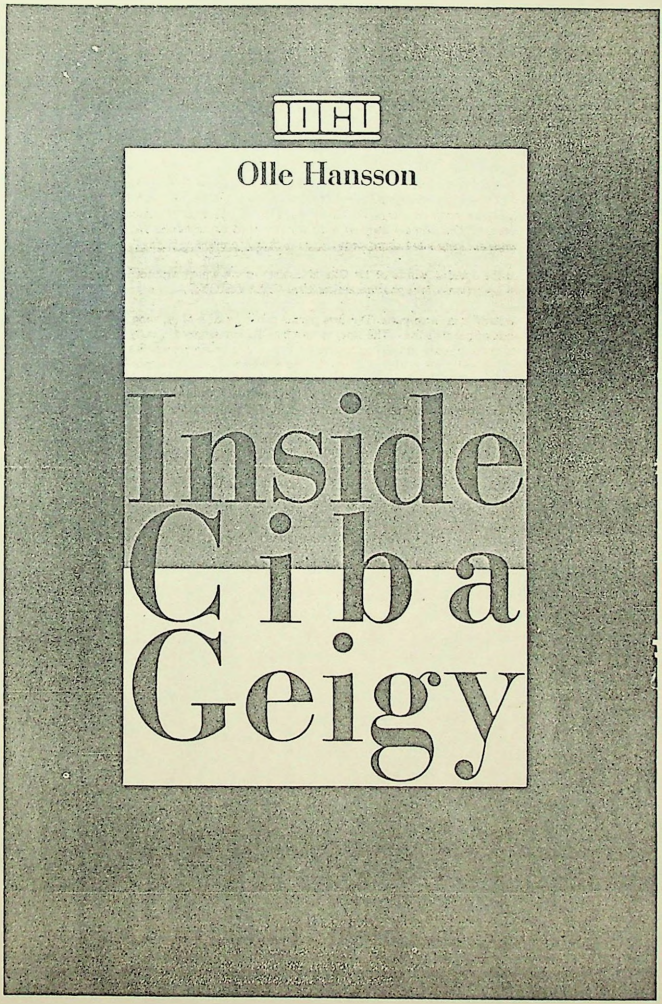
There is absolutely no alternative left to the people but to register their protest at such shameful behaviour by boycotting such companies which are challenging the orders of the highest Drug Control Authority in the country i.e. Drug Controller of India. It is obvious that these manufacturers

in the interest of profit are keen to sell their products even when they have been recognized as potentially hazardous and legally banned.

The companies who have obtained stay orders are Lyka and Deys Chemical, Roussel and Indoco.

It is hoped that the manufacturers will implement the ban. Till then socially conscious doctors are requested not to prescribe their products and people should request their doctors not to prescribe any products of the above manufacturers and prescribe an alternative. People must have a say in what cannot get pushed down their throats in the name of medicine. Since it is not possible for the authorities to ensure the ban orders the people must do so in the interest of their own health and the health of their family members.

DR. MIRA SHIVA MD
COORDINATOR, AIDAN
40 INSTITUTIONAL AREA
SOUTH OF I.I.T.
NEW DELHI 110 0016



2/6/89

Inside Ciba Geigy

Olle Hansson

"This volume has not been written in honour of CIBA-GEIGY. It is an account of facts which those in responsible positions within CIBA-GEIGY are reluctant to talk about, preferring to conceal, distort, deny or keep them secret.

Confidential internal material, that has been acquired from individuals working inside the company, will as a result, be discussed openly for the first time. One conceivable outcome is that CIBA-GEIGY's reputation and financial standing may be affected. As a doctor I have no choice in the matter. The primary duty of a doctor is not to cause harm. This necessarily implies that I must not keep silent about knowledge which may prevent suffering".

These are the opening words of Dr Olle Hansson's book which exposes some of the unconscionable operations of the pharmaceutical giant CIBA-GEIGY.

The book itself is in three parts. The first part is the story of a drug, clioquinol, which ruined thousands of people's lives. The story is told by Olle Hansson who, early on, became deeply involved in the tragedy and did more than anyone else to bring it towards a conclusion. It is a dramatic and horrifying story, but also raises the question, 'Could it happen again?'

In the second part of the book, more recent examples of drug marketing by CIBA-GEIGY and other transnational companies are examined. The picture is very disturbing.

Olle Hansson himself died before he could finish the book, so the final part was written by an associate and describes the events that followed Olle Hansson's long struggle with CIBA-GEIGY.

IOCU

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भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 575] नई दिल्ली, बृहस्पतिवार, नवम्बर 3, 1988/कार्तिक 12, 1910
No. 575] NEW DELHI, THURSDAY, NOVEMBER 3, 1988/KARTIKA 12, 1910

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके
Separate Paging is given to this Part in order that it may be filed as a separate compilation

स्वास्थ्य और परिवार कल्याण मंत्रालय

नई दिल्ली, 3 नवम्बर, 1988

अधिसूचना

सा.का.नि. 1057(अ) :—केन्द्रीय सरकार का अब समाधान हो गया है कि दमा के उपचार के लिए नियत मात्रा में संयोजन औषधियों में स्टिरायड्स के दीर्घकालीन उपयोग से मनुष्यों को जोखिम की सम्भावना है और ऐसी विनिर्मितियों का चिकित्सीय औचित्य नहीं है ;

और केन्द्रीय सरकार का अब यह भी समाधान हो गया है कि श्वासनिक उपयोग के लिए सलोरमूफेनिकाल के नियत मात्रा में संयोजन से मनुष्यों को जोखिम की सम्भावना है;

और केन्द्रीय सरकार का समाधान हो गया है कि लोकहित में यह आवश्यक और समीचीन है कि पूर्वोक्त औषधियों के विनिर्माण और विक्रय को प्रतिषिद्ध किया जाए।

अतः अब केन्द्रीय सरकार, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, भारत सरकार के स्वास्थ्य और परिवार कल्याण मंत्रालय की अधिसूचना सं. सा.का.नि. 578(अ), तारीख 23 जुलाई, 1983 में निम्नलिखित और संशोधन करती है, अर्थात्:—

उक्त अधिसूचना के नीचे सारणी में मद 14 और मद 15 के स्थान पर निम्नलिखित मदें रखी जाएंगी, अर्थात्:—

"14. आन्तरिक उपयोग के लिए किसी अन्य औषधि के साथ कॉर्टिकोस्टेराइड का निश्चित मात्रा में संयोजन।

15. आन्तरिक उपयोग के लिए किसी अन्य औषधि के साथ क्लोरएम्फेनिकाल के निश्चित मात्रा में संयोजन।

[सं. एक्स. 11014/2/88-डी.एम.एस. और पी.एफ.ए.]

श्रीमती विनीता राय, संयुक्त सचिव

टिप्पण :—भारत सरकार के स्वास्थ्य और परिवार कल्याण मंत्रालय की अधिसूचना सं. सा.का.नि. स. 578(अ), तारीख 23 जुलाई, 1983 का संशोधन भारत के राजपत्र, असाधारण, भाग 2, खण्ड 3(i) में प्रकाशित निम्नलिखित अधिसूचनाओं द्वारा किया गया, अर्थात् :—

1. सा.का.नि. 49(अ) तारीख 31-1-1984
2. सा.का.नि. 322(अ) तारीख 3-5-1984
3. सा.का.नि. 863(अ) तारीख 22-11-1985
4. सा.का.नि. 700(अ) तारीख 15-6-1988

MINISTRY OF HEALTH AND FAMILY WELFARE

New Delhi, the 3rd November, 1988

NOTIFICATION

G.S.R. 1057 (E).—Whereas the Central Government is now satisfied that long terms use of steroids in fixed dose combinations drugs for treatment of asthma is likely to involve risk to human beings and such formulations do not have therapeutic justification :

And whereas the Central Government is now also satisfied that fixed dose combinations of chloramphenicol for internal use is likely to involve risk to human beings :

And whereas the Central Government is satisfied that it is necessary and expedient in public interest to prohibit the manufacture and sale of the drugs aforesaid.

Now, therefore, in exercise of powers conferred by section 26A of the Drugs & Cosmetics Act, 1940 (23 of 1940) the Central Government hereby makes the following further amendments in the notification of the Government of India, in the Ministry of Health and Family Welfare No. G.S.R. 578 (E), dated 23rd of July, 1983 namely :—

In the Table under the said notification for items 14 and 15 the following items shall be substituted namely :—

"14. Fixed dose combination of corticosteroids with any other drug for internal use.

15. Fixed dose combinations of Chloramphenicol with any other drug for internal use."

[No. X-11014/2/88-DMS&PFA]

SMT. VINEETA RAI, Jt. Secy.

Note : Government of India Ministry of Health & Family Welfare Notification No. G.S.R. 578 (E), dated 23rd July, 1983 was amended by the following notification published in the Gazette of India, Extraordinary, Part II, Section 3(i), namely :—

1. G.S.R. 49 (E), dated 31-1-1984.
2. G.S.R. 322 (E), dated 3-5-1984.
3. G.S.R. 863 (E), dated 22-11-1985.
4. G.S.R. 700 (E), dated 15-6-1988.

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HAI Clearinghouse
Resource Sheet #6
August 1982

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RESOURCES

PUBLICATIONS RECEIVED BY THE HAI CLEARINGHOUSE

- *The Health of Nations*, by Mike Muller. Published by Faber & Faber. Price: £7.95, Faber paperback: £3.95.

  This book raises some fundamental questions including: * Is the positive contribution of the multinational drug companies towards Third World health care outweighed by the damage they do?; * Do 'eminently respectable drug companies' promote the consumption of certain drugs that are not only inefficacious but also dangerous?; * Is the Third World the centre of the pharmaceutical market place of the future?; * What should be the role of the World Health Organization in securing 'health for all'?; * What has been the drug companies' response to the growing criticism towards their practices?; * Is there a real chance of 'health for all' by the year 2000?

  For further information about the author and the book, contact Greg Hunt at Faber and Faber, 3 Queen Square, London WC1 (tel: 01-278 6881)

- *Pills, Pesticides and Profits - The International Trade in Toxic Substances*. Edited by Ruth Norris. Contributors: A. Karim Ahmed, S. Jacob Scherr and Robert Richter. Published by North River Press, Inc.

  This book traces briefly the historical development of the trade in toxic substances and deals with several specific areas - pesticides, pharmaceuticals, industrial hazards, hazardous wastes and infant formula. It also looks into possible solutions to the problem at the international, national and community levels. Also included is the transcript of the Public Broadcasting Service documentary film, 'Pesticides & Pills: For Export Only.'

  For additional copies of this book, write to North River Press, Inc., Box 241 Croton-on-Hudson, NY 10520. For information concerning a student edition and other educational materials related to the book, write to the Council on International and Public Affairs, 777 United Nations Plaza, New York, NY 10017. For information on rental or purchase of the films whose transcripts appear in the book, write to Robert Richter Productions, 330 W. 42nd Street, New York, NY 10036.

- *The Pharmaceutical Industry in ASEAN countries.* Edited by C. Sepulveda and E. Meneses. Published by UN - Asian and Pacific Development Institute in cooperation with UNIDO. UNAPDI Health Technical Paper #36/PHI 15

The following books also deal with the pharmaceutical industry in Asean

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HAI
Health Action International

Excerpts from

THE RATIONAL AND ECONOMIC USE OF DRUGS IN THE THIRD WORLD

A Health Action International briefing paper on the Bangladesh Drug Ordinance of 12 June, 1982

On 12 June 1982, the Bangladeshi Ministry of Health published a New Drug Ordinance, prohibiting the future sale of over 1,700 drugs. The Ordinance implemented the recommendations of a National Expert Committee on Drugs and Drug Policies, whose report had been published very shortly before.

The Bangladeshi Government's initiative is extremely important. Nationally and internationally it could have far-reaching effects on the health of consumers. It will certainly affect the policies and practices of the international pharmaceutical industry. And it can be expected to influence governments' drug policies and regulation of the pharmaceutical industry, throughout the world.

This HAI briefing paper summarises the arguments and findings of the Bangladeshi Government's Expert Committee; and outlines in general terms what the wider implications of this initiative are likely to be.

Need for a drug policy in Bangladesh

On 27 April 1982, the Bangladeshi Ministry of Health set up an eight-man Expert Committee '...to evaluate all the registered/licensed pharmaceutical products presently available in the country and to formulate a draft National Drug policy in consistence with the health need of the country.' The Committee identified the following as the main weakness of the national health policy:

- Poor laws, poorly enforced.
- Exploitation of consumers.
- Undesirable foreign domination.
- Waste of national economic resources.

Drug policy objectives

The Expert Committee proposed a national drug policy and proposed the introduction of new drug laws; and recommended the setting up of a greatly strengthened Drug Administration. The Committee also made specific proposals relating to the rational and economic use of drugs.

The Committee suggested first, that action be taken to identify 'a limited list of 150 essential drugs considered adequate for most therapeutic purposes.' The Committee also envisaged the need for 'a list of another about 100 supplementary drugs needed for the tertiary level of health care by specialists.'

Secondly, the Committee proposed annual reviews of all drugs on the market, to take account of their 'usefulness, essentiality and cost-effectiveness in the light of up to date available information.' It also proposed to grant licences to new products only when these were 'considered essential and relevant to (the) health needs of the country.'

Thirdly, the Committee called for 'the elimination of all unnecessary, useless drugs and drugs of doubtful efficacy from the market.'

Guidelines for drug evaluation

The Expert Committee unanimously agreed on 16 criteria to be used as guidelines for evaluating drugs on the market in Bangladesh. (These guidelines are summarised in the booklet - in some cases, with notes and examples outlining their significance.)

HEALTH ACTION INTERNATIONAL (HAI) is an informal network of consumer, professional, development action and other public-interest groups working on pharmaceutical issues. A clearinghouse is maintained at IOCU Regional Office for Asia and the Pacific, P.O.Box 1045, Penang, Malaysia. *Cable:* INTEROCU PENANG *Telex:* MA 40164 APIOCU *Tel:* (04) 885072.

General significance of the Bangladesh initiative

The importance of the Bangladeshi initiative, as health policy, is obvious. In particular, the rationalisation of the national drug list represents a substantial commitment to public health. As the Expert Committee says: 'At present, not more than 20 per cent of the population have access even to the most essential drugs for their health needs and yet the market is flooded with hundreds of useless or non-essential medicinal products.'

Bangladesh has done what any health-conscious nation should do

It is worth saying that the Bangladesh initiative is also in line with the domestic drug policies of the major drug producing nations. In the US and the UK, for example, a purging of undesirable products from the national list began about 15 years ago, following the thalidomide scandal.

The politics of the Bangladeshi initiative

A distinction must be made between the sense of the Bangladesh New Drug Order as health policy - and the national and international politics of the thing. The difference in this case is fundamental.

Limitations of national initiatives

Another reason for closely watching what happens in Bangladesh is that events there may give some clue about how other developing countries could rationalise their drug lists - inevitably in the face of opposition from drug suppliers and drug-producing countries, and probably from the medical profession and high-income consumers as well. Is there a 'right' or 'wrong' way to go about this?

International initiatives: a role for WHO?

This question arises not because the World Health Organization (WHO) has great authority over the collective will of the member nations of the World Health Assembly. The question arises because the WHO speaks for the Assembly in promoting "Health for all by the year 2000" as a formal and attainable objective.

"The rational and economic use of drugs in the Third World," 14 pp, published by Health Action International in August 1982, is available from:

HAI clearinghouse
P.O. Box 1045
Penang, Malaysia.

Price available upon request.

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RESOURCES

PUBLICATIONS RECEIVED BY THE HAI CLEARINGHOUSE

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  It contains, among others, two main reports: (a) the impact of the activities of pharmaceutical transnational corporations on the health of the population and health policies of different countries, particularly of developing countries; action by trade unions for a democratic health policy satisfying the needs of the population and aspirations of working people; (b) the situation of workers in the pharmaceutical industry, their struggles and actions against transnational corporations and for relations corresponding to a new international economic order between industrialised and developing countries. The conference was held in Moscow from November 11-13, 1981.

  Available from: Alain Covet, 1068 Bp, Benezurn 45, Budapest, Hungary.

- *Documentation about the International Trade with Blood Plasma*, by Buko Pharma-Kampagne. 39 pp, price 4 DM.

  This booklet is a short introduction to the problem containing an article in English and the rest in German.

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Dup.

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2. MEDICINE AS IF PEOPLE MATTERED

   Special Issue of HEALTH FOR THE MILLIONS.
   Voluntary Health Association of India
   New Delhi

   April-June 1981 (Rs.6.00)

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   Mukarram Bhagat
   Centre for Education and Document
   Bombay

   February 1982 (Rs.)

4. HEALTH CARE-WHICH WAY TO GO

   Medico Friend Circle (Anthology) 1982 (Rs.10-00)

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5. HEALTH FOR ALL--AN ALTERNATIVE STRATEGY

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6. INSULT OR INJURY

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Anil Aggarwal
Earthscan, 10 Percy Street
London W1 PO DR

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8. POOR HEALTH, RICH PROFITS

Tom Heller
Spokesman Books
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Gamble Street, Nottingham, England

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9. DRUGS DISINFORMATION

Charles Medawar
Social Audit Ltd
England

1980 ( )

10. BITTER PILLS: MEDICINE AND THE THIRD WORLD POOR

Dianna Melrose
OXFAM, 274 Banbury Road
Oxford OX2 7DZ
U.K. (£4.95)

11. DRUG DIPLOMACY

Charles Medawar & Barbara Freese
Social Audit Ltd
PO Box 111, London NX1 8XG

1982 (£3.95)

12. PRESCRIPTIONS FOR DEATH: THE DRUGGING OF THE THIRD WORLD

Milton Silverman et al.
University of California Press
2223 Fulton Street, Berkeley CA 94720

1982 ($19.95)

13. DRUGS THAT DON'T WORK

Sidney Wolfe, Christopher Colely and Health Research Group : 1980

Available from Public Citizen Health Research Group, Dept AC 2000
P Street N.W., Washington DC 20036, USA.

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14. 44 Problem Drugs - a consumer action and resource kit on pharmaceuticals

May 1981.

International Organization of Consumers' Union Registered Office for Asia and Pacific
PO Box 1045, Penang, Malaysia.

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3. Hungry for profits – Robert J. Ledogar, Corporate Interfaith Council, New York, USA
4. Who needs the Drug companies, a Haslemere Group, War on Want and Third World First publication
5. Poor Health, Rich Profits: Multinational Drug Companies and the Third World, Tom Heller, Spokesman Books, Nottingham, England

For further information please contact:

1. Medico Friend Circle
   50 LIC Quarters
   University Road,
   Pune 411016
2. Voluntary Health Association of India
   C-14 Community Centre, Safdarjung Development Area
   New Delhi 110016
3. Low Cost Drugs & Rational Therapeutics Cell (VHAI)
   105 Rajpur Road
   Dehradun 248001
4. Arogya Dakshata Mandal
   1913 Sadashiv Peth
   Pune 411030
5. Delhi Science Forum
   J-55 Saket P.Box 4002
   New Delhi 110017
6. Society of Young Scientists
   All India Institute of Medical Sciences
   Ansari Nagar, New Delhi 110016
7. Concern for Correct Medicine
   G-16/8 Rajouri Gardens
   New Delhi 110027
8. Consumer Education and Research Centre
   Near Law College, Ellisbridge
   Ahmedabad 380006
9. Centre for Education and Documentation
   3, Suleman Chambers, 4 Battery Street
   Bombay 400039

...contd...

10. LOCOST
C/o GVHA
G.P.O. Box 7,
Baroda 390001

11. Federation of Medical Representatives Association of India
J.S. Majumdar, General Secretary,
1-E, Rajendra Nagar
Patna 800016

Duplicate

INFANT FORMULA PROMOTION

The marketing of milk powder based products as breast milk substitutes

Please use this form to file a report whenever you witness any infant formula promotion, or give copies to any local person (project holder etc.) who is interested in the issue and might wish to file a report.

Please attach copies of photographs of relevant materials where you can or texts, slogans or gists of texts where appropriate.

i) The monitoring applies to breast milk substitutes or bottle fed supplements, not to weaning foods, (which are foods usually cereal based and given after 6 months of age).

ii) Infant formulae are in general prepared with a good deal of care. They are good alternatives to breast milk when the latter is unavailable. In poor communities, however, it is extremely difficult to use the products safely and so are to be regarded as last resorts. It is the active promotion of these products in such situations which is wrong.

iii) The use of feeding bottles may provide a useful indicator to infant formula promotion (N.B. if formulas are used they should be via cup and spoon)

iv) Not all parts of the questionnaire will apply. Ignore if not applicable.

v) Increasingly companies are using the facilities of the health service to promote infant formulae (with implied medical endorsement) rather than direct advertising. This is more difficult to observe. Sections B, C and D, then, are most relevant but are likely to need a small amount of research to complete, rather than a chance witnessing as in A.

vi) "Mother-craft nurses" are company employed sales staff working within or alongside the health service. These may be dressed in a uniform which resembles local hospital uniforms.

OXFAM staff member _____

Product Name _____ Company name and Parent _____

Date Witnessed _____ Location _____

Date of issue of promotion (if known) _____

A) PROMOTION THROUGH MEDIA

PROMOTION MEDIUM

Newspaper Advert	✓	Billboard	X
Magazine "	✓	Baby Show	X
Radio "	X	Poster, Calendar etc.	✓
T.V. "		Other (point of sale display, tee shirts, feeding bottles, baby book etc - give details)	
Film "	X		

If poster or calendar, etc., was this:-

In a hospital ☐
In a clinic ☐

Booklet on development of child provided free on demand and paying postage

Product Labels (Please send if possible)

Is the product described as "humanised" or "maternalised"	YES / NO
Is it made clear that breast feeding is superior	YES / NO
Is the label written in a local or national language	YES / NO

B) PROMOTION THROUGH HEALTH PERSONNEL

PROMOTER

Mothercraft nurse	X
Doctor	
Midwife	X
Official nurse	X
Other (please specify)	X

_____
_____
_____

PROMOTION METHOD

Giving free sample	
Giving bottles	
Other gifts (please specify	
Suggesting product as most appropriate food	
Other (please specify)	

(examples may be using company wrist bands weight cards or brochures)

_____
_____

WHERE WITNESSED

In hospital	
Clinic	
Mothers Home	
Elsewhere (please specify)	

_____
_____
_____

Does the promoter receive any inducements (commission,gifts etc.) YES | NO

Can you specify_____

If Company employee, does promoter wear a uniform YES | NO

If YES does this resemble a hospital nurses' uniform YES | CONSIDERABLY | SLIGHTLY | NO

C) PROMOTION IN INSTITUTIONS

Institution name _____

(hospital/clinic/other_____)

Does the institution automatically give newborns infant formula YES | NO

Is there a cheap infant formula sales point (milk bank) YES | NO

Is the mother offered infant formula at a lower price than local shops YES | NO

When infant formula is used, does the institution recommend: feeding bottles/cup and spoon YES | NO

ADDITIONAL INFORMATION The following details would be useful to have but might prove difficult to obtain and so are not essential. It might be that there is an appropriate local person - interested in this issues, who would research this section.

Product Name_____Company name and Parent_____

Date Witnessed_____Name of institution_____

Location_____(village/town/country wide)

D) PROMOTION TO HEALTH SERVICE (HEALTH PERSONNEL)

(i.e. promotion to rather than promotion by doctors)

PROMOTION METHOD		TO	
Free sample for distribution	☐	Hospital	☐
Free sample for personal use by health personnel	☐	Clinic	☐
Commission on sales	☐	Doctor	☐
High discount for monopoly product use	☐	Nurse	☐
Gifts or grants (please give details)	☐	Midwife	☐
_____		Pharmacist	☐
_____		Administrator	☐
_____			

E) COMPANY SALES PERSONNEL

In the country, how many 'mother care nurses' does the company employ_____

Are there ex-nurses and if not do they receive appropriate training YES | NO

Are mother care nurses' wages significantly higher than hospital nurses' YES | NO

Do Company Sales Personnel earn commission on sales YES | NO

Are there other company sales staff Numbers_____

Do sales staff have contact with: doctors/nurses/midwives/pharmacists/ hospital - administrators

Do sales staff work in: hospitals/clinics/mothers home/other_____

_____

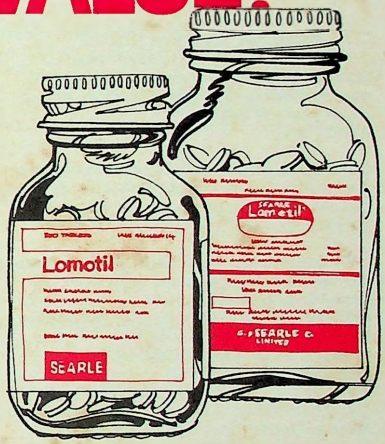
What local laws govern sales promotion personnel_____

Other Comments: (Please write seperately and attach to this form.) Such as results of medical studies on the prevalence of bottle feeding, or on the health status of bottle vs breast fed babies. Details of breast feeding promotion programmes. Availability of infant formula and cost relative to average wage of a poor family. Marketing of products other than infant formula (such as sweetened condensed milk) as a breast milk substitute.

The World Health Organization says:

"A number of medicines, which are of no value and are even dangerous, are often given to treat diarrhoea. Money and time are wasted in their use." So . . .

WHO says LOMOTIL has NO VALUE?



LOMOTIL (diphenoxylate/atropine) is made by the US multinational drug company, G.D. Searle; and promoted to physicians all over the world in terms such as "established success", "good tolerance", "excellent value" and "ideal for every situation". This leaflet — prepared and published by Social Audit Ltd., and friends* — calls into question these claims.

LOMOTIL may be of value in giving *symptomatic* relief for non-specific "travellers' diarrhoea" in adults. But experts say Lomotil — and other products like it [2] — have little or no place in the treatment of young children — especially in developing countries, where infective diarrhoeas are the major cause of death in children aged under three.[1] Lomotil's limitations include:

POTENTIAL DANGERS

"Lomotil, which is widely used in the treatment of diarrhoea in the paediatric age group, is dangerous and unwarranted . . . we urge that all physicians treating infants and children avoid the potentially dangerous use of Lomotil for the treatment of diarrhoea."
(Clinical Notes [1974])[3]

"Lomotil can relieve the symptoms of acute gastroenteritis in children, but it can also mask the signs of dehydration and cause fatal toxic reactions . . . use of this combination for treatment of diarrhoea in children is hazardous."
(The Medical Letter [1980])[4]

"Lomotil is a dangerous combination of drugs contra-indicated for children under 2 years of age and probably never indicated in childhood diarrhoea."
(Pediatrics [1980])[5]

QUESTIONABLE USEFULNESS

"The use of Lomotil as an antidiarrhoeal agent in children is difficult to justify . . . we doubt if it has any place in the treatment of diarrhoea in children."
(Arch. of Dis. in Child. [1979])[6]

"A diarrhoea that needs 4 such tablets to be cured would probably have been cured without it too. A more prolonged diarrhoea needs proper investigation and specific therapy rather than a blindly harmful stopcock."
(Leb. Med. J. [1974])[7]

ECONOMIC WASTE

Lomotil costs up to 25 times more than other widely-used symptomatic treatments for diarrhoea.
(AMREF [1980])[8]

"Lomotil (no value)." (WHO [1976])[1]

Lomotil

HOW USEFUL . . .

"The management of acute diarrhoea in childhood is essentially dietary . . . Unnecessary drug prescription for these children should be vigorously opposed."
(The Lancet [1976])[9]

. . . Against Dehydration?

"The cause of death in diarrhoea is DEHYDRATION . . . Diarrhoea is the most common cause of death in children under three years of age . . ."
(WHO [1976])[1]

LOMOTIL is not a treatment for dehydration. It may reduce the loss of fluid from the body but can also allow fluids to accumulate in the paralysed gut.

"LOMOTIL can mask fluid losses without diminishing them, and the drug itself can cause fatal adverse effects . . . there is no evidence that reduced motility diminishes the loss of fluid and electrolytes into the lumen of an inflamed intestine."
(The Medical Letter [1975])[4]

The accumulation of the body's vital fluids within the intestine can be just as dangerous as the more obvious dehydration:

"In diarrhoea, life-threatening situations are reached . . . so long as fluid and electrolytes are excessively lost into the lumen whether they are expelled from the lumen to the outside of the body or not . . ."
(J. of Singapore Ped. Soc. [1976])[10]

Small feeds of water (or a weak electrolyte solution) given frequently by mouth is the *only* first-line treatment against serious childhood diarrhoea. If this fails after 24 hours, intravenous therapy and hospitalisation may be needed.

. . . Against Infection?

"Acute diarrhoea in children is usually infective, but antibiotics and anti-diarrhoeal drugs rarely help."
(Drug and Ther. Bulletin [1978])[11]

LOMOTIL is widely and often successfully used by adults as a symptomatic treatment of bothersome, non-specific "travellers' diarrhoea" (which is rarely serious). But in children infective diarrhoea is serious. LOMOTIL prevents the child from getting rid of the infective agent and may prolong the period of infection.[12]

"In patients with infective diarrhoea, the use of constipating agents make the carrier state last longer by stopping the organism from being excreted."
(AMREF [1980])[8]

A comparison between LOMOTIL and a placebo in treatment of an infective diarrhoea reported that:

"Febrile volunteers receiving Lomotil alone experienced over a day more fever than those in other treatment groups," suggesting that "drugs that retard gut motility may facilitate intestinal infection . . ."
(JAMA [1973])[13]

HOW SAFE?

"Because of its depressant effects it is no longer recommended for children."
(Brit. Med. J. [1976])[14]

LOMOTIL poisoning in children can include atropinism, respiratory depression, coma, and even death. Symptoms can appear even at near therapeutic doses:

"Lomotil ingestion is a cause of serious poisoning in young children, especially those aged under five. It is always hard to assess the dose in patients suffering from poisoning, but it seems that young children may develop pronounced symptoms after taking only one to five tablets."
(Brit. Med. J. [1977])[15]

The difference between therapeutic and toxic dose is unpredictable:

"We were unable to find a correlation between the severity of symptoms and the dose ingested. Because of this it is not possible to predict what dose will be toxic in children, and while some may have only the mildest symptoms with relatively large doses, others develop severe toxicity on ingesting an amount near the normal dose."
(Arch. of Dis. in Child. [1979])[6]

"There is a very narrow range between allegedly therapeutic and toxic dosages, and many cases of toxicity in children have been reported."
(Pediatrics [1980])[5]

"The narrow margin between therapeutic and toxic doses, and the high incidence of atropine hypersensitivity, make Lomotil a potentially dangerous therapeutic agent."
(Clinical Notes [1974])[3]

"The dangers of this drug to children have not been well recognised. The narrow range between therapeutic and toxic doses, and also the possibility of a child being abnormally sensitive . . . may account for the severe toxicity sometimes seen with low dosage."
(Clinical Pediatrics [1973])[16]

DESPITE THE DANGEROUSLY VARIABLE RESPONSE, SEARLE'S RECOMMENDED DOSES FOR INFANTS AND CHILDREN AND THE PACKAGE WARNING INFORMATION VARY AROUND THE WORLD.

In the US, LOMOTIL is contra-indicated for children under two years old.

"This warning by the manufacturer is not because there has been inadequate paediatric testing of the drug but rather because severe life-threatening reactions (which are not rare) occur in this age group."
(Am. Fam. Phys. [1976])[17]

In Britain, however, the makers recommend it for one-year-olds; and in Hong-Kong, Thailand, and the Philippines it is offered for infants of three months old.

Special circumstances in developing countries compound the potential danger of treating infants with Lomotil in this way. In developing countries:

- children are relatively lighter than those of the same age elswhere;
- the amount of medical supervision is greatly lower;
- typically, no adverse reaction reporting systems exist; and
- drugs such as LOMOTIL (available only on prescription in the West) are in practice freely available over the counter.

HOW EXPENSIVE?

The cost of the smallest available size of LOMOTIL would for many people in developing countries be equivalent to at least one day's income. Other effective preparations for symptomatic treatment of diarrhoea[18,19] cost much less.

According to the African Medical and Research Foundation (AMREF), the cost of treatment with LOMOTIL is about twice the cost of treatment with codeine syrup or codeine phosphate. Treatment with a kaolin mixture, which may also give relief[20], costs about 25 times less.[8]

LOMOTIL WITH NEOMYCIN (an antibiotic) is recommended by Searle for the treatment of "diarrhoea of bacterial origin." This is unacceptable:

"Antibiotic and sulphonamide preparations should be avoided for the treatment of diarrhoea even when a bacterial cause is suspected because they may prolong rather than shorten the time taken to control diarrhoea and carrier states."
(BNF [1981])[21]

"Neomycin not only can cause renal damage, but also it makes diarrhoea, dehydration, and nutritional losses worse and could interfere with oral rehydration therapy."
(Population Report , 1980)[22]

"Medicines which should not be used in the treatment of diarrhoea: . . . Neomycin . . ."
(WHO [1976])[1]

Treatment with LOMOTIL plus NEOMYCIN costs about three times more than treatment with LOMOTIL alone.

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5 "Delayed Cardiopulminary Arrest after Lomotil Ingestion" (in) **Pediatrics** (Jan 1980) pp. 157-8.
6 Curtis J A, & Goel K M: "Lomotil Poisoning in Children" (in) **Archives of Disease in Childhood** (iss. 54, 1979) pp. 222-5.
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18 Smits B J: "The Irritable Bowel Syndrome" (in) **Practitioner** (July 1974) p. 43.
19 Collins C D: "Lomotil in Treatment of Post-Vagotomy Diarrhoea" (in) **British Med. J.** (Sept 3, 1966) pp. 560-1.
20 Portnoy B L, et al: "Antidiarrhoeal Agents in the Treatment of Acute Diarrhoea in Children" (in) **Journal of the American Med. Assoc.** (Aut 16, 1976) pp. 844-6.
21 British Medical Assoc. & The Pharmaceutical Soc. of G.B., **British National Formulary 1981,** No. 1, (London: The Pharmaceutical Press and the BMA, 1981) p. 40.
22 The Johns Hopkins University, "Oral Rehydration Therapy (ORT) for Childhood Diarrhoea" (in) **Population Reports** (Issues in World Health) (Nov/Dec 1980) p. 54.

*SOCIAL AUDIT AND FRIENDS

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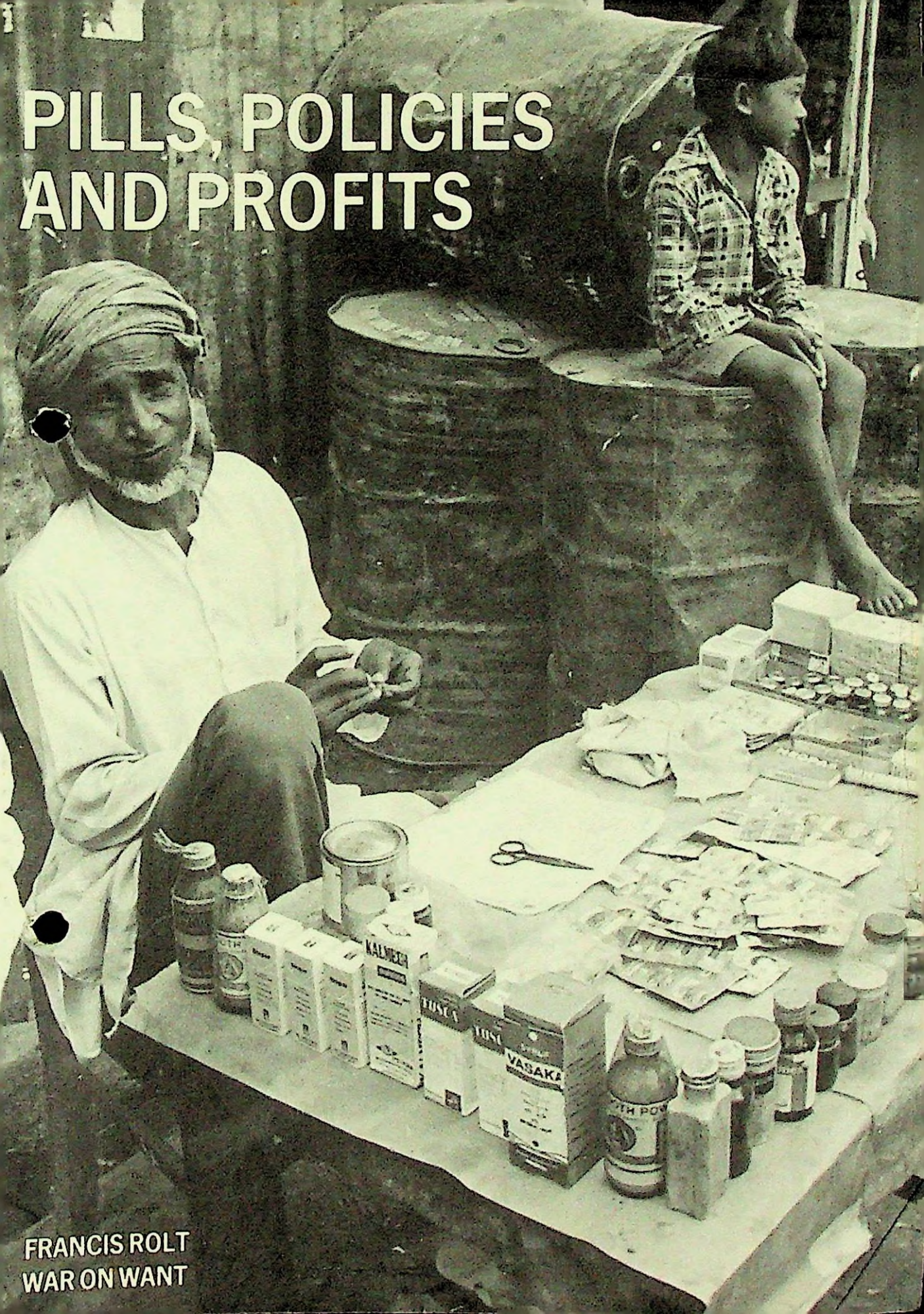
SOCIAL AUDIT LIMITED 9 POLAND STREET LONDON W1V 3DG

PILLS, POLICIES AND PROFITS



FRANCIS ROLT
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A WAR ON WANT PUBLICATION: ISBN 0 905990 22 6

A B C

Re[redacted] Materials for RBS doctors

Journals

Annual Subscription

(i) Journal of Rural Paediatrics (monthly) — Rs 12/- (add Rs 2/- if by cheque)
Dr Anil Mokashi, MD, DCH, editor
BARAMATI, Dist Pune,
Maharashtra - 413102

(ii) Journal of Applied Medicine

(iii) Pune Journal of continuing education (monthly) — Rs 10/-
Arogya Dakshata Mandal, Dr Patwardhan.
1913 Sadashiv Path
Pune 411030
Maharashtra

(iv) Drug bulletin (Prof Y.S. Mathur - Head of Dept of Pharmacology)
PGI
Chandigarh. - 160012.

(v) Health for the millions (bimonthly) — Rs 12/-
Voluntary Health Association of India (VHAI)
C-14, Community Centre
Opp IIT Main gate, SDA
New Delhi 110016

(vi) Medico Friend circle bulletin (monthly) — Rs 15/-
organization + bulletin office,
326, 5th Main,
1st Block, Koramangala
Bangalore 560034.

(vii) Medical Service
Catholic Hospital Association of India (CHAI)
CBCI centre, Goldakkhana,
New Delhi 110001

(viii) Diarrhoea Dialogue (quarterly) — Free
AHRTAG
85. Marylebone High Street,
LONDON - W1M 3DE
UK.

(ix) Contact (Bimonthly) — Free
Christian Medical commission
World council of Churches
150, route de Ferney
1211 Geneva 20
Switzerland.
[also available from VHAI Delhi]

(x) Health Action International
HAI Clearinghouse
IOCU, PO Box 1045
Penang, Malaysia
(International Organization of Consumers Unions)
(very informative newsletter concerning world drug names of special relevance for us in the third world)

(xi) The Medical letter on drugs and therapeutics
56, Harrison Street
New Rochell
New York - USA 10801
(an unbiased drug information bulletin)

(xii) Bulletin of sciences (bimonthly) Rs 15/-
Power Engineering
Indian Institute of Science
Bangalore - 560012.

Books

Available from UHAI

(1) Paediatric Priorities in the Developing World - D. Morley
(pp 470, ELBS, 1977 - price Rs 36/-)

(2) Primary child care - A manual for health workers - King
(pp 315, 1979, Rs 40/-)

(3) Practical mother & child health in developing countries - G.J. Ebrahim
(pp 106, ELBS, 1980, Rs 17/-)

(4) Health care which way to go? - examination of issues & alternatives - edited by Dr's Abhay Bang & Ashwin Patil, Medico-Friend Circle.
(pp 256, 1982, Rs 10/-)

(5) Where there is no doctor - A village health care handbook - David Werner
(pp 456, 1982 - 3 Ed, Rs 29/-)

(6) Management process in Health care - S Srinivasan (Ed)
(pp 650, 1983, Rs 58/-)

Other

(7) Health care in India - George Joseph, John Desrochers, Marianne Kolathil.
centre for Social Action,
Gundappa Block,
64, Pemme Gowda Road
Bangalore - 560006.
(pp 143, 1983, Rs 4/-)

(8) Confessions of a medical heretic - Robert S. Mendelsohn, MD.
1980, Warner Books, 75 Rockefeller Plaza, New York. 10019.

Resource Materials for RBS students

(1) Cyclostyled note on continuing educ' material

Books (i) Maurice King
(ii) David Morley
(iii) David Warner
(iv) Health care Which way to go
(v) Health care in India

VHAI calalapue

Journals (i) Journal of Rural Paediatrics.
(ii) Journal of Applied Medicine.
(iii) Pune Journal of continuing educ'
(iv) Drugs Bulletin of PGI
(v) Health for the millions
(vi) MFC. Bulletin
(vii) Medical Service

(2) Foldoms & MFC bulletin / pamplet
Pune Journal
Medical Service / pamphlet CHAI.
VHAI calalapue
SJMCH newsletter

(3) ~~Foods~~ / paper.

(4) Display — National Health policy
curriculum.
Health care Which way to go.

Resource Materials for CHAI

1. MFC bulletin.
2. Rural Paediatrics
3. Pune Journal
4. Drugs bulletin PGI
5. Health for the millions
6. Action News.
7. ? Deeds Dialogue
8. Social & Health Review

Books

1. DEEDS - book
2. MOTT Teambook
3. TRACE
4. Health care in India

Resource Grps

1. MFC
2. Dialogue
3. DEEDS.
4. Madras group - communi
5. KSSP
6. Lok Vignan Sanghatana.

Programmes

1. RUHSA
2. ISI < Delhi
3. State UHA's

Books — Widening Horizons on drug issues — Oct '84 Books

(1) Aspects of the Drug Industry in India,
Mukarram Bhagat February 1982 Rs. 17/-
From: Centre for Education & Documentation
3 Sulekhan Chambers, Battery Street
Bombay.

(2) Health for all – an alternative Strategy
ICSSR & ICMR 1981 Rs 18.
available from VHAI.
In focussing on a comprehensive national policy of health & a new operational strategy, the report is intended to be a basic document to initiate a nation-wide debate on the subject as well as a positive action towards certain radical changes to correct the present imbalances in our health care system. Has a very comprehensive chapter on drugs & pharmaceuticals.

(3) Insult or Injury.
Charles Medawar 1979 Rs 25/-
Social Audit England.
Available from Indian Social Institute, Lodi Road.
New Delhi.

(4) Health Care – which way to go
Medico friend circle (Anthology) 1982 Rs 10.00.
raises relevant but unconventional issues regarding people's health. why is there a lack of political will to solve pressing health problems of the country? How detrimental is the alliance between medical professionals & the drug industry to peoples health? etc
available from: Medico friend circle Office, 326, 5th Main, 1st Block Koramangala Bangalore 560034

(5) Hathi Committee: Report of the committee on drugs & pharmaceutical industry
Ministry of Petroleum & chemicals, government of India
April 1975 Rs 17.00
available from: –

P.T.O

(6) Drugs + the Third World
Anil Agarwal 1978 $5.00
Earthscan, 10 Percy Street, London W1 P0 DR

(7) Prescription for change -Health Action Internationals guide to rational health projects
Virginia Beardshaw Nov 1983, 85 pp, US $10.00.

Available from VHAI at 30% discount

(8) Pill-pering the Poor: Drugs + the Third World
an information/action pack on drugs + the third world
$4.00 (+ $2.70 for postage) overseas surface. 1$4.70 overseas airmail
Inter-faith Center on Corporate Responsibility,
International Health Programme,
475 Riverside Drive, Room 566,
New York, NY 10115
It provides an overview of the problems related to drug marketing in the Third World. It contains articles on the need for essential drugs, on the suffering wrought overseas by some US made drugs + on the high price the Third world poor have to pay for their medicines. This package includes an extensive annotated bibliography, basic facts + figures about the transnational drug industry, + an outline of suggestions for action on how you can get more involved in helping to stop abuses.

- More than 40 ideas for action research projects on drugs
- A summary of the main elements of the rational health issue + suggestions about how the campaign on it
- advice on how to talk to drug companies + the powers that be
- A reference section that lists the main materials you need to research on drugs

(9) Therapeutic guidelines: A manual to assist in the rational purchase and prescription of drugs
G. Upunda, J. Yudkin, G. Brown ____ 1980 pp 166 Rs 35/-
African medical + research foundation
available from VHAI

Rs 35/-

(10) Management schedules for dispensaries - a manual for rural health workers
Peter Patil
, African Medical + Research Foundation 1983, pp
Available from VHAI Rs ____

(11) KHFH formulary - Rs 12/-

Oct '84

Widening Horizons on drug issues

A) Journals

1. Pune Journal of Continuing Health Education

~~Annual subscription Rs~~ An educational publication presenting scientific information & opinion on drugs & health issues to the ~~medical profession~~ health personnel to stimulate thought & further investigation since the past 8 years. Annual subscription Rs 10/- or a five year subscription for Rs 45/- payable by MO or cheque to

Arogya Dakshata Mandal,
191.3, Sadashiv Peth, Pune 411030. Maharashtra

2. Drugs Bulletin

an informative monthly giving unbiased technical information on drugs & therapeutics.
Annual subscription Rs 10/- from.

Dr V.S. Mathur,
Professor Dept of Pharmacology &
Editor, Drugs Bulletin
PGI of Medical Education & Research
Chandigarh – 160012.

3. Medico-friend circle bulletin

A monthly which discusses issues ~~regarding~~ current health ~~care system~~ problems, ~~relevance of~~ the health care system of medical education, drug issues etc from the point of view of the needs of the majority in our country
Annual subscription Rs 15/- from.

medico-friend circle office — Rai Narayan, Convenor.
326, V^th Main, I^st Block
Koramangala
Bangalore 560034

4. HAI News

Bimonthly service of the Health Action International (HAI) clearinghouse maintained at the Regional office for Asia & the Pacific of the International Organization of consumer Unions (IOCU) HAI is an informal network of health, consumer & development oriented associations & professionals concerned with health & pharmaceutical issues, particularly those that adversely affect the poor
Annual Subscription US $10 from

HAI clearinghouse,
Regional office for Asia & the Pacific, IOCU,
PO Box 1045, Penang
Malaysia.

PTO

(5) The Medical Letter on drugs & Therapeutics published from 5/6, Harrison Street, New Rochelle, New York - 10801. This monthly publication, edited by Mark Abramowicz, MD provides updated information on a number of drugs issues.

(6) Health for the Millions

a bimonthly of the Voluntary Health Association of India. Have special issues on Medicines as if people mattered. (April-June 1981 ? Rs 6.00) also on diarrhoea & TB.
annual subscription Rs. 12/- from
Publications Dept.
Voluntary Health Association of India
C-14, community centre
Safdarjang Development Area
New Delhi - 110016 India.

(7) Contact

a bimonthly publication of Christian Medical Commission World council of Churches, 150 route de Ferney, 1211, Geneva 20, Switzerland.
Papers presented in it deal with varied aspects of the Christian Community's involvement in health & seek to report topical, innovative & courageous approaches to the promotion of health & integrated development. They brought out a special issue on drugs.

(8) World Health

special issue on drugs.

(9) Drugs & Therapeutics Bulletin (UK)

Special issues

(1) Contact — No 63 August 1981
'getting Essential Drugs to the people'
with a model list of essential drugs.
— No 73 June. 1983
Strengthening and regulating the supply, distribution and production of basic pharmaceutical products

(2) Health for the Millions

~~(3) The Lancet~~

Drugs - References

(1) Drugs - Fact fallacy + Fraud (Special feature) DR 8.13

The Journal of the CMAI — Sept 1983 Vol LX, No 9 150 pgs

Contents

1. The drugs issue - Fact, Fallacy + Fraud! - Editorial
2. Jesus' Ministry of Healing - Fr Francis Mallia
3. Role of drug industry - in perspective - Dr S Joseph
4. Essential drugs for the third world - Vittorio Fallorusso - World Health May 1981
5. Drugging the Indian - courtesy VHAI
6. Selection of appropriate Analgesic + Anti inflammatory drugs - Dr V.N. Tajor
7. The Bangladesh ban on hazardous + irrational drugs - Mia Shwa
8. A study on prevalent diseases in India + production of some essential drugs - J.S Majumdar, L.N Chakravorty Sourav Chatterjee
9. The harmful food-drug combinations - New York Times
10. The great health Robbery - CMAI courtesy Hyderabad Oct 24, 1984
11. Causes of Diarrhoea - VHAI
12. Management of Acute Diarrhoea - VHAI
13. Drugs in the Rx of diarrhoea - VHAI
14. Controversies in contraception S. Moghissi
15. Review of supportive hormone therapy in obstetrics - VHAI
16. The clioquinol controversy - VHAI
17. Banning of drugs VHAI
18. IFMA code of pharmaceutical marketing practices
19. Are hormonal pregnancy tests safe - VHAI
20. Low cost drugs + rational drug therapy - International Codes + you! - VHAI
21. Why not to prescribe anabolic steroids VHAI
22. Why amidopyrines must go - VHAI
23. Using tetracycline for children + pregnant women VHAI
24. Model list of essential drugs - contact - CMC, WCC

annual subsc: - Rs 25/-
payable to - The CMAI office, Christian Council Lodge, Nagpur-1, Maharashtra.

Editor - Dr S Joseph, MD, Mar Geevarghese Dionysius Memorial Hospital, Devagiri PO, Kanjazha 686 575 Kottayam, Kerala.

"physicians prescribe medicine of which they know little, to cure diseases of which they know less in human beings of which they know nothing" Voltaire - 18th century famous.

(2) WHO Technical Report Series No 641 – 1979
1981 – new list

(3) World Health - July 1984
The Magazine of the World Health Organization
Special Issue : Essential drugs for the world
from World Health, WHO, Avenue Appia, 1211 Geneva 27, Switzerland.

Contents

1. But some are more essential than others - Ernest Lauridsen
2. Bangladesh : the nettle grasped. ABM Ghulam Mostafa
3. Combined operations ! Fernando Antezana
4. Generic drugs : the real implications : Barrie James
5. Experiment in Egypt : AW. El Bendary
6. Seven steps to success in essential drugs supply
7. "Rationing" in Rural Kenya : Jens Erik Steenstrup
8. Where the tom-tom beats : Pascale Brudon Jakobowicz
9. Drug revolution in Mozambique : Malcolm Sepall + Carlos Manzagao
10. Books + publications
11. A guide through the maze - Sister L Nightingale
12. Glossary of technical terms
13. Name page.

— x —

- In 1977, WHO expert committee brought out the WHO Model List of essential drugs (– 200 drugs + vaccines)
- Revised twice since then – now 220 essential drugs + vaccines
- A strategy drawn up towards the end of the 1970's eventually became the Action Programme on Essential Drugs + Vaccines. + is becoming a world wide effort.
- More than 80 countries in the Third World have adapted the model list to their requirements.
- This programme addresses the complexity of the world of pharmaceutical products + their utilization. In line with WHO's social goals, it focuses on essential drug availability in primary health care.
If a limited number of essential drugs cannot be delivered on a regular basis to rural areas + the poorer sections of cities, the whole strategy of Health for all by the year 2000 will face partial or even total failure
- It is not that drugs are the only important element in health care, but drugs make the health services credible because they can cure disease + alleviate symptoms. Once patients are assured that their

symptoms + diseases can be taken care of, they have confidence in the health staff and in the preventive + promotive elements of primary health care.

- factors necessary - analysis of the pharmaceutical sector, formulation of national drug policies, selection of essential drugs, procurement, quality control, storage, distribution + training of health staff. — (UNICEF/WHO helps countries with this)
  transfer of pharmaceutical technology + the development of national capacity to formulate or produce a range of essential drugs (UNCTAD/UNIDO helps with this)
- The pharmaceutical industry is in a unique position. It has amassed huge resources which allow it to undertake the lion's share of pharmaceutical research + development. This concentration of power carries with it a special responsibility to support the developing countries in their drive to make essential drugs + vaccines available to their people.
  The pharmaceutical industry is often criticized for being part of the problem. There are indications however, that the industry would prefer to become part of the solution
- development agencies
- Physicians + other health workers who prescribe, + dispensing pharmacists, are obvious partners for the Action programme. The individual physicians prescribing pattern carries consequences not only for the patient's health but for the national health
- New information + training have to be provided for students of medicine, pharmacy + pharmacology. Before we can expect an improvement in the future art of prescribing medicines
- Patients - better informed — consumer unions
- Less than a dollar per year, it seems, meets the cost per person for the drugs most needed in primary health care.
- However, possible problems in making essential drugs available to all citizens — would that be desirable? Is it the ultimate medicalization of humanity) will "availability" pave the way for an avalanche of drugs, so that we imagine that there is a drug for every human ill? will drugs mask the real problems of poverty + unequal distribution of the worlds resources)

Resource materials on Drugs

Books / kits etc

(1) Pill-ferring the poor: Drugs + the Third World
An information / action pack provides an overview of the problems related to drug marketing in the Third World.
Send $4.00 (+ 2.70 (surface) + 4.70 airmail postage) to
Interfaith centre on Corporate Responsibility
International Health Program.
475 Riverside Drive.
Room 566,
New York,
NY 10115

(2) Health, Safety + the consumer - proceedings of the IOCU Seminar, Ranzan, Japan (April 6-9 1983).
Send orders to
IOCU Regional office for Asia + the Pacific,
PO Box 1045
Penang, Malaysia.
price: US $15.00 a copy - covers surface mail postage
for airmail add $4.00 for Asia.
- Bankdraft - drawn on any bank in Malaysia - made out to the International Organization of consumers Unions.

(3) Prescription for change: Health Action Internationals guide to rational health projects - by Virginia Beardshaw IOCU, The Hague: November 1983, 85pp, US $10.00
Available from
(1) IOCU Secretariat.
9 Emmastraat,
2595 EG The Hague
Netherlands
or (2) IOCU Regional office for Asia + the Pacific
PO Box 1045, Penang, Malaysia.

(4) A draft international code on pharmaceuticals. A Health Action International discussion document, 1983
24pp, US $2,
available from: IOCU Regional office

(5) A Resource Kit on drug marketing in the Third world: 12pp.
Australian consumers Association.
28, Queen street, chippendale, 2008, Australia,
or community Aid Abroad, 262 Pitt street.
Sydney, 2000 Australia.

(6) The Rational & economic use of drugs in the Third World
14pp by HAI, August 1982,
available from: HAI clearinghouse
PO Box 1045,
Penang, Malaysia

(7) Prescriptions for death: the drugging of the Third World
by Mitten Silverman, Phillip R Lee + Mia Lydecker
208pp Price US $ 19.95, July 1982
Available from: University of California Press,
2223 Fulton Street, Berkeley, California 94720 USA.

(8) Drug Diplomacy by Charles Medawar + Barbara Freese
price £ 3.95 + £ 1.50 for postage
from Social Audit,
9, Poland Street,
London W1V 3DG
UK.

Med Serv Co
Nov-84

...ning Horizons : on Drug issues

II Periodicals

1. Pune Journal of Continuing Health Education

Presents scientific information and opinion on drugs and health issues to stimulate thought and further investigation.

Annual subscription Rs.10.00 or a five year subscription for Rs.45.00 from Arogya Dakshata Mandal, 1913, Sadashiv Peth, Pune 411030

2. Drug Bulletin

An informative monthly giving unbiased technical information on drugs and therapeutics.

Annual subscription Rs.10.00 from Dr VS Mathur, Professor, Department of Pharmacology and Editor, Drugs Bulletin, PGI of Medical Education and Research, Chandigarh 160012.

3. medico friend circle bulletin

A monthly which discusses issues regarding health problems, the health care system, medical education, drug issues etc., from the point of view of relevance to the needs of the majority in our country.

Annual subscription Rs.15.00

Write to Convenor, medico friend circle, 326, V Main I Block, Koramangala, Bangalore 560034.

4. HAI News

A very informative bimonthly of the Health Action International (HAI), covering world drug news of special relevance for the third world. HAI is an informal network of health consumer and development oriented associationsand professionals concerned with health and pharmaceutical issues, particularly those that adversely affect the poor.

.....2

Annual subscription : US$10.00 from HAI Clearinghouse, regional office for Asia and the Pacific, International Organization of Consumer Unions (IOCU), PO Box 1045, Penang, Malaysia.

Special Issues: A number of journals have brought out special issues on drugs. These may be available [redacted] on request for back issues.

1. Contact: from Christian Medical Commission, World Council of Churches, 150 route de Ferney, 1211 Geneva 20, Switzerland or VHAI, New Delhi.
   a. August 1981 No.63: 'Getting Essential Drugs to the People' with a model list of essential drugs.
   b. June 1983, No.73: 'Strengthening and regulating the supply, distribution and production of basic pharmaceutical products'.

2. Health for the Millions
   From Publications Department, Voluntary Health Association of India, C-14, Community Centre, SDA, New Delhi 110016.
   a. Medicines as if people mattered - April-June 1981
   b. Special Issues on diarrhoea and tuberculosis

3. The Journal of the Christian Medical Association of India
   From: The CMAI Office, Christian Council Lodge, Nagpur 1, Maharashtra.
   Sept 1983, Vol LX, No.9, Drugs--Fact, fallacy and fraud.

.....3

4. World Health: The magazine of the World Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland. July 1984, Essential drugs for the World.

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WIDENING HORIZONS - on DRUG ISSUES

Duplicate

Books

1. Hathi Committee: Report of the Committee on the Drugs and Pharmaceutical industry.
   Ministry of Petroleum and Chemicals, Govt of India,
   April 1975, Rs.17.00.

   [redacted] The essential drug list suggested here could provide the foundation for a demand for a Rational National Drug Policy.

2. Health for All - an Alternative Strategy
   ICSSR & ICMR, 1981, Rs.18.00 Available from VHAI.
   In focussing on a comprehensive national policy of health and a new operational strategy, the report is intended to be a basic document to initiate a nation wide debate on the subject as well as positive action towards certain radical changes to correct the present imbalances in our health caresystem. Has a very comprehensive chapter on drugs and pharmaceuticals.

3. Aspects of the Drug Industry in India.
   Mukarram Bhagat, Feb 1982, Rs.19.00
   From Centre for Education and Documentation (CED),
   3, Suleman Chambers, Battery Street, Bombay.

4. Insult or Injury
   Charles Medawar, 1980, Rs.18.00, 139 p.
   Social Audit, England. Available from : Indian Social Institute, Lodi Road, New Delhi 110003. Highlights marketing and sales of British drugs and food products. Illustrated easy reading.

.....2

5. Health Care Which Way to Go

Medico Friend Circle Anthology II, 1982, Rs.10.00

from : medico friend circle office, 326, 5th Main, I Block

Koramangala, Bangalore 560034

Raises relevant issues regarding peoples health. Questions why is there a lack of political will to solve pressing health problems of the country. How detrimental is the alliance between medical professionals and the drug industry to people's health.

6. Under the lens: health and medicine

III Anthology of medico friend circle is due shortly and will be available from VHAI and mfc office (above).

7. Kurji Holy Family Hospital: Formulary and Therapeutic Guide.

January 1983, Rs.12.00

Available from VHAI. It is the result of the accumulated experience of senior medical staff of the hospital over the last 10 years. It gives a comprehensive list of drugs to treat 98% of hospital admissions - it also gives the generic name, dosage, indications, contraindications and main side effects in the same page. Information about comparative cost of treatment is also provided.

8. Drugs and the Third World

Anil Agarwal, 1978, $5.00

From Earthscan, 10 Percy Street, London W1 PO DR

A very comprehensive overview of the drug situation in the third world and the problems and causes.

....3

9. Prescription for change

Health Action Internationals guide to rational health projects, Virginia Beardshaw, November 1983, 85pp US$10.00 from Health Action International Clearing House PO Box 1045, Penang, Malaysia.

Gives more than 40 ideas for action research projects on drugs :

- a summary of the main elements of the rational health issues and suggestions about how to campaign on it;
- advice on how to talk to drug companies and the powers that be
- a reference section that lists the main materials you need to research on drugs.

10. Pill-fering the poor: Drugs and the third world.

An information/action pack on drugs and the third world from Interfaith Center on Corporate Responsibility, International Health Programme, 475 Riverside Drive, Room 566, New York, NY 10115. US$4.00 plus postage surface mail $2.70/air mail $4.70.

It provides an overview of the problems related to drug marketing in the third world. It contains articles on the need for essential drugs, on the suffering wrought overseas by some US made drugs and on the high price the third world poor have to pay for their medicines. This package includes an extensive annotated bibliography, basic facts and figures about the transnational drug industry and an outline of suggestions for action on how you can get more involved in helping to stop abuses.

11. Therapeutic guidelines: A manual to assist in the rational purchase and prescription of drugs.

Upunda, Yudkin et al 1981, pp. 166, Rs.35.00 African Medical and Research Foundation. Available from VHAI.

.....4

An excellent guideline for rational therapeutics, giving special emphasis on drug cost as criteria for choice of drug diagramatico format.

12. Management schedules for dispensaries: A manual for rural health workers
Peter Petit, 1983, Rs.35.00
African Medical and Research Foundatioh.
Available from VHAI.

13. 44 problem drugs: a consumer action and resources kit on pharmaceuticals.
IOCU, May 1981.
Available from HAI Clearing House (see 9)
Gives information about 44 problem drugs, along with articles by some of the leading drug compaigners.

14. A number of interesting papers to keep you upto date about the drug issue is available from Low Cost Drugs and Therapeutics Cell, VHAI, C-14, Community Centre, Safdarjung Development Area, New Delhi 110016.
(write to them for a list)

DR Deccan Herald 21/8/94

'Publicise info on banned drugs'

By Our Staff Reporter

BANGALORE, Aug 21

Doctors and consumer activists today made a strong case for widely publicising names of banned drugs to check the exploitation of consumers by manufacturers.

They also stressed the need for enhanced consumer awareness on the use of drugs at a symposium on "Health, Drugs and Consumers" here, organised by the Consumer Rights Education and Awareness Trust (CREAT), a voluntary agency.

Participating in the symposium, Dr Shiradi Prasad of Community Health Cell regretted that the Government was weak-kneed before the powerful drug lobby and, hence, even banned drugs were able to survive in the market. It was an irony of sorts that a drug like "analgin", banned in several countries, was freely used in India.

Even priorities for drug manufacture in the country were totally misplaced. There was less production of drugs in common use, while a higher investment was made on "elitist" drugs. If the Government could provide clean drinking water and environment over 80 per cent of the diseases could be prevented, he noted.

Pointing out the negative influence of advertisements and medical representatives on drug use, Dr (Ms) Chanda Kulkarni, Assistant Professor of Pharmacology, St. John's Hospital, expressed concern over the inaccurate information propagated through these two media. However, doctors should "prescribe rationally and not fashionably" and patients should avoid self-medication, she advised.

Regretting that research on essential drugs was minimal she said that there was an absolute dearth of funds and trained manpower to carry out research. Whatever little information available with the Government on banned and bannable drugs was not being adequately advertised, she said.

Ms Niraja of the Voluntary Health Association of India said the Government was unable to announce the new drug policy even after its promise to that effect made four years ago. The Hathi committee report, submitted in 1979 with an aim to evolve a better drug policy, was implemented only in parts.

Opposing the move to include doctors within the ambit of Consumer Protection Act, Indian Medical Association President Dr Nanjundaiah described it as a populist move of the Government, which was not advisable in the interest of the public. The process of medical treatment would be unnecessarily delayed with general practitioners shoving the buck on specialists at every stage.

Stating that such legislation did not exist anywhere in the world, he said medical science was not "as exact as mathematics" and a minor mistake can ruin a doctor's career. However, the reckless money-mongering attitude among doctors should be controlled, he admitted.

Strongly opposing the entry of multinationals on the drug front, Dr Prakash Rao maintained that indigenous drug industries would suffer a lot if past experiences were any indication. He said 20 to 40 per cent drugs in the Indian market were spurious. Consumer awareness was the only cure to the problem.

APPEAL: Earlier inaugurating the symposium, State Assistant Drugs . Controller G.B. Prabhakumar appealed to voluntary agencies to bring spurious, harmful and defective drugs to his notice so that action could be initiated against errant industries after due analysis.

Referring to blood banks, he expressed his happiness over the growing popularity of voluntary blood donation. AIDS test has been made mandatory in all blood banks, he clarified.

IN THE CITY TODAY

Indian Institute of Science: Union Minister for Environment Kamal Nath inaugurates International conference on 'Bio-diversity of Asian Regions,' Chief Minister Molly chief guest, Dr C V Raman Road, 10 a.m.

GENERAL

● **Karnataka Forest Department:** Union Minister for Environment Kamalnath unveils forest martyrs' memorial, Chief Minister Molly presides, Forest Minister Vishwanath chief guest, Aranya Bhavan, Malleswaram, 9.30 a.m.

● **Sri R Gundu Rao Mithra Koota:** Observance of first death anniversary of Late R Gundu Rao, former Chief Main road, Gandhinagar, 9.30 a.m.

● **Rotary Club of Bangalore Indiranagar:** Lecture on 'Why Polio Plus', 2143, 16 E main, HAL II Stage, Indiranagar, 7 p.m.

● **The Bangalore Social Science Forum:** Lecture on Gandhi-Indian National Movement, National College, Basavangudi, 6 p.m.

● **Alpine Robotics Limited:** Demonstration of Educational Programme of 4 Axis Robotics Arm,

● **Sathsanga Goshthi:** 203rd Geetha Gnana Yagna by H N Ramatheertha, Sri Uma Maheshwara Temple premises, K R Road, 11 a.m. and 6.30 p.m.

● **Basava Samithi:** Discourse on Nuliya Chandiaiah, Basava Samithi, Sri Basaveshwara Circle, 6 p.m.

● **Sri Raghavendra Seva Samithi:** Aradhana Celebration and Pooja, 6/CA, 13th main road, 4th T block, Jayanagar, 7.30 a.m.

Sri Gururaja Association: 323rd Aradhana Mahotsava of Sri

Doctors' strike hits hospitals

By Our Staff Reporter

BANGALORE, Aug 21

The indefinite strike of junior doc tors in the State entered the thir day today, affecting medical ser vices at several hospitals.

The doctors struck work in sup port of their demands, includin the one on bringing admissions t PG medical courses within th purview of a Supreme Cou verdict on professional courses.

The authorities at major hosp tals in the City, includin Bowring Hospital and Victori Hospital, claimed, however, tha services had not been affected, a patients were being attended b assistant professors and lecturer Operations had been conducted i all emergency cases.

Chain snatched from woman

By Our Staff Reporter

BANGALORE, Aug 21

Two unidentified persons snatc ed a gold chain, valued at arou Rs.11,600, from a woman as sh was walking on Link Road, 5 Main, in the Madivala police st tion limits on Saturday. The p lice have registered a case and a investigating.

THEFT: Dr. S.P. Padma, a reside of 1st Cross, 2nd Sta Banashankari, has in a compla with the police alleged th unidentified persons broke in her house on Saturday night a decamped with gold ornamen and Silver articles and cash, in valued at around Rs.33,(BAnashankari police are inve gating.

In a similar case Bhadraiah resident of Unasamarah Teacher's Colony, in

New Drug Policy

Betrayal of Consumers' Interest

The following is a statement issued by the Voluntary Health Association of India on the new drug policy. It was issued on September 16, 1994. — Editor

The Voluntary Health Association of India (VHAI), New Delhi, a federation of more than 3000 organisations involved in community health, has noted with great concern the announcement of the new drug policy. The policy was announced at a press conference on September 15, 1994. We are shocked that the policy is totally in the interest of the industry and the consumers basic needs are neglected. We are dismayed at the callous indifference of the government towards the health needs of the people. Even the way the government chose to announce the drug policy (which has far-reaching implications as far as the health and life of millions of people are concerned) through a press conference rather than after a proper discussion in Parliament itself is undemocratic.

Drug prices will shoot up because the number of drugs in the price control range has been brought down to 73 from 142. Increasing the profitability ceiling for bulk drugs will directly further worsen the situation as far as the prices are concerned.

The rationale for allowing price decontrol, can in no way be justified if the figures for the last few years are studied. There has been a steady increase in sales, profits and dividends of the drug companies. It is sad that the government has 'bought' the drug industries' argument that drug production is not profitable and drafted the policy accordingly.

The total liberalisation will further worsen the existing anarchic situation in drug production. In the absence of a mechanism to ensure the production of essential drugs, its acute shortage will hit all national health programmes. Its implications are far-reaching as it will lead to further proliferation of hazardous and irrational drugs. The argument of the industry that trade is a fundamental right should not be at the cost of the public's health and life.

The present policy as such will open the gates for the multinationals. High priced, useless and hazardous drugs will be pushed down the throat of the gullible Indian consumer. Increased dependence on imports, higher prices and proliferation will happen due to the policy which allows companies with 51 per cent equity participation to be treated on par with Indian companies. This policy will further hit the Indian industry resulting in import and increasing prices.

It is further disappointing that there has been no reference to the irrational and hazardous drugs which are still being sold.

The neglect towards such an important issue where thousands of products keep the life of the public at stake is very critical. These products will pose a continued threat as far as safety is concerned because the new drug policy does not address this critical issue.

Even in developed countries where the industry has been enjoying a "free-hand" it is under criticism of late. The spiralling costs in health care in the USA is just an example. Recent studies from different parts of the world point out that competition by market forces need not bring down prices. For example, the Office of Technology Assessment in the US was forced to study the costs and profits of pharmaceutical manufacturers because of the ever-spiralling drug costs.

The OTA report dated Februray 25, 1993 tells why drug prices in the US are high and it also shows that *competition simply does not work in the market for prescription drugs which are becoming unaffordable even in the US.* The OTA report states that to *reduce* prices there is room to reduce profits, advertising costs, unimportant research while leaving breakthrough drugs intact and leaving industry a generous profit.

These lessons of failures of such liberalisations and Structural Adjustment Programmes initiated in those countries, instead of being taken as an eye-opener, are being ignored.

The drug companies have proved in the past that

their organised sales promotion propaganda with advertising and marketing strategies will leave no chance for the medical profession to make a free decision. Furthermore, drug is not a substance which an ordinary consumer/patient can decide upon.

The government is giving a 'false hope' to the public that if required the government will bring back decontrolled drugs to the price-control category. But lessons from past experiences show that giving even a chance for overcharging for drugs by drug companies has never benefited the consumer.

The VHAI urges the government to reconsider the policy. We urge that a "rational drug policy" which will ensure the concerns of the consumers [namely, (a) availability of essential and life-saving drugs, (b) withdrawal of hazardous and irrational drugs, (c) adequate quality control and drug control, (d) technological self-reliance] is to be formulated in a democratic process by discussions at various levels, like with professional bodies, health groups, rational drug groups, consumer groups, voluntary organisations, people's organisations and in the Houses of Parliament. ■

Allround Decadence and Ray of Hope

NIKHIL CHAKRAVARTTY

While there is no doubt a lot on which to attack those in authority for their dereliction in running an orderly system of governance, one has to ask at the same time why there has been such an appalling deterioration in social conscience in most of our public activity. In other words, the corrosion of values in public life is not confined to Ministers and top bureaucrats, but has become all-pervasive, the pollution of morals seem to choke out public service.

If we look around, there is undoubtedly a widespread feeling of being let-down by those in power, those who have been assigned the mandate to rule by the public that has elected them and placed them on the position of authority. It is precisely because of this reason that the Chief Election Commissioner has suddenly become a phenomenon—applauded by the public that expects him to weed out corrupt practices from the business of election, while he is the target of attack largely by those who feel that their citadel of vested interests in the business of vote-collecting is being invaded by Seshan's attempt at weeding out irregularities in the running of the election machinery. Khairnar might be reckless in his charges against Sharad Pawar, but the fact that he, a minor fry in the bureaucratic set-up, could brace up to make such charges of corruption against the Chief Minister, who is patently on the defensive, shows that in the public mind Pawar's reputation cannot smother out such a critic from inside the very government over which he presides. And quite likely there are many more Khairnars waiting to be counted in the months to come. Obviously the ministerial standing for probity has plummetted so much that it cannot make short shrift of critics from within the bureaucracy itself.

• If we look back on the immediate past, we find that in the last ten years corruption has become a by-word in our public life and is having a deleterious effect on the stability of the government. The fact that criminalisation of politics has become a serious item of concern for responsible people in politics irrespective of party labels—and not just the exaggerated outburst of some chronic critics of the establishment—shows the dangerous deterioration in our public life. All this has begun to stir the public in general. The shock of the scam, that nobody in authority is prepared to take the responsibility for, has contributed in no small measure towards the sapping of public confidence in the government.

But the government apart, the callous irresponsibility of people at different stations of public life is now becoming an issue of intense comment and concern all over the country. The scandal of the capitation fees for entry into educational institutions—and the angry objections at any ban being imposed on this vicious practice—has been widely commented upon, and one would not be surprised if this touches off violent protests. It is not merely the

Tonics : How Much An Economic Waste

KAMALA S. JAYARAO*

AMONG the pharmaceutical preparations that are indiscriminately prescribed are the vitamins, particularly those of the B-complex group. "Probably no single class of drugs (*Sic*) has been the target of as much quackery, misunderstanding, misrepresentation and misuse as the vitamins....."[1]. There are however a number of reasons for this, some in my opinion condonable.

Patients often come with vague symptoms which can be correlated to no known disease. The complaints may be genuine or psychosomatic, but the patient expects treatment. For example, a common complaint is pain in the back or pulling sensation in the legs. Or, it may be a simple complaint of general fatigue or loss of appetite due to no organic cause. What is one to do? One usually prescribes a multivitamin or a B-complex preparation. This may be done for three reasons. The physician may sincerely believe that vitamins will help the patient or he may feel compelled to prescribe something. Thirdly, the patient himself may demand some medicine, generally a 'tonic'. What does a tonic mean, anyway? In general parley it has come to mean a liquid preparation. However we do come across advertisements of 'nervous tonics' 'tonic for muscle strength' 'for energy' etc.. This is pure baloney. One of the definitions given by the Webster Dictionary for tonic is 'something that invigorates, restores, stimulates or refreshes'. Could it be the generous quantity of alcohol in these preparations?

If the physician believes that B-complex would be beneficial, even if he has no scientific evidence or therapeutic basis, he need not in my opinion be castigated. We still do not know all the metabolic functions for which one or more members of the B-complex may be needed. Hence, we are probably not in a position to recognize all situations which may respond to vitamin therapy, though severe deficiencies of single vitamin have been well characterized in most cases.

The trouble arises with the dose that is prescribed. The physician should realise that in such undefined situation, the therapy is purely empirical. The burden rests on him to know whether he is prescribing the right amount, less or more. This brings us to the question of what the right amount is. Here we must defferentiate between vitamins taken as nutrients to ward off deficiency and taken for therapeutic purposes, in established deficiency. The latter dosages are not based on as careful a scientific scrutiny as the former. They are prescribed for **acute and severe,** single deficiency states like beri-beri, pellagra, keratomalacia etc. Since water-soluble vitamins are considered to be relatively innocuous, the amounts prescribed are very high, the main aim being to tide over the acute situation.

On the other hand, we have these various undefined situations which we attribute to vitamin deficiencies or anaemia. These are neither acute nor proven states of defeiency. If the condition is due to a nutrient deficiency, the deficiency is probably chronic and marginal or moderate in nature. Here the implication probably is that the individual is unable to meet his nutrient requirements. This is perhaps a justifiable premise since the prevalence of B-comlex deficiency in our country is relatively high. According to certain surveys the prevalnce rate is 5 per cent in pre-school children and 17.8% in pregnant women (assessed by the presence of angular stomatitis and glossitis)[2]. The percentage of those with less severe deficiency is expected to be higher.

* National Institute of Nutrition, Hyderabad-500 007

What is a nutrient–requirement ? The requirement for a specific nutrient is defined as the smallest amount of that nutrient that will ensure a good state of health. This will however, vary from person to person. Therefore, nutrient requirements are set down as recommended dietary allowances (RDA). These levels are believed to 'meet the known nutritional needs of almost every healthy person.' By experimental procedures, the highest requirements in a population are assessed, some further allowances are added and the RDA for each nutrient is fixed. Thus for many individuals the RDA will be higher than their actual requirement. No person need take more than the suggested RDA. The RDA for various nutrients have been fixed by international organizarions like the FAO and WHO[3] and by various national bodies including the Indian Council of Medical Research[4].

I was interested to know how some of the commonly available vitamin preparations fare when compared to the RDA suggested by the ICMR. *Table I* shows the RDA for some nutrients, for various physiological groups. For specific reasons, I have not taken the RDA for infants and children but in absolute terms these values will be less than those for adults. In *Table II*, I have presented the quantities of various vitamins purported to be present in each commercial preparation. It is however not the complete formula of the preparation. I have taken only some important vitamins into consideratoin. The list is by no means exhaustive. I culled them from some recent issues of the Journal of the Indian Medical Association. They are marketed by leading pharmaceutical companies.

In the process of this search, I came across an interesting or disturbing feature, depending on how you wish to perceive it. Many advertisements do not say what ingredients the preparation contains, leave alone their quantities. Many inform you that the preparation is a unique formulation of **generous** amounts of vitamins or that it is a vitalizer with **balanced** amounts of vitamin (Incidentally, IDPL is one of them). The advertisement merely proclaims the efficacy of their product in specified condition. There is one advertisement by a leading company, which reveals nothing about the formula but claims that it is good for memory ! It contains nothing but vitamins B_1, B_6 and B_{12}. The companies are probably cocksure that the physician will rely more on their advice than on his own judgement (and they are dead right).

This lack of needed information is one of the reasons why *Table II* does not have more preparations listed. But this is ample for what I have to say. There is also no reason to believe that those which escaped inclusion would be any different.

The RDA for any nutrient is the amount which if taken regularly will ensure that a deficiency state of that nutrient will not develop. For example if a sedentary, house–wife takes 1.0 mg riboflavin daily, she is expected not to develop riboflavin deficiency. As I said earlier, 1.0 is the highest level and most can afford to live on lesser amounts. The situations which are under discussion now, are considered to be deficiency states of mild or moderate degree. The individual might have depleted levels of the nutrient and **may need** higher amounts than the RDA. What

Table–I **Recommended Daily Allowances***

	Thiamine (B_1) mg	Riboflavin (B_2) mg	Nicotinic acid mg	Pyridoxine† (B_6) mg	Folic acid mg	Vitamin B_{12} mcg
Man :						
Sedentary	1.2	1.3	16	—	0.1	1
Moderate	1.4	1.5	19	1.4	0.1	1
Heavy work	2.0	2.2	26	—	0.1	1
Woman :						
Sedentary	1.0	1.0	13	—	0.1	1
Moderate	1.1	1.2	15	2.0	0.1	1
Heavy work	1.5	1.7	20	—	0.1	1
Adolescents :						
13–15 yrs	1.1–1.3	1.2–1.4	14–17	1.6	0.1	0.5–1
16–18 yrs	1.1–1.5	1.2–1.7	14–21	1.8	0.1	0.5–1
Pregnancy (Second half)	1.2–1.7	1.2–1.9	15–22	2.5	0.15–0.3	1.5
Lactation	1.4–1.9	1.4–2.1	18–25	2.5	0.15	1.5

* Taken from reference 4

† Taken from RDA of Food and Nutrition Board, U.S.A. 1968.

should this higher level be ? For acute and severe states like beri-beri or keratomalacia text-books prescribe doses, empirically arrived at and found to bring quick relief. These are usually much higher than what would be required even for that degree of amelioration. *Table III* shows the prescribed therapeutic doses, as obtained from various standard books on nutrition and medicine.

For chronic, moderate deficiency states or for situations where vitamins are prescribed empirically, we may assume that levels much lower than the therapeutic doses and slightly higher than the RDA should be enough. Let us be generous and double the RDA, remembering that the patient does receive a certain amount from his diet too. With this information I would like you to critically compare *Table II* with *Tables I* and *III*.

Much of the time drugs are not prescribed according to any therapeutic schedule. They are usually prescribed as ' 1 dose or 1 tablet, three times a day '. Items No. 1-4 in *Table II* are close to the RDA with respect to vitamins B_1 and B_2. Given as per the above mentioned schedule they supply 2-4 times the RDA, and it was argued above that double the RDA should be enough in moderate or doubtful deficiency states. We must also remember that when a diet is considered to be low in a nutrient, it is not totally lacking in that nutrient. The average diets of the low socio-economic groups provide 0.5 to 0.8 mg each of B_1 and B_2. Items 7-9 provide about 5-25 times the RDA in a single dose. If even such preparations are prescribed thrice a day, the intake would be 15-75 times the RDA. Item 8 in a single dose supplies thiamine in a quantity prescribed for the whole day in beri-beri ? Moreover in beri-beri it is not necessary to prescribe very large amounts of other vitamins. Thus preparations like 8 and 9 are not necessary at all.

An argument may be put forward that since water-soluble vitamins are harmless compounds there is no necessity to raise a hue and cry about the dosages prescribed. This is no doubt true but, ' such practice is economically wasteful and in some instances, causes financial hardship '[1].

Table-II Composition of some multivitamin and haematinic preparations available in India.

	1 Capsule	2 Cap.	3 5 ml.	4 5 ml.	5 Cap.	6 Cap.	7 Cap.	8 Cap.	9 Cap.
Vitamin B_1 mg	1	2	1.0	1.6	3.0	5	10	50	20
Vitamin B_2 mg	0.5	2	0.75	0.8	1.0	2	10	25	5
Vitamin B_6 mg	0.6	1	0.15	0.8	0.5	1	5	10	2.5
Niacin mg	4	..	7	4.0	30.0	10	100	100	100
Vitamin B_{12} mcg	2	..	0.45	2.5	5.0	5	5	5	5
Folic acid mg	2	..	...	..	..	1	...	0.5	1.0
Vitamin C mg	..	50	..	..	..	50	200	300	100
Iron	..	Sulp.	F.A.C	Gluco.		Sulp.	Sulp.		
(Type of salt) mg		150 timed release	185	35		200	41		
Vit. A. I.U.	..		250				25000		10000
Vitamin D. I.U.	..	..	90				1000		1000

Table-II (Contd)

	10 5 ml	11 Cap.	12 Cap.	13 Cap.	14 5 ml.	15 5 ml.	16 Cap.	17 3. ml I.M.	18 5ml. I.M
Vitamin B_1 mg				..				100	100
Vitamin B_2 mg				..				..	..
Vitamin B_6 mg				10				27.5	25
Niacin mg				..				..	..
Vitamin B_{12} mcg	25	25	15	50	7	15	25	1000	500
Folic acid mg	2.5	2.0	2	2.5	1.75	2	2.5		
Vitamin C mg	..	200	150	100	..	..	..		
Iron (Type of salt)	Colloidal oxide	Fuma-rate	Fuma-rate	Fuma-rate	Colloi-dal ox.	Fuma-rate	Fuma-rate		
mg	100	350	350	300	500	125	250		
Vitamin A									
Vitamin D									

It must also be remembered that water–soluble vitamins cannot be stored in large amounts unlike the fat–soluble ones. This of course is one of the factors underlying their low toxicity. ' In prescribing thiamine it should be remembered that the healthy human body contains only about 25 mg of the vitamin. Furthermore, it has no means of storing any excess taken in the diet; the excess is **lost rapidly in the urine.** The human body is certainly an effective machine for dissolving thiamine pills and transferring the solution to the urinal '[5]. Moreover it has been shown, atleast for riboflavin that intestinal absorption is limited by saturability and that higher the dose, smaller the fraction absorbed. This is no case in favour of parenteral administration either, because higher the amount in circulation greater the excretion in urine.

Thus, most of the ' high–potency ' or ' Forte ' preparations of multivitamins are a sheer economic waste. It is a drain on the patients' purse and the onus is on the doctor because he is making the patient buy a specific preparation. If bought by goverment or public sector dispensaries, it is a national waste. If preparations with smaller and yet adequate quantities were bought, for the same money more tablets could be purchased and a greater number of patients benefitted. Manufacture of such ' high–potency ' preparations must also use up an unnecessary amount of the scarce foreign exchange resources, since quite a few, and probably all vitamins (raw materials) are imported.

Thus it is not proper if one merely prescribes B–complex tablets and avoids brand name because he is a ' conscientious objector ' to brand names. As long as there is no uniformity in the dosage employed in various preparations, it is necessary to know which brand supplies or claims to supply requisite quantities of vitamins. Also, there is no need to blindly follow the ' one t.d.s. ' schedule. How much and how frequently, should be decided on the merits of the case.

Table–III

Suggested doses of vitamins for single, acute and severe deficiency

Condition	Vitamin	Dose (Oral)
Beri–Beri	B_1	10–25 mg bid or tds
Riboflavin deficiency	B_2	5–10 mg
Megaloblastic anaemia	Folic acid	5–10 mg
	B_{12}	5–10 mg
Megaloblastic anaemia of pregnancy	Folic acid	10 mg
Corneal xerosis	Vitamin A	5000-10,000 I.U
Bitot's spots	Vitamin A	5000-10,000 I.U
Rickets	Vitamin D	1000–5000 I.U.

I also wish to draw your attention to one or two additional points. There is a widely held belief that a combination of vitamins B_1 B_3 and B_{12} is good for neuropathies and other nervous disorders. I don't think this is based on any solid therapeutic evidence. The reason the three are combined, I think is because each one has been shown to be effective in a specific disorder of the nervous system. Hence the triad is used as a short–gun therapy, indiscriminately. In fact, the brand names of certain such preparations incorporate Greek terms like ' encephalo ', ' neuro ' etc. The manufacturers of one preparation even claimi ts efficacy in improving memory.

' It (thiamine) may be given, though **without expectation of dramatic results,** in cases of nutritional neuropathy. There is no reliable evidence that it is useful in any other disorder of the nervous system. The prescription of synthetic thiamine, **either alone or in combination with other vitamins, as a general tonic or appetiser,** is supported by no scientific evidence and is now discredited. '[5]

' Vitamin therapy is often given to patients with polyneuropathy, although it is clear that polyneuropathy is not due to deficiency of vitamin B_1, B^{12} or any other known vitamin. Such treatment has a placebo value and probably no other, but is not to be decried....'[6].

For reasons mentioned right at the beginning I too do not decry the use of the combination as I do the dosage in such preparations. Items 17 and 18 in Table–II are two classical examples. Both are meant for parenteral use, another characteristic of this triple combination, probably because of the presence of vitamin B_{12}. The conventional prescription by physicians for parenteral B–complex is ' 2 ml I.M. once a day or once on alternate days '. Assuming the patient receives 6 ml in a week, he is given 600 mcg to 2 mg of vitamin B_{12}! What a collossal waste considering that vitamin B_{12} is an expensive substance. The prescribed dose even for pernicious anaemia is 2 mg weekly. even those who may argue that unlike the other B–complex vitamins. vitamin B_{12} is stored to a certain extent in the body may note that with each 1 ml goes 20–33 mg thiamine.

Many of the oral preparation too contain unnecessarily high amounts of B_{12}. The RDA for this vitamin is 1.0 mcg and in pregnancy and lactation, 1.5 mcg. Even conceding that a majority of the population cannot afford animal foods and hence many may suffer from vitamin B_{12}. deficiency, I see no

reason why any preparation should contain more than 2 mcg. and at the most 5 mcg vitamin B_{12}. This criteria is met by only 7 of the 16 oral preparations listed. If the preparations are haematinics combined with iron, they have to be prescribed three times a day. In which case the preparation should not contain more than 2 mcg B_{12}. Items 10–13, 15 and 16 must be very expensive and those who really suffer from B_{12} deficiency can ill-afford then. I also wish you to note that mixed haemanitics–iron preparation containing vitamins and minerals, are condemed by authorities in the field of anaemia. " Recovery of the patient with uncomplicated iron-deficiency anaemia is not helped by vitamin supplements or minerals"[7]. In our experience vitamin B_{12} and folic acid are not needed till haemoglobin levels come upto 11 gms. % or more.

Let us now consider the vitamin A content of these preparations. The prescribed dose of vitamin A for corneal xerosis and Bitot's spots is 1500–3000 *µg* (5000–10,000 I.U). daily[8,9]. The RDA during lactation, the maximum suggested for any group, is 3500 I.U. Notice the vitamin A content of items 7 and 9. Who needs **25,000** I.U. vitamin A daily ? Severe cases of deficiency like keratomalacia are not to be treated with oral preparations[9,10]. Those who really develop xerosis can never afford a pharmaceutical like 7 or 9, whose price is further raised due to presence of other nutrients. Imagine to what extent the price can be reduced simply by bringing down the vitamin A content, even to 5000 I.U., which itself is a high amount.

Then, there is the practice of adding glycerophosphates to liquid, multivitamin preparations. I do not know of what therapeutic value these compounds are. They are not mentioned in any standard text–book of pharmacology and therapeutics. As far as I know (see any pharmacopoea) they only form basic ingredients of syrups, possibly for flavour. However, a widespread misunderstanding is that they are ' energy givers ' or ' tonics '. Some brand names carry a prefix or suffix of 'phospho' and the advertisement says 'energy givers', ' vitalizer ' etc. This in my opinion is a fraud perpetuated by the drug companies and worse still, an unpardonable ignorance on the part of the doctor. The vitamins atleast, despite the excess and the wastage, do some good. I see no nutritive or therapeutic value for the glycerophosphates. Their presence is needed for syrup preparation but its name should not be included in the brand name and no claims should be made for its therapeutic efficacies.

One of the nutrients commonly added to multivitamin preparations is iron. Witness that out of the 16 listed items, only 4 do not contain iron. It is well-known that ferrous compounds are better absorbed than the ferric, and it is heartening to note that most are ferrous salts. A preplexing form is the colloidal iron oxide (items 10 and 14) which finds no mention in any book on pharmacology or iron metabolism. Since it is a colloidal preparation I doubt if the iron in it is easilly available to the body.

Of the various ferrous salts, ferrous sulphate is the least expensive and should be the treatment of choice, yet only 3 preparations contain it. It is said that contrary to popular thinking and claims, gastrointestinal intolerance to iron preparations depends on the **total amount of elemental iron** in the gut and on psychological factors; it is **not a function of the form in which iron** is administered.[1,7] Thus claims made for compounds other than ferrous sulphate, of increased tolerance or decreased toxicity, are not genuine. Also, sustained – release (timed–release) compounds (no. 2) take the compound beyond the duodenum and proximal jejunum and thus reduce iron absorption. Therefore it is wasteful to prescribe such preparations.

The RDA for iron ranges from 20–40 mg per day depending on age, sex, physiological state etc. This of course is for food iron and for free inorganic salts would be less. The therapeutic dose, on the other hand, is 60 mg elemental iron, thrice a day. Ferrous sulphate, fumarate and gluconate contain 20%. 33% and 12% elemental iron respectively. Items 11–13 and 16 are probably meant for iron deficiency anaemia. Prescribed twice a day they supply 250–350 mg elemental iron which is higher than the therapeutic dose. Thus taken, 13 supplies 150 mcg vitamin B_{12}. On the other hand, no. 7 supplies only 8 mg elemental iron per capsule. One may argue that this may be used as for prophylaxis and not treatment. Have a second look and tell me the situation where in an individual is **grossly deficient** in every vitamin one can think of and is yet not deficient in iron ? This is a pure commercial gimmick to claim haematinic value for the preparation. As early as 1936 Strauss said " shot–gun therapy is to be deplored for a number of reasons. Most mixtures of substances **fail to contain enough of any one ingredient to give maximal effects.** The patient must pay not only for the material he needs but also for the non–essentials " (cited from ref. 1).

One can go on endlessly in this manner. My intention in writing this is to bring to the notice of MFC members the fact that all multivitamin and haematinic preparations are not same.

1. There is no uniformity in dosage employed.
2. There is no authority to lay down criteria for
3. There is no authority to check whether the claimed doses are actually present.
4. Doctors prescribe these preparations with total ignorance of or indifference to principles of nutrition and therapeutics.
5. High-potency preparations should be available separately for single vitamins. Multivitamins need not contain amounts much higher than RDA. They are economically wasteful.
6. The false claims made for improvement of unspecified and unproven conditions are perpetuated due to the ignorance or compliance of the doctors.
7. Most of the companies have foreign collaboration. Most of the raw ingredients are to be imported. Could this be one of the reasons for the high dosages employed ?

I am sure you will find asking yourself many more such questions.

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A to Z of Drug Policy Issues and A to Z of Problem Drugs

A=

Advertising
is one of the main tools of drug companies to create a need for their products. Includes appeals for status, modernity, even unnecessary uses and cosmetic embellishments.

Analgin
is a potentially toxic drug and may cause agranulocytosis. Fixed dose combinations (FDC) with any other category of drug in oral dosage forms are considered harmful.

Amidopyrin
was used as an analgesic, anti-inflammatory agent for over 7 years. It has now been found to increase the risk of agranulocytosis and in large doses to be associated with renal tubular necrosis (Banned in July 1983)

Ancoloxin
a widely used anti-nausea drug, reported to have teratogenic potential and hence is a hazard to pregnant women. Sold in India without warning.

Anabolic Steroids
are synthetic derivatives of male sex hormones which have an androgenic and anabolic (body building) effect. It is chiefly indicated for treatment of senile and post-menopausal bone disorders and aplastic anemia. In India it is advised for malnutrition, as appetite stimulant and for increasing growth. All these are foolish especially in the light of irreversible harm it can have on children's growth and sexual development. After much publicity of these side effects, CIBA Geigy has withdrawn Dianabol, one of the commonest available. Many more preparations continue to be marketed in India.

Anti-Diarrhoeals
Have no value in the treatment of diarrhoea, but are commonly available as over-the-counter drugs. Non-specific diarrhoeas need only ORT, antibiotics are needed only when specific organisms have been detected as in amoebiasis, giardiasis, cholera etc.

B=

Bulk Purchasing
Buying of drugs in bulk by competitive buying of generic drugs in the international market. It does away with brand names and private importers.

Basic Research
This implies fundamental and innovational process or product research. A necessary step to prevent dependence on foreign companies.

Bio-Availability
This means that the same chemical ingredient, may be therapeutically different because of the way of formulation. A common but unconvincing argument against generic prescribing by drug companies.

Bromides
On prolonged administration, they replace chloride ions in the body. Cumulative poisoning manifests as conjunctivitis, gastro-intestinal symptoms, dermatitis and mental disturbances. It was commonly used as a hypnotic of low potency but unreliable (Banned in July 1983)

C=

Consumer Alert And Consumer Action
An important and growing need in the formulation & the implementation of a safe drug policy.

Combination Drug
A pharmaceutical product containing more than one active ingredient.

Chloral Hydrate
used as a hypnotic; has been found to be an irritant of the gastric mucosa causing nausea, vomiting, flatulence and epigastric distress. It can also cause hepatic or renal damage. It should no longer be used as a hypnotic. (Banned in July 1983)

Clioquinol
or hydroxyquinolines have been popularly used for prophylaxis and treatment of gastro-enteritis, amoebiasis and traveller's diarrhoea. Ever since the report of its association with SMON (subacute myeloptic neuropathy), its use has been restricted or banned in many countries. In India they are supposed to be prescription drugs but are obtainable over the counter. A warning in English small print, is given on the product but it hardly succeeds in warning consumers.

D=

Dumping
Passing of old, unwanted, out-dated and banned or otherwise inferior products on an unsuspecting public. A common practice of multinationals operating in third world countries.

Drug Price Control Orders
Government orders to control prices of drugs and profits issued in 1963, 1966, 1970, 1979 and 1987.

Dipyrone
is the sodium sulphonate of amidopyrine having similar properties and adverse effects particularly fatal agranulocytosis. The incidence and risk of this hazard far outweighs any benefit that can be derived from its use.

Pg2/PT/4 (contd.)

E =

Essential Drug List
A list of medicinal products of proven efficiency, acceptable safety and suitability to satisfy the health needs of the majority of the population.

Expiry Date
The date appearing on a drug product and established by the manufacturer, beyond which the manufacturer will not guarantee the potency, purity, uniformity, or bio-availability of the product.

EP Forte
High dose estrogen-progesterone combinations which are dangerous for use in pregnant women because of associated fetal malformation. In spite of the banning of production and sale of these drugs by the Drug Controller in March/June 1983 they continue (on stay orders) to be misused for hormonal pregnancy tests and for induction of abortion. (Banned on June 30, 1988)

Enzymes
A very wide range of enzyme preparations are available in India as digestives. Though by themselves they are not harmful, their production in large amounts along with tonics, vitamins and health restoratives are an indication of our irrational durg policy at the cost of larger social needs. These are mostly consumed by the relatively well-fed urban population.

Ergot
is an alkaloid effective in the treatment of migraine. However fixed dose combinations with drugs like paracetamol, prochlorperazine etc., have no therapeutic advantage and hence are irrational (FDCs of ergot are banned since July 1983)

F =

Formulations
are finished products which are directly consumed and contain in addition to the active drug compound other ingredients such as diluents, binders, flavouring/ colouring agents, gelatin shells, chemical bases, waxes and preservatives.

Formulary
A list of approved or recommended drugs compiled by an individual practitioner or a group of medical and scientific professionals or a hospital for the purpose of a specific medical practice or supply system, e.g., St. Martha's Hospital Formulary.

FDC or Fixed Drug combinations
are formulations where two or more drugs are combined for the following reasons: (a) synergistic action; (b) corrective action; (c) two or more drugs normally prescribed together and taken by patient simultaneously; (d) when dosage of each drug need not be individualised; (e) where combination ensures better patient compliance due to convenience of administration. Conversly FDCs are irrational and should not be permitted if a) adverse interactions occur; b) when one of the combined drugs becomes toxic on prolonged use; c) When abrupt withdrawal of one causes withdrawal symptoms; d) if subtherapeutic doses are used in the absence of clinically demonstrable synergism; e) when pharmacokinetic behaviour of individual agents is different. (22 FDCs were banned in July 1983-refer Government order)

G =

Generic Prescribing
Prescription of drugs using the official, international, non-proprietary name and not trade or brand names eg. aspirin, not Aspro or Piusprin.

Gripe Water
These popular preparations promoted for colic in children contain alcohol and sodium bicarbonate. Chronic use of the latter can cause milk-alkali syndrome. Uncomfortable but rarely dangerous gastric distension can also occur. Despite toxicity and side effects gripe water does a thriving business through medical and consumer ignorance (Banned in Bangladesh in June 1982).

H =

Hathi Committee Report
An exhaustive report of far-reaching importance, by the Committee on Drugs and Pharmaceutical Industry, Government of India, published in April 1975.

Hydroxyquinolines
or halogenated oxyquinoline derivatives which include iodochlor-hydroxyquinoline, Proxyquinoline, halquinol, diiodohydroxyquinoline, chlorquinaldol, chiniofon). For hazard see clioquinol.

Hormonal Pregnancy Tests
Estrogen-progesterone combinations have been indiscriminately used in pregnant women as a hormonal test to detect pregnancy (see EP Forte). Since there is an increased risk of foetal abnormalities and the test is false positive in one out of five women these tests should no longer be done. The Drug Controller had issued a directive to strengthen warning on packages (March 1982) and banned manufacture (Dec 1982) and sale (June 1983). Due to legal controversy, and professional and consumer ignorance it still continues to be used. (Banned on July 3, 1988)

I =

International Codes
These are codes of quality or safety of products or business procedures eg. Code of Ethical Marketing Practices of Health Action International. An important step in pressurising multinationals to stop exploiting the Third World.

Injectable Contraceptives
DEPO-PROVERA and NET-EN are examples of long acting injectable hormonal contraceptives which have and are being introduced into Third World countries. Animal experiments and human use show toxic side effects. They have been banned in many countries.

Irrational Prescribing
Extravagent prescribing, over prescribing, incorrect prescribing, multiple prescribing or under prescribing of medications, as compared to good standards of treatment.

Injections
have played a very important role in modern medicine and form one of its most distinctive features. However, it has also lent itself to a very large degree of misuse-overuse because of the mystique associated with it in the minds of the public and the temptation of the medical practitioners to pander to this need and use it for their own economic gain.

B2/PT/4 (contd.)

J =

'Junk Drugs'
are newer drugs in the market whose only additional value are cosmetic embellishments, elegant packing and irrational combinations, all of which help to increase its cost.

K =

Know-how
An important requirement for the technical improvement of the drug industry. Often controlled by patents, royalty rules and monopoly of foreign companies.

Kaolin
is hydrated and purified aluminium silicate, a common addition in anti-diarrhoeal mixtures. Along with pectin and bismuth salts, it forms a group called absorbents, astringents and binding agents. These drugs may cause loss of electrolytes by preventing absorbtion through gastrointestinal tracts. If at all, they are of cosmetic value and may actually mask the severity of disease.

L =

Labelling
Placing written or symbolic instructions on the immediate container in which drugs are dispensed. Depending on the motive this could be either a hall mark of consumer safety awareness or a focus for consumer misinformation.

Level of Use
A classification of drugs according to the medical practitioners who use them and the clinical facilities at which they are used.

Lomotil
or diphenoxylate and Loperamide are drugs whose risks of treatment outweigh their benefits especially in children. Used in diarrhoeas. Dangers of paralytic ileus and toxaemia if associated with gut infections. Especially dangerous in pediatric practice. Their use for children under six has been banned in India. In most other countries its use is banned altogether.

"What people really need, first and foremost is clean drinking water, latrines, school and land, not urban hospitals with their wonder drugs".
- Planning Commission

M =

Me-Too Drugs
These are products of research using molecular manipulation which are profitable but not necessarily a scientific advance.

Mark Up
Is the hike in the price above the basic production cost. It is presently fixed by government orders. The less essential the drug formulation the higher the mark up allowed in India.

Methapyrilene
and its salts (Banned in July 1983)

N =

Net Worth Returns
Is an expression of the profit potential of a drug company and is one of the highest in the chemical industry in India.

Nialamide or Niamid
an MAO inhibitor used in the treatment of depressive disorders (Banned in July 1983)

O =

OTC Drugs
or over-the-counter drugs. These are drugs that are available to consumers without prescription and are mainly painkillers, anticold preparations, cough mixtures, tonics, food substitutes and protein powders. Many of them are costly compared to the benefits they render, have some ingredients which are unnecessary or useless but help to push up costs and are widely advertised with false claims to push up sales. Their scientific scrutiny is a need as also a systematic campaign against their irrational ingredients or claims.

Oxyphenbutazone
A group of non-steroidal antiinflammatory drugs which also have mild antipyretic and analgesic properties. The dangers associated with its use are bone marrow toxicity and liver toxicity. They are a widely used/overused/misused group of drugs, there is great need for building professional awareness and consumer alert on this group of drugs. Recently these drugs have been banned in UK.

ORT or Oral Rehydration Therapy
A very important need in the rational management of diarrhoeas in children and its popularity will prevent use of many anti-diarrhoeals that have doubtful therapeutic value.

P =

Public Sector
Includes drug manufacturing companies owned by the Central Government. These have pioneered the production of bulk drugs in the country. The Government policy attempts to give it a leadership role

Patents
Exclusive rights given to manufacturers for fabrication of a specific product, use of a specific process, or application of a product or process in a specific way.

Phenacetin
was a commonly used analgesic/antipyretic agent which has been reported to cause kidney damage and failure and haemolytic anemia. Fixed dose combinations containing it are considered hazardous. These have been recommended for weeding out by the Hathi Committee.

Phenylbutazones
Another group of non-stenodal anti-inflammatory drugs which give only symptomatic relief and in no way alter the course of the illness. Its main indications are for ankylosing sponlitis and rheumatoid and gouty arthritis, though they are being widely promoted and used for non-rheumatic disorders and aches, pains and fever. Bone marrow toxicity is a real danger with the use of this drug and hence its use should be severly restricted. Its present availability - freely over the counter - should be

B2/PT/4 (contd)

drastically controlled and its deadly combinations with amidopynn, analgin paracetamol, diazepam, vitamin B, dextrapropoxyphene, acetaminophen should be banned or adequate warnings in labels instituted.

Practolol
(Banned in July 1983)

Pencillin
Still an important constitutent of antibacterial therapy in spite of the risk of anaphylactic reaction and allergic reactions (Its combination with sulphonamides and its preparations as skin/eye ointments are banned from July 1983)

Q=

Quality Control
The testing of drug samples against specific standards of quality. A very important step in manufacture and distribution of drugs. In India this is organised by the Drug Controller.

Quinine
Was the sheet anchor of anti-malaria treatment till safer 4 aminoquinolines and 8 aminoquinolines were developed. Its use leads to black water fever so is restricted now-a-days for treatment of chloroquin resistant cases or sometimes in cerebral malaria.

R=

Research and Development
A much neglected area in the drug industry. A very necessary requirement for a country to evolve its own indigenous drug policy

Rational Drug Therapy
is the art/science of prescribing the best suited drugs to individuals who need them. It takes into account factors like efficiency, safety (low incidence of side effects), cost and ease of administration. It scrupulously avoids extravagent prescribing over or under prescribing, multiple prescribing or incorrect prescribing.

Resistence
of organisms to various antibiotic drugs are on the increase due to irrational and unnecessary prescribing. It necessitates the use of second line drugs which have more side effects and are more expensive.

S=

Sales Promotion
Techniques aimed at consumers, dealers or intermediaries to increase short term sales and inspire goodwill. For drug companies it includes bonuses with purchase, contests and competitions, samples and give-a-ways.

Samples
Commonest method by drug companies to woo doctors. Other methods are advertising in medical journals, leafleting, sponsoring medical events, hospital and providing gifts.

Shelf Life
The length of time a material may be stored without affecting the usability, safety, punty or potency of the item.

Symbolic Labelling
A system for providing written instructions for patients using sketches and other graphic representations.

Sulphonamides
These have an important role to play in the treatment of infections. The combination with pencillins is undesirable because of the antagonism of antibacterial effect when bactenostatic and bacteriocidal drugs are given together. (FDCs of sulphonanamides and penicillins are banned since July 1983)

Streptomycin
Since it is one of the most effective drugs in anti-TB treatment its use should be limited to TB treatment and mixed infections of the gut. Its combination with penicillins is undesirable since its use in small doses promotes development of resistence.

Steroids
One of the most misused drugs in general practice because of quick effects. Patients are exposed to a wide range of toxic cumulative effects and adrenal insufficiency due to adrenal suppression. It is a life saving drug to be used in special circumstances. Their doses should be adjusted to the minimum that can produce the effects. Fixed dose combinations with other drugs are irrational and objectionable since individualization of the dose cannot be done. (FDCs of steroids for internal use except for treatment of asthma are banned since July 1983)

Strychnine
This was a drug formerly used as an appetiser. Its use in tonics can induce convulsions particularly in susceptible individuals As obsolete drug! (FDCs of strychnine with caffeine, yohimbine, testosterone and vitamins are banned since July 1983)

T=

Transfer pricing
Importing of raw materials from parent companies by multinational subsidiaries, very often at rates higher than the prices in the international market thereby transfering costs to the local consumer.

Tetracyclines
One of the most commonly misused/overused broad spectrum antibiotics mistakenly thought to be free of dangers. Reports of its ability to cause discolouration of teeth, catabolic effect on protein synthesis, diarrhoea, increased intracranial pressure in children, Fanconi syndrome (if outdated, degraded drug is used) and liver damage in pregnant women have put it on the list of hazardous drugs. It should not be used in paediatric practice and in pregnant mothers. Its manufacture is supposed to be banned from January 1982.

Tonics
Apart from being an economic waste, most tonics in the market contain alcohol, which is the main appetite stimulant and also vitamin and mineral constituents in amounts greater than the physiological absorptive capacities of average GI tracts. Their overuse mainly helps to vitaminise our sewage systems!

Helpful

Nurse, showing a new patient to his room: "Now, we want you to be happy and enjoy yourself while you are here, so if there's anything you want that we haven't got, let me know and I'll show you how to get along without it."

Fast drivers get everywhere a little sooner - even the cemetery.

B2/PT/4 (contd.)

U=

UN Agencies
These include UNIDO, UNCTAD, UNICEF. All of these are gearing up to help developing countries evolve relevant drug policies.

Unani and Ayurvedic drugs
These are difficult to standardise since official standardisation methods are not available. FDCs of these with allopathic drugs have no therapeutic rationale or justification or proven efficacy. (FDCs of ayurvedic and unani drugs with modern drugs have been banned since July 1983)

V=

Voluntary Action
Only voluntary action and initiative can tackle many drug policy issues. The Gonoshasthya Kendra and GK Pharmaceuticals are one example of such an initiative.

Vitamins
Misused/overused group of agents especially as combinations and tonics. They are essential nutritional requirements but most people get adequate amounts in a balanced diet. Specific and separate preparations are required for specific deficiency states or as adjuncts to therapy. (Their FDCs with analgesics, tetracyclines, anti-inflammatory drugs, tranquilisers have no proven therapeutic effects and have been banned since July 1983)

W=

World Health Organization
Their expert committee reports and working group reports are providing technical back up for the evolution of a more health oriented policy in member nations.

Waterbury's compound
is one of the brand leaders in the tonic market whose main effects, if any, are because of the 9-10% alcohol content. It contains an insufficient amount of iron, and creosates and guaicols whose role in man has not been definitively established. Like incremin, phosphomin hemiphos their advertised claims far surpass their actual chemical content. Advertisements of such tonics are the most symbolic of the high pressure, half-truth gimmicry of medical advertising.

Y=

Yohimbine
a drug often combined with strychnine, vitamins, testosterone, arsenic, iron and vitamins has been found to penetrate the CNS and cause central excitation including rise of blood pressure, heart rate, hyperexcitability and tremors (its use especially in such combinations is banned since July 1983)

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B2/PT/3

Rational Drug use

Dr Ravi Narayan, MBBS MD DIH
Community Health Cell Bangalore

Drugs are the hallmark of Modern Medicine. The 'healing professions' throughout the ages have always used 'natural' or 'synthetic' products for their medicinal value, to treat various common ailments of people. Drugs, however, have never in the past dominated the medical scene as they have done in the second half of this century. Today, the *'pill for every ill'* culture is well established. It has ensured that we are probably the most 'drugged generation' of all times. Not a very healthy thought!

Throughout the centuries, philosophers, social activists and concerned doctors have warned against the dangers and problems of overuse or misuse of drugs by doctors and the people.

The Indian Situation

The Indian Council of Medical Research and the Indian Council of Social Sciences Research set up a joint study group to study the health situation in India and evolve an alternative strategy for our commitment to 'Health for All by 2000 AD." This high powered expert committee had some very interesting things to say about the present situation of drugs and prescribing practices, in their Report published in 1981. (1)

★ "There is now an over-production 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. This skewed pattern of drug production is in keeping with our inequitous social structure which stresses the production of luxury goods for the rich at the cost of the basic needs of the poor.....

★ One of the most distressing aspects of the present health situation in India is the habit of doctors to over-prescribe glamorous and costly drugs with limited medical potential. It is also unfortunate that the drug producers always try to push doctors into using their products by all means - fair or foul. These basic facts are more responsible for distortions in drug production and consumption than anything else.

★ Eternal vigilance is required to ensure that the health care system does not get medicalised, that the doctor-drug-producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill-health."

These warnings are a serious indictment of the medical profession and the drug industry in the country. It confirms the growing evidence that drugs are being pushed on an unsuspecting public by devious methods which masquerade as 'sales promotion' of drug companies and 'professional prescribing practice' by doctors and health workers. All of us who are committed to 'Health' need to be concerned about this situation. The promotion of a *'Rational Drug Use'* by the medical profession and health workers and ultimately by the consumers - the patient community and the public, is an important item on the agenda of HEALTH ACTION.

> ***"There are two types of physicians - those who promote life and attack diseases; those who promote diseases and attack life."***
>
> **- Charaka Samhita**

Irrational Drug Use - some dimensions

To understand the principles of Rational Drug Use, one needs to first identify and appreciate the elements of irrationality in the present situation. A spate of reports appearing in our newspapers and periodicals highlight these elements. Of all of them, however, the report of the recent 'Lentin Commission' and its shocking findings are the most telling.

Irrationality in drug use arises out of three sets of factors:

A Irrationality in drug production, marketing and availability

B Irrationality in prescribing practices of doctors and health workers

C Irrationality in drug use by the consumer public.

All these taken together result in the situation we find ourselves today.

A Irrationality in drug production, marketing and availability

★ **Industrial Policy**
Drug policy continues to be part of the industrial policy and not part of the health policy. Industrial growth and profit margins determine the policy and not health needs of the people.

★ **Over abundance**
There is a plethora of drugs produced in the country. The Hathi Committee recommended 116 as essential and the WHO says 200 are necessary. At present there are over 60,000 formulations in the country.

★ **Quality of drugs**
Twenty percent of the drugs available in the country are substandard and spurious. Many are adulterated. Many are sold and being sold after the expiry dates are over.

Turmeric powder in tetracycline capsules and poor quality intravenous fluids have been reported. The substandard 'glycerol' in J J Hospital highlighted by the Lentin report is another example.

★ **Unwanted Drugs**
The formulations available include the following:

i **Banned drugs:** Drugs which have been banned in many countries such as Lomotil and Clioquinol.

B2/PT/3 (contd.)

ii **Irrational combinations:** Formulations which have combinations that are antagonistic or irrational. The Hathi Committee had suggested weeding out of atleast 23 such groups of preparations. These were finally banned by a gazette notification in July 1983 but continue to be available.

iii **Hazardous or Bannable drugs:** Hazardous drugs which should not be available without prescription or adequate medical supervision. Preparations containing analgin, oxyphenbutazone and cortico-steroids are the commonest examples (Refer A to Z of Drug use - page 31)

iv Drugs promoted for indications that are not clinically proven or are potentially dangerous, eg., promotion of EP Forte combinations for pregnancy testing and induction of abortion even when there is well documented evidence that risk of foetal deformity is increased by the use of these preparations. (now banned since 1988 June 30.)

v **Costly Drugs:** Drugs which are inflated in cost by inclusion of costly, additional, often unnecessary ingredients or by cosmetic embellishments in manufacture and packaging. Tonics and high protein foods especially baby foods are good examples.

★ **Wrong Priorities**
There is over-production of unimportant drugs or drugs for the rich while drugs for some common health problems are in short supply. Tonics, vitamins, hormone preparations and high protein substitutes are being produced in wasteful abundance while drugs for leprosy and tuberculosis (two major public health problems) are produced at one third and one fourth of actual requirements. Similarly Vitamin A and many vaccines urgently required for child care programmes are frequently in short supply.

★ **Over-the-counter sales**
Sale of drugs over-the-counter without doctor's prescriptions or the necessary statutory checks are not at all uncommon. This results from inadequate drug legislation and even more inadequate drug controls. Over-the-counter unauthorised sales of prescription drugs, which now-a-days do not even have the precautionary product information make the situation even more hazardous.

"The physician who sets about to treat a disease without knowing anything about it is to be punished even if he is a qualified physician; if he does not give proper treatment, he is to be punished more severely; and if by his treatment the vital functions of the patient are impaired, he must be punished most severely."

- Koutilya Arthashastra

★ **Escalating Prices**
Price control policies have been both inadequate and ineffective and hence the cost of drugs has been constantly escalating. With liberalization policies of the present government this is bound to increase further. The purchasing power of majority of our patients is limited. With increasing prices, patients are forced to buy only part of a prescription or go in for sub-standard alternatives promoted by the drug shops.

B Irrational Drug Prescribing

Doctors, nurses and health workers often prescribe or administer drugs irrationally. The types of irrational drug prescribing has been classified as follows: (4)

Type of irrational drug use	Occurs if a drug is prescribed when:
1 Extravagant prescribing	- A less expensive drug would provide comparable efficacy and safety - symptomatic treatment of mild conditions divert funds from treating serious illness - a brand name is used where less expensive equivalents are available.
2 Over-prescribing	- the drug is not needed - the dose is too large - the treatment period is too long - the quantity dispensed is too great for the current course of treatment
3 Incorrect prescribing	- the drug is given for an incorrect diagnosis - the wrong drug is selected for the indication - the prescription is prepared improperly - adjustments are not made for co-existing medical, genetic, environmental or other factors.
4 Multiple prescribing	- two or more medications are used when one or two would achieve virtually the same effect.

- several related conditions are treated when treatment of the primary condition will improve or cure the other conditions.

5 Under prescribing
- needed medications are not prescribed
- dosage is inadequate
- length of treatment is too brief.

How does such prescribing take place?

There are many background factors which lead to such prescribing practices.

a Inadequate training

Doctors, nurses, pharmacists and health workers may be inadequately trained in the use of drugs. The training may be theoretical and not geared to the practice of prescribing in the real life situation. Technical minutiae may be stressed at the cost of information on cost, social context and hazard.

b Inadequate continuing education

The doctor, pharmacist, nurse or health workers in field practice are inadequately supported by a process of continuing education by their professional associations and training institutions. Once graduation is over, there is little opportunity to refresh one's knowledge of drugs and medical matters through unbiased sources of information.

☼c Unethical medical advertising

Medical advertising of drugs has been more often than not, found to be full of unproven claims of efficacy. In addition, promotional literature all over the world by the same company for the same drug has been found to be vastly different. Facts are withheld or modified. Statistics are used in a biased manner. Drug company sponsored misinformation is not uncommon.

Drug: **Tetracycline** (antibiotic used against various infections; Lederle Laboratories)

	Caution against use	*Adverse reaction publicized*
U.S.A.	By infants, children; during pregnancy: liver or kidney impairement (latter can be fatal) or if overly sensitive to light.	Vomiting, diarrhoea, nausea, stomach upset, rashes, kidney poisoning, can poison fetus.
Mexico	By infants, children, during pregnancy or if overly sensitive to light.	vomiting, diarrhoea, nausea, stomach upset.
Brazil	By infants, children, during pregnancy	vomiting, nausea, stomach upset, rashes
Argentina	None	None

Courtesy: Mother Jones, USA

"Physicians prescribe medicine of which they know little, to cure diseases of which they know less, in human beings of which they know nothing."

- Voltaire
18th century

d Prescribing for prestige/ power

Doctors especially often prescribe extravagantly as a sign of 'prestige' and 'power'. In India people often consider a good doctor to be one who gives a long, costly prescription, in keeping with his list of degrees. Many doctors succumb to this cultural status symbol. A vicious cycle is maintained thereby.

e Busy outpatients

Many of our institutions are understaffed especially those run by the government. The queues at the out-patient clinic are long and there is a heavy rush. Lack of time to make a good clinical judgement often results in an irrational prescription including drugs for all eventualities.

f Inducements by medical companies

Misinformation is not the only method by which doctors are made to prescribe irrationally by medical companies. Sales promotion includes a host of practices such as unethical trade discounts, bribes, gifts, sponsorship for conferences and travel. The commercial proposition induces many doctors to prescribe unethically.

g Unauthorised prescribing

Health workers and practitioners of other non-allopathic systems of medicine are often by virtue of their training unauthorised to prescribe all the drugs in the medical armamentarium. Health workers may be trained to prescribe only a few drugs. Too often they get a larger number of drugs and dispense them to get the community's approval and get greater prestige. Many traditional medicine practitioners, dispense allopathic drugs with little background training or knowledge.

h Drugs as a substitute for caring

Drugs have become a symbol of the new medical culture, where

treatment is primarily drug oriented and all other aspects of 'caring' and nursing of the patient are relegated to the back ground. When simple home remedies like hot water gargles and nursing procedures can provide relief to many symptoms of the patients, doctors prefer to prescribe symptomatic drugs instead, thus increasing drug consumption irrationally.

i Commercialisation of the medical profession

There was a time not so long ago when the doctors' profession was a vocation. Aspirants to the profession saw service to the sick and ailing as more important than the financial rewards they would get, if at all, from their grateful patients. Today the situation has changed drastically. Parents are willing to pay lakhs to get their children into medical school. No such investment would be made if the returns were not equally rewarding. Aspirants today therefore see medicine as a business investment. In such a social ethos 'irrational prescribing' for pecuniary benefits would not at all be frowned upon. In fact it may even be seen as a stepping stone to success.

c Drug use by Consumer Public - irrational dimensions

i Self-medication

Medication by patients themselves is not an uncommon problem. Either they are too poor to consult doctors or because of the easy availability of drugs they medicate themselves, encouraged by the pharmacists, advertisements, peer group information or advise of family members. A survey conducted by the National Institute of Nutrition in the twin cities of Hyderabad and Secunderabad covering 10 percent of the 330 retail Pharmaceutical shops showed that self-medication rate was an alarming 46 percent.

ii Use of unutilized drugs

It is a very common habit among the consumer public to take a medicine, not as the doctor has directed but just enough to feel better. This is often the case with antibiotics and particularly for children. Unused medicine is kept in the home pharmacy and given to one or other of the children or family member who gets the same symptoms, next. Unused or unutilized portion of prescribed medicine is often kept beyond expiry date. If proper storage precautions are not taken, it may also get denatured. Use of such medicines is a major cause of untoward reactions.

"The incidence of disease cannot be manipulated and so increased sales volume must depend at least in part on the use of drugs unrelated to their utility or need or in other words improperly prescribed. Human frailty can be manipulated and exploited and this is fertile ground for anyone who wishes to increase profits."

- Kefauver Committee Hearing on Drugs, USA

iii Inadequate labelling or storage of medicine

Medicines prescribed by doctors are often inadequately labelled by the dispensing pharmacist. Storage instructions are not very clearly explained to the patient. The medicine cupboard is often a source of irrational drug use. Children may have access to it and this may lead to accidential poisoning.

iv Peer-group exchange

Consumers of drugs often advise relatives, friends and neighbours about the benefits a particular prescribed drug has given them. They are advised to take these drugs for what is thought to be a similar complaint or disease. This peer group exchange is often the cause of much irrational drug use by the lay public.

v Status-symbol drugs

Capsules, injections, and tonics have become status symbol drugs. They are thought to be more effective and also being costlier are considered to be of greater prestige value. Patients often demand or pressurise their doctors to prescribe one or more of these and doctors often comply with the request to retain the patient and family in their practice.

vi Multiple consultations

Patients often go to many doctors seeking quick relief of their symptoms. The doctors are not often aware that consultation with them is one of many such concurrent events. Generalists and Specialists may both be consulted. Practitioners of different systems may be consulted simultaneously. Different medicines given by different doctors are then consumed with the hope of getting relief. When relief does occur it is not easy to decide which medicine brought it about.

Multiple prescriptions then become a way of life when symptoms recur. Many drugs may potentiate one another. Others may work at cross purposes. When the consultation is of plural systems the confusion is worse.

vii Inadequate Consumer Awareness

Probably one of the key factors for irrational drug use by

consumers is the absence of awareness of drug use, misuse and the effects of overuse. Consumer education is next to absent in India. Due to loopholes in the existing laws, precautionary product information is not supplied with the medical products. The media, the medical profession, the educational system and the social welfare agencies concentrate on the misuse of psychotropic substances and drug abuse. Misuse, overuse or abuse of commonly prescribed drugs is not considered to be an adequately serious problem for consumer education. The problem is further compounded by a large illiterate population and the need of such efforts to be in multiple languages when they do get organized.

Rational Drug use - Principles

The irrationalities and predisposing factors promoting unsafe drug use in our country have been described. The challenge that faces all of us today is: How to counter this phenomena? Health for All by 2000 AD would be an empty slogan if we did not join and participate actively in a consumer and professional movement to tackle the 'irrational drug use' problem. In the absence of prompt efforts in this direction, we would probably arrive at a situation-over abundant drugs and ill-health for all by 2000 AD.

What could be our prescription for action?

A thorough understanding of the situation would lead us to appreciate the following principles. (3)

Rational Drug Use

★ means practice of socially conscious, relevant and scientifically sound medicine

★ emphasises the selective use of drugs based on
- essentiality
- efficacy
- safety
- easy availability
- low cost
- ease of administration
- adequate quality
- preferably of indigenous production

★ recognises the concept of essential drugs and the concept of graded lists for different levels of health personnel

★ recognises the non-role of drugs in certain conditions, the role of alternative systems of medicine in some other conditions and recognises the overall limitations of allopathic medicine in our economic, social and cultural context.

★ accepts a conscious decision to boycott certain drugs which are hazardous or bannable or banned and use all others only when they are really needed.

★ means prescription with awareness, to avoid as far as possible iatrogenesis (doctor induced disease) which includes -
- drug induced problems
- drug interactions
- adverse drug reactions
- emerging drug resistance

★ recognises the rights of health personnel and consumers to unbiased drug information and its effective communication.

★ understands the role of drugs in the emerging health movement.

For all of us concerned about the increasing *medicalising of health* action and the *'over abundance of drugs'* becoming a *'vested interest in ill health'* **there is a phenomenal challenge in making the above principles of Rational Drug use**
- **common knowledge**
- **common practice**
- **commom commitment.**

In conclusion, drugs have allayed pain and suffering over the centuries. They have helped many live more comfortable, productive and meaningful lives. All of us committed to the health movement must ensure that drugs should continue to play their limited but useful role in medical service. However, the use of drugs knowingly and unknowingly, to make profit out of human health must stop.

And it will only if
Governments;
drug industries;
planners;
health professionals;
medical colleges;
pharmacy colleges;
nursing colleges;
drug controllers;
pharmacists;
journalists and media persons,
teachers and educators;
social development activists;
consumer groups;
and
the public
commit themselves to promoting a Rational Drug Use.

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women, scheduled castes and tribes, non formal education, continuing education, universalisation of elementary education geared to the dis-advantaged of the present system. On the other hand it is also committed to pace-setting schools, computer literacy, modern communication technologies and electronic audio-visual equipment to help the 'haves' school keep up with the rest of the world.

The government had promised to follow up this policy statement with a separate one on Higher Technical Education but none has been announced so far. In the absence of such a statement one has to study the Educational Policy and derive pointers towards new directions in Medical Education and Health policy for the 90's.

An indepth review of the statement brings out the following issues as of relevance :

* A commitment of human values and social justice
* Equal access to education of comparable quality to all irrespective of caste, creed, location or sex
* A core curriculum promoting common India heritage, democracy, secularism, egalitarianism, equality of sexes, protection of environment, removal of social barriers, small family norm and scientific temper.
* Future thrust to 'open' and distance learning and continuing education.
* Strengthening National Councils like UGC, MCI, ICMR etc., and promoting integrated planning and functional linkages.
* *Explore and operationalise health-related vocational courses by interlinking health planning. health service*

management and health manpower training

* Promotion of autonomy/freedom of educational centres with accountability.
* Improvement of pedagogical skills of teachers at all levels.
* Examination reform.
* Curbing commercialisation of technical and professional education and preventing emergence of substandard institutions.
* Regular review of curriculum to phase out obsolescence and introduction of new dimensions/disciplines.
* Overhaul in management of education with promotion of perspective planning, decentralisation, autonomy, people's involvement, greater role to women and accountability.
* Increasing role of communities in school education and greater role for NGOs/Voluntary agencies/Social activist groups in educational efforts.

It is clear that Medical Education reform cannot occur in a vacuum in 1990's and will be affected by the above changes in orientation if 'political will' can actually see it through, beyond the paper phase. Though three years have already passed since the policy statement, this 'political will' is yet to be perceived.

5) Some Disturbing Trends

The National Health and Education Policies have clearly defined their overall options for social justice and reducing the disparities in standards and opportunities and the 'haves' and

FROM INTRACELLULAR TO SOCIETAL RESEARCH

The Research and Research Centres given below is a sub-section of the July 1989's Cover Story "Community Health Scene in India"

The new approaches to Community Health evolving in the country have shown that a very important but neglected area is research into socio-economic-political-cultural factors that affect health and disease and determine the nature of health care development as well as the response of the people.

Medical research in India has been preoccupied as in other parts of the world with intracellular or molecular biological roots of disease and much of the research efforts sponsored by ICMR and other national and regional, government and private research centres has been in this direction. Most of it has been imitative research. 'we too have done it in India' sort of focus and there is the continued myopic view that the future of health in the country will be determined by the discovery of a few more vaccines and maybe the odd drug or contraceptive. This technological focus has blinded us to the fact that the world- over health care action initiators are proving again and again that the clue to health of the people is in greater societal problems in the wider social reality and to study them in a socio-epidemiological context to determine bottlenecks and to evolve creative innovations is the need of the hour. Some ICMR institutions like the National Institute of Nutrition in Hyderabad, National Tuberculosis Institute in Bangalore and the Vector Control Research Centre in Pondicherry have treaded the path of societal research and made unique contributions to Primary Health Care and Community Health but these are the exceptions to the overriding rule.

Have the NGO Health action initiators fared better? Is anyone interested in health related societal research in the country?

The development of NGO health research units keeping in tune with and exploring in depth issues arising out of the emerging Community Health movement are few but these are atleast positive signs.

The Foundation for Research in Community Health (Bombay) the Action Research in Community Health, Mangrol (Gujarat), Society for Education Research and Training in Health, (SEARCH) Gadchiroli (Maharashtra), Community Health Cell (Bangalore) are examples.

A few of the larger NGO Health Projects like CHOP, Pachod, (Maharashtra) SEWA-Rural (Gujarat), CINI (Calcutta), Jamkhed (Maharashtra) and RUHSA (Tamilnadu) have also begun to take up some key research issues but this whole interest is still in a nascent state.

The Social Medicine and Community Health Department at JNU is the only other national centre which is undertaking societal research relevant to Health Care and Health policy issues. The medico friend circle's efforts in providing counter research expertise in the Bhopal disaster and its aftermath was also a beginning of this new trend.

Much needs to be done by both governmental and non-governmental groups, if the emerging 'Community Health' approach and movement has to be put on a sound researched social and epidemiological basis. But this needs people who see *Research* as an important need. It also needs innovative 'researchers' who will be willing to learn existing health care research methodologies and then creatively adapt it through interactive, participatory approaches to study the dynamics of Community Health care and the evolving movement.

With the preoccupation with 'microscopic research' are such 'baloonist researchers' available for the task?

NGO Research Centres in Community Health: Some Profiles

★ Foundation For Research in Community Health, Bombay, (Maharashtra), Estb: 1975

Non-government research centre which undertakes conceptual as well as field level research to study, analyse and wherever possible influence the cultural, economic and political factors that affect the health of the people.

Initiatives and studies include evolution and study of low cost community based health systems in Uran and Mandwa. Socio-economic study of rural transformation; Women's work fertility and access to health; PHCs in Maharashtra; Health Service projects (NGOs in Maharashtra) Health Financing in India, Stigma against leprosy, Alternative school health project, Facilitation of ICMR-ICSSR Joint study group on Health for All an alternative strategy.

★ Action Research in Community Health — (ARCH) Mangrol, (Gujarat), Estb: 1978

A group of individuals of diverse background got together to establish this centre in the eastern tribal belt of Gujarat to study the developmental process using the health of children and women of the poorer sections of society as the guiding thread.

The approach was to get involved in the complex process of development (ACTION) and to study critically the health of the community and the processes which results in ill health (RESEARCH).

Field based strategies evolved were programmes to attack prevalent diseases, methods and skills of community diagnosis and intervention, training of health assistants and part time community health workers, non-formal school and finally a just and human rehabilitation policy for tribals displaced by an ambitious irrigation project in the area.

★ Society for Education, Awareness and Research in Community Health (SEARCH), Gadchiroli (Maharashtra) Estd: 1984

This Society has adopted Gadchiroli district, a predominantly tribal district in Maharashtra, for its education, awareness building and research activities. Presently they have long term projects on the study of Active Respiratory Illnesses in children; and a study of women's health focussing on the community. The Society also seeks to evolve methods of intervention which will be at the level of the multipurpose workers of the government PHC.

Due to its increasing community involvement the Society has also begun to explore the dynamics of women's health and other related issues, the forest issues affecting tribal and the illicit liquor issue in its community context. It has also tried to modify the health care/medical practices at the District level to make it more responsive to the needs of the people's situation.

NGO (Non-Governmental Organizations) Research Centres in Community Health: Some Profiles

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Health financing in India;

Stigma against leprosy;

Alternative school health project;

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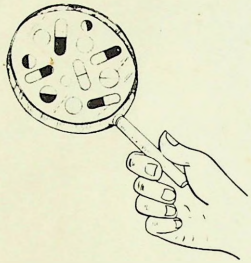
DRUG UPDATE



Safer analgesics — alternatives to Analgin

Dr Wishvas Rane

Analgin is known to cause
agranulocytosis
circulatory shock
gastric irritation, bleeding and dyspepsia
significant increase in liver toxity, and skin reactions.

Because of the known serious adverse reactions, most of the advanced countries have banned analgin, wherever it is used, the use is restricted to terminal cases only. The following countries, among others, have banned its use:

Great Britain and Canada	— 1960
Australia	— 1965
Sweden	— 1974
Norway	— 1976
USA	— 1977
Ireland and Singapore	— 1979
Denmark	— 1979
Malaysia	— 1986

Should Indians continue to be exposed to the great risks posed by analgin and its combinations? Should we not join with the progressive countries and protect our people?

Sometimes arguments are put forward that analgin is required because there are not enough, safer alternatives readily available. The continued use of this dangerous drug is promoted by stating that its use is necessary in patients with post operative pain, cardiac pain, and biliary and renal colic. It must be remembered that none of the standard textbooks mention analgin as a pain killer or as an anti-spasmodic in above referred conditions.

What are the safer alternatives?

The Management of pain:

Whereas most pain occurring immediately after trauma or operation responds to conventional analgesics that is not necessarily true in chronic pain. The simplest clinical guideline is that where pain occurs in a numb area (e.g. dysaethesia) or in non-existent areas (phantom limb pain) conventional analgesics are unlikely to be helpful. In the Oxford Regional Pain Relief Unit, approximately one-third of patients with either malignant or non-malignant pain show a poor response to conventional analgesis.

Table 1
Analgesics

Conventional analgesics

Mild	Acetyl salicylic acid (aspirin) Paracetamol Dihydrocodeine Non-steroidal anti-inflammatory drugs Levorphanol (dromoran) Phenazocine
Strong	Morphine Other agonist opioids Buprenorphine Other partial agonist opioids Phenazocine

Unconventional analgesics

Antidepressants	Tricyclics	Amitriptyline Dothiepin
	Benzodiazepines	Clobazam
	Other	Nomifensine Mianserin
Anticonvulsants	Sodium valproate Clonazepam Phenytoin	

As in other branches of medicine the concept of a ladder, with the mild peripherally acting analgesics at the bottom rungs and strong narcotics at the top, is helpful (Table 1). The major limitations in implementing the ladder for non-malignant pain is the problem of using strong opiate analgesics with their potential for dependence.

The use of antidepressants in chronic pain management is widespread, but with little support from controlled studies. The dosage used (e.g. amitriptyline 25 mg nocte) do not result in plasma concentrations required for treatment of depression, any benefit is unlikely to be from measurable antidepressant effect. Despite the uncertainties over mode of action, in post-herpetic neuralgia, this is the single most effective treatment.

The use of anticonvulsants is best known from the prescribing of carbamazepine in trigeminal neuralgia. Sodium valproate and clonazepam are probably the commonest anticonvulsants used in the management of chronic pain, and it is encouraging that this unconventional approach is now being recognised by the major pharmaceutical companies as it is likely that the breakthrough will come in this group[1].

Biliary colic (acute cholecystitis):

Conservative treatment: Oral feeding is stopped. Intravenous fluids, and analgesia with pentazocin or pethidine and atropine are administered. Antibiotics are given to all but the most mild cases; tetracycline, ampicillin, or a cephalosporin are satisfactory for general use[2].

Myocardial infarction
Clinical Management
Geheral measures
Pain relief

Rapid and effective analgesia is the main requirement of most patients in the early stages of myocardial infarction. The opiates, morphine, and diamorphine, are most effective for this purpose. When given by slow intravenous injection, either morphine, 10-15 mg, or diamorphine 5-10 mg, result in rapid pain relief. The emetic effect of both drugs results in unwanted circulatory stresses but may be lessened by the routine intravenous use of cyclizine 50 mg. Among alternative drugs are pethidine, methadone, and pentazocine. Pentazocine has been a source of some concern because, following its administration a rise in pulmonary artery pressure has been observed in several studies. This finding has been associated with an elevation of left ventricular end-diastolic pressure in one study; This has not, however, been a uniform observation. In any event, pentazocine, although an effective analgesic in doses of 30-60 mg intravenously, is probably best avoided because of its tendency to produce hallucinations. Some patients require a second or third dose of analgesic during the first 24-48 hours of admission; others are anxious and benefit from sedation with a benzodiazepine, e.g. diazepam 2-5 mg thrice daily. When potent analgesics may not be available, a period of prolonged pain and distress can be avoided by the use of a 50 per cent nitrous oxide/oxygen mixture, which can also be used during transport to hospital. The analgesic effects are rapidly reversed, which allows the patient to provide a history free from sedative effects of analgesia[3].

Renal and ureteric colic:

Atropine and other anti-cholinergic agents, narcotic analgesics, papaverine hydrochloride, amyl nitrite, glyceryl trinitrite are effective[4].

Dysmenorrhoea:

Aspirin and other similar analgesics, hyoscine butylbromide, papavarine hydrochloride and sex hormones are useful[5].

Hyoscine butylbromide is a quaternary ammonium anti-cholinergic agent. The peripheral effects are similar to those of atropine, but weaker and of shorter duration. Hyoscine butylbromide is used in the treatment of conditions associated with gastrointestinal spasm. The usual dose is 20 mg intramuscularly or intravenously, repeated after 30 minutes if necessary. It is also given by mouth in doses of 20 mg four times daily, and is claimed to be of value in spasmodic dysmenorrhoea[6].

Flavoxalate hydrochloride counteracts smooth muscle spasm of the urinary tract. It is indicated for symptomatic relief of dysuria, urgency, nocturia, suprapublic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis/ urethrotrigonitis.[7]

Dicyclomine hydrochloride is an anticholinergic agent with peripheral effect similar to but much weaker than those of atropine, it also has direct antispasmodic action and a local anaesthetic action. It is used in biliary, gastrointestinal or urinary tract spasm and is given with antacids in the treatment of gastric and duodenal ulcer[8]. Dicyclomine is indicated in functional bowel/ irritable bowel syndrome (irritable

colon, spastic colon, mucous colitis) and acute enterocolitis. It is contra-indicated in obstructive uropathy, (for example bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastro-intestinal tract (as in achalasia, pyloroduodenal sterosis), paralytic ileus, intestinal atony of the elderly or debilitated patients, unstable cardio-vascular status in acute haemorrhoage; severe ulcerative colitis, toxic megacolon, complicating ulcerative colitis; myasthenia gravis[9]

Phenazopyridine hydrochloride is useful for the symptomatic relief of pain, sense of burning, frequency, urgency, and other discomforts arising from irritation of the lower urinary tract mucosa. Its topical analgesic action may reduce or eliminate the need of systemic analgesics or narcotis. It is contra-indicated in renal insufficiency. A yellowish tinge of the skin or sclerae may indicate accumulation due to impaired renal excretion and the need to discontinue therapy[10].

Dextropropoxyphene hydrochloride (Propoxyphene hydrochloride) is a centrally acting narcotic analgesic agent. It is structurally related to methadone. The potency of propoxyphene hydrochloride is from two-thirds to equal that of codeine. Do not prescribe propoxyphene for patients who have suicidal tendencies or are accident prone. Prescribe propoxyphene with caution for patients taking tranquillisers or anti-depressant drugs and patients who use alcohol in excess. Tell your patients not to exceed the recommended dose and to limit their intake of alcohol[11]. Prolonged use of higher doses of dextropropoxyphene may lead to dependence of the morphine type. Liability to abuse is reported to be a little less than for codeine[12].

Pentazocin is a potent analgesic which when administered orally is approximately equivalent, on a mg for mg basis, in analgesic effect to codeine. The respiratory depressant effects of pentazocin and its potential for elevating cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury[13]. For the relief of moderate to severe pain, 30 mg of pentazocin intramuscularly is reported to be equivalent to about 90-100 mg pentazocin by mouth, about 10 mg of morphine subcutaneously or intramuscularly, or 50 to 100 mg of pethidine intramuscularly[14]. Pentazocin 60 mg intravenously appeared to be a suitable analgesic for patients with a recent myocardial infarction. Unlike morphine, its use was not generally followed by hypotension, an increase in the respiratory dead-space/tidal volume ratio or an increase in the difference between alveolar and arterial oxygen tensions. It was suggested that pentazocin should be used in preference to morphine as an analgesic in patients with myocardial infarction[15]. Dimorphine might be considered to be the analgesic of choice in a situation where rapid relief of pain was essential but pentazocin with its low addiction potential and lower incidence of blood pressure reduction might be the most suitable treatment of pain in patients with a suspected cardiac infarction[16].

Drugs available in India

Amitriptyline Hcl: 10,25,75 mg tab
Buprenorphin as Hcl: 0.3 mg per ml
Carbamazepine: 100,200,400 mg tab
Dicyclomine Hcl: 20 mg tab
Dextropropoxyphene: Available only in combination form with other analgesics like aspirin, paracetamol etc.

Flavoxalate Hcl: 200 mg tab
Glyceril nitrate: 0.5 mg tablet
Hyoscin-N-Butylbromide: 10 mg tab
Pentazocin: 30 mg per ml inj.
Phenazopyridine Hcl: 100 mg tab
Sodium Valproate: 200 mg tablet ■

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(17)

Says the company's young managing partner Deepak Bhandari, "Our plan is to ultimately stop the 15% import of herbs we require. We are encouraging farmers in Ooty to raise nurseries of herbs - vitex negundo, strychnos nux vomica messua ferrea etc. The temperate climate in Ooty is conducive to the growth of these herbs."

The company is exporting its products to West Asia and South East Asia and by 1991-92 expect to reach an export figure of 15% to 25%. The race has begun

With the growing interest in alternative medicine, the Government of India too has decided to set up a Medicinal Plant Board. Its functions will include assessment of herb requirement, organised cultivation, distribution and export. The demand for herbal products is growing fast. Let us hope that the government and more private companies will soon enter the national and international market and provide people with a safe and sure cure for many of the ailments that plague us today.

— Hindustan Times

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CLINICAL COMPARATIVE STUDY OF INTRAVENOUS AMPICILLIN AND AMOXYCILLIN AT HALF THE DOSAGE IN THE TREATMENT OF INFECTIONS OF THE LOWER RESPIRATORY TRACT

Y. MOUTON, G. BEAUCAIRE, M. BRION, R. MBELEPE, A. FOURRIER, AND M. CAILLAUX

Unit for Reanimation of the Regional Department of Infectious Diseases (Pr. Agr. Y. Mouton), C.H. Tourcoing, 59208, France

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ABSTRACT

The results obtained in this study in 19 patients with essentially bronchopulmonary infections treated at 50 mg/kg/day amoxycillin intravenously were identical with those obtained in 19 patients receiving twice as much ampicillin, i.e. 100 mg/kg/day intravenously. This similarity of clinical and bacteriological results has to be seen in context with the hope of reduced dosage of antibiotics — often hoped for in theory but rarely possible. It can be achieved with amocycillin.

INTRODUCTION

The object of our study was to compare the efficacy of amoxycillin intravenously at a dose of 50 mg/kg/24 hours in the treatment of pulmonary or lower respiratory tract infections, with that of ampicillin intravenously in a dose of 100 mg/kg/24 hours. The daily doses of each antibiotic was given as 6 rapid intravenous injections (1 injection every 4 hours).

Amoxycillin is a semi-synthetic penicillin, the anti-bacterial spectrum of which is identical to that of ampicillin,[4] but the bactericidal activity of which is more rapid.[2,3,5] This rapidity of bactericidal action is explained by a preferential binding of amoxycillin to Penicillin Binding Protein 1a (PBP 1a) on the target membrane of the bacteria, whilst ampicillin preferentially binds to PBP 2 and 3.[6]

The intravenous administration of 500 mg amoxycillin produces concentrations giving therapeutic activity for a duration of 4 hours and the bioavailability of amoxycillin is 2 times greater than that of ampicillin.[5]

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PATIENTS AND METHODS

Type of Trial

This was a comparative controlled trial of amoxycillin against the reference product ampicillin. Two groups of subjects received either amoxycillin or ampicillin, the treatment being allocated according to a randomisation table.

Patients

The patients were adults, of either sex suffering from pneumonia, broncho-pneumonia, or bronchopathies caused by bacteria assumed to be or identified as sensitive to ampicillin, in the Intensive Care Unit of the Regional Service of Infectious Diseases (Prof. Agr. Y. Mouton).

Criteria of Exclusion

The following were excluded from the study: patients with allergy to penicillins or cephalosporins; patients who had received a combination of antibiotics; and patients with infectious mononucleosis.

Bacteriological Examinations

Bacteriological examinations were carried out by the Bacteriological Laboratory of the Hospital Centre of Tourcoing (M. Caillaux). After isolation and identification of the bacteria responsible for the infection, a quantitative analysis was carried out where possible. The sensitivity to amoxycillin and to ampicillin was established by the agar-diffusion method. The examinations were repeated on the 2nd day and 5th day and at the end of the treatment.

Evaluation Criteria of Efficacy

Clinical assessment — Cure: the complete disappearance of the majority of the clinical and radiological signs. *Considerable improvement*: the disappearance of most clinical signs but including fever and notable regression of any radiological signs. *Failure*: the presence or persistence of clinical signs or their aggravation.

Bacteriological assessment — Success: disappearance of the bacteria responsible for the infusion. *Failure*: persistence of the bacteria and/or development of other pathogenic flora. *Indeterminte*: if no bacteriological control was carried out.

Assessment of Tolerance

Clinical tolerance was monitored, in particular any local reaction on the skin and veins. Biological tolerance was evaluated by systematic examinations of the blood to include: all causes and differential platelets, urea, creatinine, transaminases, alkaline phosphatase, Coombs test, tests for proteinuria and glycosuria and radiography of the thorax. These examinations were carried out on the 1st and 2nd day of treatment and repeated at the end of treatment.

Analysis of the Comparability of the Groups

It is essential to test the randomisation of the 2 groups to receive either ampicillin or amoxycillin at half dosage in order to determine the comparability of the groups. The use of

Table I — *Demographics of the two groups of patients*

	Ampicillin Group	Amoxycillin Group	Test & Result
NUMBER OF CASES	19	19	
WEIGHT (Kg).	75.99.87.86.65.74. 64.39.90.60.70.62. 56.60.57.58.87.56	50.60.58.65.78.67. 68.63.53.75.70.48. 60.60.110.70.61. 57.67	Mann & Whitney NS
Average & Range	70 - 39 to 99	66 - 48 to 110	
SEX: Male	13	11	NS
Female	6	8	NS
AGE (yrs).	85.62.83.80.70.83. 74.76.40.35.19.57. 55.2 .60.57.87.83. 57	81.79.66.70.77.36. 43.65.87.34.81.77. 70.72.73.89.83.29	Mann & Whitney NS
Average & Range	62.3 - 19 to 85	66.8 - 36 to 87	
INITIAL CONDITION:			
Good	3	3	
Moderate	7	9	
Critical	9	7	
TYPE OF INFECTION:			
Pneumonia	8	4	
Bronchopneumonia	4	6	
Bronchitis	3	6	
Pure septicaemia	3	2	
Pyelonephritis	1	1	
BACTERIA			
Streptococcus pneumoniae	6	4	
Streptococcus alpha-haemolytic	1 7	1 6	
Streptococcus Group D	0	1	
Haemophilus	3	6	
Escherichia coli	5 8	2 9	
Salmonella	0	1	

the Mann & Whitney Test showed no statistically significant difference in the parameters of entry into the study of these 2 groups which consequently may be compared. (of Table I)

RESULTS

Results of Treatment with Ampicillin 100 mg/kg/24 hrs.

Clinical Results

In the 19 patients treated with ampicillin we noted:

— 11 *cures* (6 pneumonia including 2 with pneumococcus-positive blood cultures; 2 bronchopneumonia; 1 bronchitis; 2 pure septicaemia). Four of these patients were in a critical condition and 5 were moderately ill.

— 2 *improvements* (1 bronchopneumonia and 1 bronchitis) both in a critical condition and mechanically ventilated.

— 6 *failures* (2 pneumonia; 1 bronchopneumonia with positive pneumococcal haemocultures; 1 bronchitis; 1 pyelonephritis, and 1 septicaemia, both due to sensitive *Escherichia coli*). Three of these patients were in a critical condition and 2 were in a moderate condition.

Bacteriological Results

Out of 15 bacteria isolates before treatment we noted:
— 5 *cures*
— 4 *failures* of which 2 were superinfections (sensitive *pneumococcus* replaced in a mechanically ventilated patient by a resistant *Acinetobacter;* a sensitive pneumococcus replaced in a patient by an *Acinetobacter* and a resistant *Pseudomonas aeruginosa*.

Tolerance

There was one phlebitis and a moderate eosinophilia evaluated at 452 mm^3, which recovered after cessation of treatment. No other undesirable effects were detected.

Results of Treatments with Amoxycillin 50 mg/kg/24 hrs.

Clinical Results

In the 19 patients treated with amoxycillin we noted:
— 13 *cures* (3 pneumonia; 3 bronchopneumonia, including 1 with a positive pneumococcus haemoculture; 4 bronchitis; 1 urinary tract infection, and 2 septicaemia caused by *Escherichia coli*). Two of these patients were in a critical condition and 7 in a moderate state.
— 2 *improvements* (1 bronchopneumonia and 1 bronchitis).
— 4 *failures* (1 pneumonia due to *Haemophilus* and 3 bronchopneumonias, all 4 in a critical condition).

Bacteriological Results

Of 15 bacteria isolated before treatment we noted:
— 9 *cures*
— 4 *failures* of which 3 were superinfections (a sensitive *pneumococcus* replaced by a resistant *Enterobacter* in two mechanically ventilated patients; the appearance of a resistant *Escherichia coli* septicaemia in a patient with bronchopneumonia with positive haemocultures to *pneumococcus*).

Table II — *Comparison of clinical results*

	Group Treated With AMPICILLIN 100 mg/kg/24 h.	Group Treated With AMOXYCILLIN 50 mg/kg/24 h
Number of cases	19	19
Cures		
Pneumonia	6	3
Bronchopneumonia	2	3
Bronchitis	1	4
Septicaemia, pure	2	2
Infection, urinary	—	1
	11	13
Improvements		
Bronchopneumonia	1	1
Bronchitis	1	1
	2	2
Failures		
Pneumonia	2	1
Bronchopneumonia	1	3
Bronchitis	1	
Pyelonephritis	1	
Septicaemia to *Escherichia coli*	1	
	6	4
Secondary Effects		
Phlebitis	1	
Eosinophilia	1	3
	2	3

Table III — *Comparison of bacteriological results*

	Group Treated With AMPICILLIN 100 mg/kg/24 h	Group Treated With AMOXYCILLIN 50 mg/kg/24 h
BEFORE TREATMENT		
No. of bacteria isolated before treatment (see Table I)	15	15
No. of cases with indeterminate flora*	4	4
AFTER TREATMENT		
Cure	5	9
Failure**	4	4
Superinfections	2	3
Superinfecting bacteria	3 (2 *Acinetobacter* R, 1 *Pseudomonas* R)	3 (2 *Enterobacter* R, 1 *Escherichia coli* R)

* lack of bacteriological control

** failure — due to persistence of bacteria and/or development of other pathogenic flora

Tolerance

We noted 3 moderate cases of eosinophilia at the end of treatment (520, 460, 355/mm³). No other undesirable clinical or biological effect was detected.

Comparative Results (Cf. Table II and III)

In Table II and Table III the data describing the clinical results and the bacteriological results are presented.

DISCUSSION

Ampicillin and amoxycillin are similar antibiotics in their antibacterial spectrum, their pharmacokinetics, their antibacterial activity, and their tolerance. However, they differ in the speed of their bactericidal action and their site of membrane fixation.

We wished to verify whether the benefit noted in favour of oral amoxycillin in comparison with an identical dose of oral ampicillin[1] would also be found after the intravenous administration of these products. With this object in mind we have taken two groups of patients who were comparable as regards:

- their diagnosis (pneumonia, bronchopneumonia, bronchitis, septicaemia, urinary infections) and their initial condition
- the bacteria responsible
- the weight, sex, age of the patients and the duration of treatment.

These patients received, by drawing lots from a randomisation table, either 100 mg/kg daily of ampicillin intravenously or 50 mg/kg daily of amoxycillin intravenously. The results obtained in the 2 groups were comparable although amoxycillin at the beginning had to compensate for the handicap of a dose only half that of ampicillin. This similarity of clinical results is similar to that obtained after oral administration by other authors.[1-7]

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ANALGIN--A STUDY

1. The Drug

A class of chemicals called PYRAZOLONES have been used as medicines for over ninety years. Pyrazolones include drugs like Antipyrine, Aminopyrine, Phenylbutazone, oxyphenbutazone, sulfinpyrazone and a derivative of aminopyrine called dipyrone or analgin. The pyrazolones share similar pain killing, fever reducing, inflammation reducing and also toxic properties. Analgin being more water soluble is amenable to use in injections and liquid oral preparations (for children). They are rapidly absorbed in the stomach and intestine and spread in various tissues of the body in proportion to their water content. While 30 to 40% of the drug is altered in the liver and eliminated in the urine, 5% is eliminated unaltered. The fate of a significant fraction is not known.

The range of actions of Pyrazolones is similar to that of Salicylates (Aspirins) except in reducing fever in diseases like Hodgkins' disease and Periarteritis nodosa, where aspirins are not completely effective.

The most important and potentially fatal adverse effect of Pyrazolones (Analgin) is Agranulocytosis. This is a condition where the Granulocytes which form the major part of the white blood cell population and are the first line of the body's defence against infection are destroyed. It is an allergic reaction and can occur suddenly even after a fraction of a dose in any person who has been previously taking Analgin with no bad effects. Within 6 to 24 hours, the white blood cell count fall and granulocytes disappear from the blood. They start reappearing 5 to 10 days after the drug is discontinued and rapid recovery occurs.

The incidence of agranulocytosis has been variously estimated from 0.01% to 0.86%. If infection occurs now, it starts as a sore throat of sudden onset, high fever and prostration, which even on proper treatment carries a mortality of 20 to 50%.

The other adverse effects of Analgin documented in a study are: skin rashes, dyspepsia, fever, analphylactic shock and bronchospasm. Analgin can aggravate a bleeding tendency and produces a serious fall in body temperature when given along with Chlorpromazine. Liver cancer in mice has also been reported by Japanese.

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Even now--

a. the mode of action is not known;

b. which are the metabolites which cause agranulocytosis and how is not known;

c. basic pharmacological data, like potential for causing cancer, congenital malformations, kidney and liver damage and damage in elderly patients are not known;

d. interactions with other drugs for diabetes, hypertension etc., have not been investigated because pyrazolones were introduced in the pre-Thalidomide era when registration was easy.

2. History and present status

1897 Aminopyrine was first introduced and became very popular in 1920s for pain killing and fever. By 1930s its use was world wide.

1922 Agranulocytosis was first described by W. Schulz

1922 Dipyrone or Analgin was introduced by Hoechst. Not being recognised as a derivative of Aminopyrine, it gained popular use.

1933 Madison and Squier established a causal relation between Amidopyrine and agranulocytosis.

1935 Kracke and Parker established its relationship to agranulocytosis beyond doubt

1938 O.T.C. sale in U.S.A. was prohibited.

1955-1959 The American Medical Association Registry on Adverse Reactions recorded only 10 reports of leucopenia (fall in WBC count) and none in children.

1960-1964 18 cases reported (7 children).
An increase in the import into USA of dipyrone from nil in 1958 to 18,879 lbs in 1962 was noticed.

1964 American Council of Drugs--Section One: adverse reactions: studied the case of Dipyrone (Analgin) and questioned the justification of continued use of this drug.

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1960 Great Britian and Canada revoked the licence of Dipyrone

1965 Australia and New Zealand issued an import ban on dipyrone

1974 Sweden revoked Dipyrone licence

1976 Norway revoked Dipyrone licence

1977 USA revoked Dipyrone licence
Japan banned free O.T.C. sale

1978 Ireland and Singapore revoked licence of dipyrone

1979 Denmark revoked licence of Dipyrone

1980-1984 An international study for agranulocytosis and aplastic anaemia was done in Europe--called the Boston Study, since coordination and data analysis was done at the Drug Epidemiology Unit at Boston. This was primarily financed by Hoechst, and the results published in the JAMA of Oct 1986.

1983 The Government of India banned the manufacture and sale of Amidopyrine

1986 Malaysia banned dipyrone.
FRG banned OTC sale
In Netherlands, Dipyrone use is only allowed for uncontrollable fever.

Following reports of anaphylactic shock, Italy, Egypt and Saudi Arabia have prohibited manufacture of injectible preparations.

3. The Issues

i. According to Hoechst, approximately 25 tonnes or 18.5 million doses of Novalgin are used world wide everyday. With most of the developed nations banning or restricting its use, it is obvious that it is sold mainly in third world countries.

The countries which have banned Dipyrone have been managing pain without Dipyrone by using equally effective and safe analgesics.

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ii. The 'Boston Study' generated a lot of controversy since Hoechst used the results even before publication for a misleading advertisement campaign showing the occurrence to be 1 per million. The hearing of the German Federal Health Office finally confirmed the assumption of 1 per 30,000 to 60,000 to be nearer the mark, or one tablet per 70,000 consumed could cause agranulocytosis based on this same study.

The limitations of this study are that--

a. it excludes all patients

i. who die of agranulocytosis without receiving medical aid;

ii. who die without having a white cell count; and

iii. who have undiagnosed agranulocytosis and recover from it.

b. it does not look into other side effects of dipyrone, like shock, fall in BP, Urticaria etc.

c. the data presented in the intermediate and final reports are inconsistant

d. whereas 400 cases of agranulocytosis were registered to assess risk properly, only 221 cases were analysed in the final report;

e. there is extreme variability in data between different countries and even within the same country; and

f. some data were seen to be clearly unreliable.

iii. The findings of the controversial 'Boston Study' is being utilised by Hoechst the largest manufacturer of Analgin for sales promotion in Germany, Eastern Bloc countries and the Third World. Unethical propaganda practices with different types of promotional literature in different countries is being practiced. Even claims of anti-spasmodic action which is not scientifically substantiated is being made. Any source of detailed scientific literature is virtually non-existant beyond the literature supplied by the drug companies.

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iv. Since 1985, Dipyrone (Analgin) has not found mention in any standard medical text books, except for naming it as a drug which can cause agranulocytosis.

v. Even in our country, medical students do not learn about analgin while doing their Pharmacology.

4. In India

i. In 1983, the Government of India banned the manufacture and sale of amidopyrine but not dipyrone. The Drugs Consultative Committee had recommended ban on FDCs of dipyrone also but this seems to have slipped from the banned list.

ii. The government is the largest manufacturer of dipyrone in this country.

iii. Analgin is among the largest selling analgesics in the country with sales figures accounting for Rs 70 million. There are approximately 200 formulations containing Analgin, including injectibles and drops for newborns and infants for colic.

iv. Analgin is available as OTC in spite of its being a Schedule H drug in our country and the attitude of the prescribing doctors as per a study (Lancet 86) was "if I prescribe it 30 times a day and it is available over the counter, it must be safe". In a field study (Lancet 86) it was seen that the pyrazolones made up the majority of both GP prescriptions and OTC sales of analgesics. One more of these drugs were given to over 50% of patients requesting an analgesic.

v. Drug action groups have initiated a campaign on Analgin especially at ACASH, Bombay, DAF-West Bengal and AIDAN, New Delhi.

vi. Analgin induced agranulocytosis does occur in India, aspecially if one looks for it systematically as a Bombay haematologist BC Mehta has done. He reports 12-15 cases of agranulocytosis a year, of which 10-12 are caused by Dipyrone or Dipyrone containing drugs. Even by the risk estimation of the Boston Study, in India, one person develops analgin induced agranulocytosis per day by other reasonable estimates, it could be 15 times this figure.

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5. Wider Issues

Developing countries like ours are ill placed to afford expensive and useless health care products and definitely not the frankly dangerous ones.

We have unsophisticated consumers and poorly developed regulatory and advisory systems--this is fertile ground for pharmaceutical companies to indulge in unacceptable practices.

The vast majority of rural doctors working in professional isolation have no access to independent information on drugs they prescribe. Here, the representative of the pharmaceutical company who is ill-informed himself and paid by commission on drug sales becomes an ideal tool to promote the interests of the Pharmaceutical company.

Thus, it appears that the consumer is at the mercy of drug manufacturers. Other than an appeal to the Food and Drugs Administration, the Central Government and the MRTP Commission the consumer is virtually without recourse to any independent body such as the judiciary. The JJ Hospital Commission (Lentin Commission) enquiry reveals the ineffectiveness of these agencies. The Consumer Protection Act of 1986 is expected to offer some hope.

In effect only a public outcry by the consumer can force voluntary withdrawal by or reform by drug companies.

--S P TEKUR, Community Health Cell
47/1 St Mark's Road, Bangalore 560001

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Rational Therapeutics

Dr. Shirdi Prasad Tekur
Community Health Cell, Bangalore

The most rational approach to a rational drug policy is *rational prescription**

"The flood of new drugs in recent years has provided many dramatic improvements in therapy, but it has also created a number of problems of equal magnitude. Not the least of these is the "therapeutic jungle", the term used to refer to the combination of the overwhelming number of drugs, the confusion over nomenclature and the associated uncertainty of the status of many of these drugs."

- Goodman and Gillman, 7th Ed. 1985

Drugs play an useful role in treatment of disease and alleviation of symptoms. Optimal and rational use of drugs is an obvious but imprecisely defined pre-requisite of good medical practice.

An understanding of the pressures operating at the levels of Policy, People and Practitioner could clarify present irrationalities.

Policies

Policies determine the availability of medicines in terms of production patterns, distribution, marketing, pricing and ultimately, drug usage. To be rational, availability should match the need - but does it? See box 1 for some realities in our context.

People

Peoples/Patient behaviour in diseases is governed by numerous variables based on their culture, traditions, socio-economic status, access to medical aid, life-styles and imperatives of their daily existence. The bottom-line is a lack of awareness of factors affecting health and disease.

This leads to

- self-medication in an empirical manner, based on: experience, peer group advice, high pressure ad-

Box 1

- There are 20,000 pharmaceutical units producing over 60,000 formulations. The Hathi Committee in 1976 recommended 116 drugs as essential and the WHO says about 250 are necessary!
- Every 5th drug tested is sub-standard due to lack of good manufacturing practices. Also, the drug controlling and inspecting apparatus is grossly inadequate.
- Almost 50% of drugs are sold over-the-counter (O.T.C.) without proper prescription.
- The bulk of drugs produced and sold are tonics, cough syrups and pain-killers, while drugs for diseases like TB, Leprosy and Malaria are in short supply.
- The drug policy is formulated by the Ministry of Chemicals rather than the Ministry of Health and the Drug control policy is limited to a drug pricing policy.

vertisements, etc., with the attendant hazards (NIN study-46% in Secunderabad and Hyderabad);

- inordinate fear of the medical system and its processes; promoting self-manipulation of drug therapies against advise;

- cross consultations and alternating different systems of medicine; e.g. Ayurveda, Unani, Homeopathy etc. whose understanding and treatment methods of disease processes differ at a fundamental level. This gives conflicting signals to the consumers, compounding their confusion and complicating the outcome. The prescription of allopathic medicines by unauthorised personnel and a faith in 'tonics' and other nutritional supplements add to the problems.

These practices are based on the flawed belief that *There Is A Pill For Every Ill!*

Practitioner

The Practitioner is considered to be in a position to understand rationality by virtue of training. The first fact faced is a training in pharmacology in 'generic' names of drugs, while practice means choosing from a plethora of 'brand' names. Not having learnt the economics of drug prescribing leads to easy manipulation by pharmaceutical producers as part of their promotional and marketing strategies.

Continuing education from unbiased sources of information on rational therapy is not available to a majority of practitioners.

The pressures of practice and patient expectations leading to:

- emulating and competing with peer-groups and 'specialist' and consultant behaviour in prescriptions, leads to:

extravagant prescribing, over-prescribing, under-prescribing and incorrect prescribing.

- accepting patient behaviour patterns listed earlier, or condemning them without rational discussion.

- erosion of clinical skills instead of honing them, while high-tech diagnostics of limited utility are relied upon more and more.

- not appreciating the high incidence of iatrogenic disease, adverse drug reactions and the limited role of drugs in treatment.

- succumbing to marketing strategies, inducements and biased information provided by pharmaceutical companies.

It means substituting '*medicine*' for '*caring*' and acquiring of '*experience*' which '*justifies*'! Is this '*rationalisation*', rational?

What does all this mean?

1. We do not have a Rational Drug Policy at the National Level (see box 1). The Hathi Committee Report (1976) universally considered as the most authentic and exhaustive study of Indian Pharmaceutical Industry, is largely ignored.

2. The plethora of drugs available in our country do not match our health needs.

3. Drugs banned elsewhere in the world are freely available in our country (e.g., Analgin, Clioquinols, Oxyphenbutazone etc.)

4. Irrational combinations of drugs are in plenty, while very few combinations are considered rational (see Table 1).

Table 1

Rational Combinations

Fixed dose combinations included in the WHO list	
Ferrous sulphate	+ Folic Acid (anti-anaemic)
Isoniazid	+ B6 (anti-tuberculosis)
Sulphamethoxazole	+ Trimethoprim (anti-infective)
Ethinylestradiol	+ Levonorgestral (Contraceptives)
Ethinylestradiol	+ Norethisterone (Contraceptives)
L Dopa	+ Methyl Dopa (Anti-parkinsonism)
Neomycin	+ Bacitracin (Anti-infective dermatological ointment)

5. Tonics (multiple combination), Cough syrups (containing sedatives and expectorants) and Nutritional supplements, flood the market. These are sold

at exorbitant costs, and cannot be considered rational in our socio-economic millieu.

6. The practitioner has a greater responsibility in questioning the present trends and consciously promoting rationality.

Attempts at rationalisation

The World Health Organisation and Health Action International have been drawing attention to rationality at the international level.

At the national level, the Indian Academy of Paediatrics and Indian Medical Associations at some regional levels have started activity in this direction.

The Voluntary sector has been particularly active in

- promoting rationalisation at hospital levels in developing Hospital formularies (CHAI-CMAI and Holy Family Hospital formularies);

- starting ADR (Adverse Drug Reaction) reporting cells to monitor drug reactions;

- promoting quality drug manufacture and distribution at low cost through agencies like LOCOST, etc.;

- sensitising professional groups and lobbying with the Government through bodies life the m.f.c. (medico friends circle) AIDAN (All India Drug Action Network) and DAF-K (Drug Action Forum - Karnataka) and DAF-WB (Drug Action Forum - West Bengal);

- creating awareness among professionals and the public through publications like Drug-Disease-Doctor and 'Health Action'; and,

- reaching the consumer to create awareness through many of the above, including the KSSP (Kerala Shastra Sahitya Parishad), AIPSM (All India Peoples Science Movement), DSF (Delhi Science Forum) and other such fora.

The practitioner can contribute towards rational therapeutics by

- being aware and supporting attempts at rationality.

- 'auditing' his/her own prescriptions and practices. Actively looking out for iatrogenic problems. Updating knowledge from unbiased sources. - believing that the patient's right to information and a firm adherence to medical ethics is the basis or rationality.

- deciding that if drugs are the appropriate therapeutic option. GIVE THOUGHT TO THE IMPLICATIONS OF THIS DECISION.

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I.M.A. Rohtak

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Drug Divide

GURINDER OSAN

Drug cocktails have reduced AIDS deaths in the West by 75%. In poor countries victims die in six months or less because of high cost of drugs. 95% patients are in poor nations

Leading lights of the scientific community, economists and non-governmental organisations are calling for a rethink on the issue by policy makers. Even if faint, there is an echo in ministerial chambers where two major policies are being formulated: the national health policy and the drugs and pharmaceuticals policy. For the many organisations and individuals involved in the TRIPs battle, the more important document is the Patents (Second Amendment) Bill 1999 which has been sent to the joint parliamentary committee.

Udyog Bhavan, headquarters of the commerce ministry, is being inundated with representations — accompanied by vast documentation — from different quarters. Among those beating a path to the commerce minister's office is the Indian pharma industry, which fears that unless the regulatory safeguards are in place — particularly the Patents Bill — the outlook would be rather grim. Four years down the line, India will have to accept product patents instead of just process patents as is the case today.

Elsewhere, earnest confabulations are taking place to put together a strategy that will help developing countries adopt the right strategies to outflank the MNC lobby. There's a sense of urgency as a top-level MSF delegation arrives in Delhi for a series of meetings with officials and NGOs involved in the TRIPs campaign.

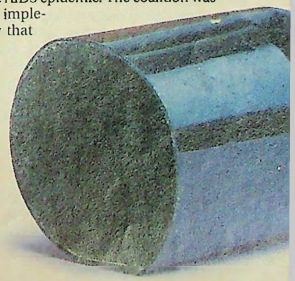
These are turbulent times for the global pharma industry.

The most serious fallout of the patent regime is the increasing gap between those who can buy medicines and those who cannot. For the most vulnerable population in poor countries, essential drugs are becoming far too costly

Africa is only one area of conflict; in the Americas, a more crucial battle is under way. The US has taken Brazil to the disputes settlements body of the WTO over what it claims is a violation of the TRIPs agreement. The Americans want Brazil to drop the compulsory licensing provisions in its patent laws, provisions that the latter claims are fully in line with the letter and spirit of TRIPs. The battle is over Article 31 of the TRIPs agreement.

This is a test case that is being watched with as much concern in Delhi as in Brasilia. It's not merely on account of the burgeoning collaboration on health and pharma issues between the two countries. Brazil and India, it is generally accepted, will be facing the brunt of the legislative assault from the rich countries because both have a well-developed domestic industry. The Aurangzeb Road embassy of Brazil is thus a focal point for officials and pharma industry executives.

The confrontation with Brazil has major implications for TRIPs and the drug MNCs who are losing face — and key patent battles. Soon after they caved in on the price issue, the pharma giants conceded defeat on a more substantive issue. On 19 April, a coalition of leading pharma companies dropped a landmark suit against a South African law enacted in 1997 to help it fight the AIDS epidemic. The coalition was set on preventing the implementation of the law that would have allowed South Africa to import cheaper versions of patented AIDS drugs or the manufacture of generic versions of these high-cost formulations.



The withdrawal of the case may have been a tactical retreat.Or it may have

Industry Prescription

The IPA has its own views on what the patents bill should contain

LATHA JISHNU

IF there are still many bureaucrats in the commerce ministry who have not heard of Articles 7, 8, 30, 31 — in fact, the entire gamut of regulations — of the WTO agreement on TRIPs, it would be surprising. In recent months, the Indian Pharmaceuticals Alliance (IPA) has been producing a steady stream of representations and documents in the emerging issues on the patent battle.

DILEEP PRAKASH

B.K. Raizada, senior vice-president, Ranbaxy: the TRIPs expert

The IPA brings together the big names in domestic pharma: Ranbaxy, Dr Reddy's Labs, Cipla, Cadila Healthcare, Alembic, Lupin Laboratories, Nicholas Piramal India, Sun Pharma, Wockhardt, Unichem Laboratories and Torrent Pharmaceuticals. They account for 30% of the domestic market, a similar share of the exports, and almost the entire (92%) Rs 255-crore R&D spend.

Dilip G. Shah, IPA's secretary-general, says that the forum's primary agenda is to help bring in a patent regime that will conform to TRIPs but will primarily serve the national interest. Although it is lobbying actively to whittle down the price controls on drugs, IPA's focus is the Patents (second amendment) Bill 1999 that is now before the joint select committee of Parliament.

Its worry: several amendments proposed in the bill would have a serious impact on the domestic industry. For starters, there's the issue of patentability. Given the trend in the US of extending the patent life without the involvement of any new technology, the IPA has warned policy makers that product patentability should extend only to new chemical entities and not to their formulations or usage.

The omissions are equally grave. Foremost among them is compulsory licensing for local working of a patent. Although TRIPs allows flexibility on compulsory licensing to address urgent issues and national healthcare concerns, the proposed Indian legislation has been timid on this score. To remove this lacuna — experts like James Love of the US-based Consumer Project on Technology believe it could severely affect developing countries — the IPA has been beefing up its arsenal of arguments.

The association has been bombarding the ministry with laws enacted in other countries to provide for compulsory licensing under different circumstances. The IPA — and NGOs — believe this is an effective instrument for keeping healthcare costs down. Brazil has demonstrated this, but it appears that the US case against the South American country has given bureaucrats cold feet on the issue. The IPA's efforts have thus been directed at showing that the US itself has resorted to this measure time and again.

The abuse of monopoly is another worry for the IPA — the bill has failed to specify what would constitute abuse. Countries such as Brazil, Israel and China have provisions saying that inadequate production at affordable prices would qualify as abuse. Strong deterrents must be in place to prevent abuse, say IPA members.

DINESH KRISHNAN

Dilip G. Shah, secretary-general, IPA: industry voice

The moving force behind the patent initiative is B.K. Raizada, senior vice-president, Ranbaxy, who is the acknowledged expert on TRIPs. "We're missing the point on many issues. On data exclusivity, the Bolar exception in particular," warns the executive, who examines TRIPs issues with a fine toothcomb. What's at stake is the right of a country to undertake R&D.

The Bolar exception is intended to allow pre-patent expiry work leading to the development of products. The Indian amendment has enunciated a fixed period of just three years before the patent elapses when research and development can begin. "This is surprising, since no country, not even America, has included such restrictions in its regulation. This would seriously impede the development of science and technology," warns Raizada.

For an association that believes the pharmaceuticals industry is always up against a hostile government, the IPA has been rather effective in persuading the authorities of the critical role it can play under a more stringent patent regime. It has managed to secure a Rs 150-crore funding from the finance ministry to advance R&D as part of its grand strategy of moving to an R&D spend of Rs 1,500 crore by 2005. The IPA is clearly making its voice heard in the corridors of power.

But whether it will succeed in getting the drug control order relaxed is another matter. This, claims Shah, is a major impediment to the growth of pharma companies and would leave them far too weak to take on the MNCs. Currently, the government is in litigation with over 100 drug companies for overpricing. "How do you expect a strong pharma industry when the CEOs are all busy with court battles?"

been a secret deal struck with the South Africa government to keep cheap imports in return for cut rate AIDS medicines by the patent holders. Whatever the reasons, the backing down by the giants has opened up the familiar arguments about TRIPs.

The most serious fallout of the patent regime, according to its critics, is the increasing gap between those who can buy drugs and those who can't. As MSF points out, two different worlds exist in healthcare. In industrialised nations, there is a huge choice of medicines. But for the world's poorest and the most vulnerable lot (one-third the total population), essential drugs are too expensive or aren't available. In the impoverished parts of Asia and Africa, the drug divide is sharper: half the population doesn't have access.

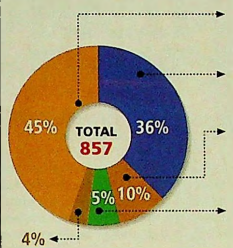
Is TRIPs to blame? Research compiled by campaigners worldwide would appear to reinforce the claim that the patent regime, which is intended to stimulate innovation and give access to new medications, has only 'conferred multiple and additive protection to prescription (branded) drugs'. The result: delayed entry of cheaper generic drugs. This is the finding of the National Institute for Health Care Management (NIHCM) Foundation, a Washington-based NGO seeking improved medicare for Americans.

It warns that efforts to increase patent protection will go up as manufacturers try to protect the $20 billion worth of drugs going off-patent over the next five years. The foundation's concern is not about access to medicines for the impoverished of the world; its agenda is the rising cost of healthcare in the US, which it believes is on account of the laws passed by the US Congress to prolong the effective patent life enjoyed by prescription drugs.

The pricing power provided by patent protection has certainly given the pharma industry an enviable position. It is the most profitable. According to a Fortune 500 profitability analysis, pharma posted 14.7% net profits as a percentage of assets while net profits were as high as 18.3% on revenues (1999 figures). The nearest competitor was the beverages industry with 11.1% and 10.1%, respectively.

As for the most common argument that patent protection is vital for drug breakthr-

60% Of New Drugs Approved By FDA In 1990-1999 Contained Existing Active Ingredients



Source: FDA/Center for Drug Evaluation and Research 2000

Graphics: SAYANTI DATTA, AMPIT SHARMA

R&D Is Not The Big Tab

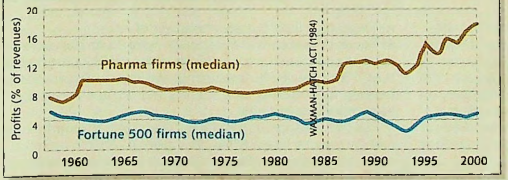
(1999 data, as percentage of sales)

	R&D	Marketing & administrative
Bristol-Myers Squibb	9.1%	34.6%
Eli Lilly	17.8%	27.6%
Glaxo-Wellcome	14.6%	35.2%
Merck	6.3%	15.9%
Pfizer	17.1%	39.2%
SmithKline Beecham	9.7%	46.1%

Source: Consumer Project on Technology (based on company SEC 10K filings and annual reports)

Pharma Industry Profitability Is Soaring

Profitability gap between pharma firms and Fortune 500 firms is growing



Source: Prime Institute 1999, Stephen Schondelmeyer, data from Fortune 1958-2000

The Cost Of Patents (Rs)

All countries, except India, have product patent; India recognises only process patents

Drugs/brands	Patent holder	India	Pakistan	Indonesia	UK	US
Ranitidine (Zantac) 150 mg X 10s	GLAXO	7.16	127.08	142.68	339.45	739.60
Times costlier			(17.75)	(19.93)	(47.41)	(103.30)
Diclofenic (Voltaren) 50 mg X 10s	CIBA-GEIGY	5.64	69.38	47.96	132.86	505.68
Times costlier			(12.30)	(8.50)	(23.56)	(89.66)
Piroxicam (Dolonex) 20 mg X 10s	PFIZER	24.64	97.23	61.32	254.04	1,210.88
Times costlier			(3.95)	(2.49)	(10.31)	(49.14)

Source: US (Red Book 98); UK (MIMS June 98); Pakistan (Pharmaguide Mar 98); Indonesia (IMS No. 1, 98); India (Drug Index 98)

Of the 1,223 new drugs developed between 1975 and 1996, only 11 are for the treatment of tropical diseases. Several have become orphan drugs because the drug companies don't find them profitable

'You can't have the same rules for all. There must be a TRIPs North for the developed world and TRIPs South for the developing countries'

Yusuf K. Hamied, chairman & MD, Cipla

oughs and innovation, the scepticism is mounting. On the one hand is the break-up of expenditure: *Fortune*'s analysis is that R&D accounts for a significantly low proportion of costs incurred by drug firms in launching new products in the market (see 'R&D is Not The Big Tab'). It's promotional costs that add heavily to the tab.

Besides, studies show that most drugs were developed at public expense. A World Bank study puts R&D expenditure currently at an estimated $70-90 billion. Half of this is funded by the taxpayer. For instance, the AIDS drug stavudine was discovered in 1966 by Yale University on a grant given by the government. So were four other AIDS drugs.

If these are known arguments, what has changed? In the early 90s, the anti-TRIPs lobby did not count for much. It comprised scattered NGOs, and little-known activists. Today's campaigners may belong to the same genre but they cannot be taken lightly. MSF has a Nobel Peace Prize tag (1999) and in the last two years it has transformed itself into a formidable lobbyist. Aligned with it are outfits like the Consumer Project on Technology (CPT), a non-profit research and advocacy organisation set up by legendary consumer activist Ralph Nader. There are half-a-dozen other heavyweights among the campaigners.

Moreover, a host of UN organisations are taking a humanitarian view on the patent debate. The UN itself, following the new gloves-off approach adopted by secretary-general Kofi Annan, is encouraging the wider use of cheaper generic alternatives to branded drugs in the fight against HIV/AIDS. Annan has also praised Brazil for its exemplary public health campaign against AIDS — a campaign that relies on generic drugs and mandatory local manufacture. And, Unaids — the agency set up to fight the scourge — is backing MSF and Oxfam in their anti-MNC stance.

The issue has overshadowed discussions in other forums too. The World Health Organisation (WHO) strongly favours policies that encourage the production of generic medicines and believes that implementation of TRIPs should take into consideration the health concerns of different nations. The sharpest indictment was made by a sub-committee of the UN Commission on Human Rights which noted that the TRIPs agreement is a contravention of the international human rights law.

R.A. Mashelkar, one of India's top scientists, is not surprised at the groundswell of support for reviewing the TRIPs provisions relating to pharma. Mashelkar, director-general of the Council for Scientific & Industrial Research (CSIR), is a member of the Committee for Intellectual Property Rights set up by the UK government to examine the working of TRIPs. Such a move by a developed country which is home to some big pharma companies (GlaxoSmith-Kline Beecham and AstraZeneca), he believes, is a signal that there are growing and serious concerns over TRIPs.

These concerns relate primarily to the price and accessibility of drugs. Increased patent protection can, and does, mean higher costs for consumers and governments (see 'The Cost Of Patents'), and it keeps life-saving and essential drugs out of the reach of vast sections of the population in impoverished countries. Other worries are:

- Local manufacturing will be put under controls and remove a vital source of generic, innovative drugs that poor countries depend upon. India is a prime example of this.
- There is no incentive to encourage research on diseases that afflict the poor, such as tuberculosis and malaria. It is estimated that 97% of the deaths from communicable diseases occur in developing countries and the burden it imposes on their economies is devastating.

All this is happening when old diseases are re-appearing and are proving resistant to existing drugs. Amidst such concerns, are sinister new threats. Not from new diseases but from the pressure that the developed world is putting on developing countries to implement stricter patent legislation than is required under TRIPs. The new TRIPS-plus legislation is lethal for poor countries. It excludes safeguards such as compulsory licensing or parallel imports (shopping globally for the cheapest source of patented products) that are available in TRIPs to offset the negative impact of patents. In western Africa, the stringent legislation was forced upon 15 countries, most of whom are least developed countries!

TRIPs-plus is not the only threat. There is the problem of evergreening, a strategy used by drug firms to increase the patent on a molecule by deriving new products from compounds or introducing a 'purified' form of the drug. The

'We should use this momentum to prise open the TRIPs agreement, and question the issue of patents on drugs. It must not be reduced to a quibble'

Amit Sen Gupta, secretary, NCCDP

DILEP PRAKASH

DILEP PRAKASH

'There should be a clear-cut correlation between the health policy (people) and the drugs policy (domestic industry) with the patent laws'

B.K. Keayla, convenor, NWG on patent laws

Brazil Shows The Way

This country sets an example by giving free drugs to AIDS patients

LATHA JISHNU

JOSE Serra is something of a hero here — and, one imagines, in most parts of the developing world. The Brazilian health minister has come to symbolise the doughty spirit of a poor country that has taken on a big bully (the US) and the might of drug multinationals. Since January, when the US took the South American country to the disputes settlement body of the World Trade Organisation for alleged violation of the TRIPs agreement, Serra has gone on a diplomatic offensive. He has taken the issue to the World Health Organisation and the UN Human Rights Commission and got their backing for the right of poor countries to access cheap medicines.

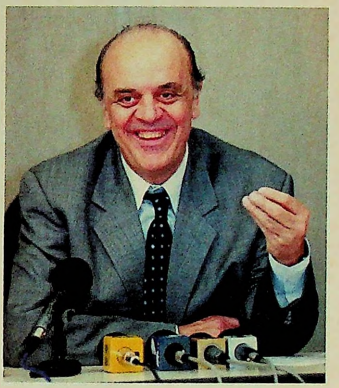
Brazil's rallying cry — and one that has worsted MNCs like Merck — is that the price of a drug should not determine whether people live or die. When the AIDS crisis erupted in the 90s, it was one of the countries most at risk with the fourth-highest number of HIV/AIDS patients. The WHO forecast that it would have a total of 1.2 million patients by 2001. But an exemplary public healthcare programme (cost: $300 million last year) has kept the figure to just 531,000. The death rate has been cut by half and it has saved $472 million in hospital costs.

At the core of Brazil's success is its ability to supply drugs free to AIDS patients. By locally manufacturing drugs at a fraction of the cost charged by MNCs, the country was able to cut costs by $200 million a year. It also imports drugs at the best price going and has bought substantial quantities from India.

With a $10-billion market for pharma products, the fifth-largest in the world, Brazil is a lucrative proposition for MNCs. But its vibrant public sector makes it a tough market to crack. After these firms began generic production of the anti-retroviral drugs that keep AIDS patients alive, the prices of equivalent branded products fell by as much as 80%.

But the WTO case which was initiated in May last year has put a question mark over Brazil's healthcare and drugs policy. The US believes Article 68 of Brazil's patent law — it provides for compulsory licensing and local manufacture of a patented product if it is not made within three years of a license being issued to the patent holder — violates TRIPs. Washington insists the dispute is not about healthcare or access to drugs but about a discriminatory regulation.

No developing country, least of all Brazil, is buying this. An indignant Serra says what's bothering the US is his country's policy of producing generic drugs. And the fact that it keeps a strict control on drug prices. Brazil's patent laws are completely TRIPs-compliant, explains Vera Barrouin Machado, ambassador to India. "The WTO case has become a showpiece conflict because it undermines what is possibly the best AIDS programme in the world."



Brazilian health minister Jose Serra believes that poor nations have a right to cheap drugs

In a response to the US trade representative, Serra points out that Article 68 sets two conditions for compulsory licensing: one, if production of a drug has not taken place after a period of three years, and two, when prices of certain patented drugs are considered an abuse of monopoly. Brazil has not resorted to the use of either proviso so far. It's only the generic production that has prompted the US action.

Besides, the US itself has a provision for compulsory licensing and has used it as a remedy for anti-competitive prices, specially in the case of mergers in the pharma industry. At a recent seminar in Delhi, legal experts from the US were of the opinion that Brazil would win its case because the TRIPs rules allow the use of compulsory licensing under Article 31 although it does not specifically use the term. Jerome Reichman, professor of law at Duke University, says: "On compulsory licensing you simply cannot fight a government that's decisive. Brazil is clearly that or you wouldn't have seen Merck drop prices so sharply."

Indian industry is also betting on a favourable outcome for Brazil. B.K. Raizada, senior vice-president of Ranbaxy, which was the first Indian company to set up shop in Brazil, believes that the US will back off for two reasons. Apart from the fact that the US also resorts to compulsory licensing, a bill was introduced in the US House of Representatives on 3 May, to provide for compulsory licensing of certain patented products relating to health. In short, the US position is untenable.

Raizada says Brazil's example has to be emulated on another count: it has a proper healthcare system in place and a public sector that has to face global competition. This is what gives the country an edge in coping with the kind of emergency it faced on AIDS. Which might explain how Brazil has the strength to take on a superpower.

US, not surprisingly, has taken the lead in this case.

For countries like India and Brazil, with a large domestic industry, the pressures are expected to mount. Brazil is on firmer ground because of well-considered regulations ('Brazil Shows The Way'), whereas India, with none of the critical laws and policies in place, is on a sticky wicket. Among the worries: the patent law doesn't have a provision for compulsory licensing for local working of a patent which is critical for maintaining an affordable health system. Nor does it address the issue of data exclusivity.

Cipla's Hamied believes the solution is to seek renegotiation of TRIPs. "There must be a TRIPs North for the developed world and its 600-million population and a TRIPs South for the over 3-billion population of the developing countries. You can't have the same rules for the two worlds." Hamied takes a rather extreme stand: if renegotiation of TRIPs doesn't work to India's advantage, it should quit the WTO.

Few would go along. The domestic drug industry is convinced it would be suicidal for India to seek the reopening of TRIPs. The strategy, instead, should be to have in place a strong patent law that would ensure the safeguards embodied in the TRIPs agreement. The domestic industry, which is as unhappy with TRIPs as the developing world although for different reasons, is seeking a regulatory framework that will encourage local production, support exports to global markets, ensure equity in pricing regulations and provide incentives for R&D.

Production of eflornithine, a drug used to treat sleeping sickness, was stopped in 1995 because it wasn't making a profit. The active ingredient is now used in a vanity product meant for removing facial hair

Such a strategy has the backing of economist James Love, who works for CPT. He insists that TRIPs "is actually fairly liberal in terms of government decisions to authorise third parties to use patents without the permission of patent owners." The moot point is national legislation to cover this eventuality. But what TRIPs permits and what countries actually do are two different things. Ultimately, it is national law and practice that will be decisive, both in terms of providing access to inventions, and in establishing the legal framework in which TRIPs rules will be interpreted. Love's tip: "No developing country should have statutory public use provisions that are weaker than American, German, Irish or UK provisions."

This is exactly what the newly-formed Indian Pharmaceutical Alliance (IPA), which clubs 11 of the top R&D-based drug manufacturers, is seeking to do. Dilip Shah, secretary-general of IPA, believes that the forum is lobbying for a balanced policy (see 'Industry Prescription') on patents. "Opening up the whole gamut of TRIPs negotiation would subject the developing countries to more intense pressure from the developed world for doing away with the present safeguards," warns Shah, who worked in Pfizer India for three decades before setting up his own pharma consultancy.

On this issue at least, the IPA shares common ground with the MSF which believes that TRIPs should be harnessed to serve development goals. So, while MSF will push for implementation of the existing safeguards in the agreement, it will pin its hopes on public funding for drug R&D to meet public health requirements of poor countries.

James Orbinski, former president of MSF, who is currently spearheading its efforts to find drugs for forgotten diseases, advocates a global health security tax to fund R&D. This will entail a multilateral treaty to tax drug sales in the richest markets (the US, the European Union and Japan) to provide funds for Third-World diseases.

MSF is creating a not-for-profit fund of $1 million (70% from public funding and the rest from private NGOs) for drug development. It is also pushing for a treaty on burden-sharing of neglected diseases to stimulate R&D. This means that the cost of research and capacity-building will be shared equitably on researching diseases prioritised according to public need.

This Pricing Tack Will Work

TO EACH according to his or her need. This dictum has rarely been tried in healthcare, much less in the pricing of drugs. Patented drugs, especially, are priced exorbitantly, thus keeping them out of reach of the common man in poor nations. Differential pricing is an effort to do away with uniformity and introduce prices according to the purchasing power of the people in that country. Sensible as it may sound, differential pricing is far from easy. Research shows that those who can least afford to pay for drugs out of their pocket pay the most. Public spending on healthcare in developing nations is poor. Just to take some examples, the public share of healthcare spending is 95% in the UK, 45% in the US and 78% in Japan. This is compared to 20% in Vietnam, 15% in Pakistan, and 20% in Nigeria. It's a paltry 10% in India.

Such lopsided spending has an effect on the health of the people in these countries, where two-thirds of the children under 15 die from seven preventable communicable diseases, for which treatment also exists. One of the reasons for this is the high-priced drugs, the others being lack of rational selection and use, sustainable financing, and a reliable health and supply system. High prices have an impact on household expenditure in poor nations. Drugs form the main component of a household's healthcare spending. WHO research shows that in poor nations, 50-90% of a household's health expenditure is on drugs. To take two extreme examples, 85% of an Indian's health expenditure is on drugs, while it's less than 5% in the UK. But one of the problems is that drug development is almost entirely in the hands of private firms, who write the entire project cost into the price of a drug. Also, they price the drug in a way that they recover the project costs in four to five years, which gives them another eight years of profits before the patent expires. So what is the way out?

A WTO-sponsored workshop on differential pricing held last April offers some solutions.The participants discussed mechanisms like financing, concentration of demand through pooled procurement arrangements and elimination of tariffs and taxes, etc. Drug companies agreed that differential pricing was necessary, but they had reservations. Says Mike Rance, senior vice-president (corporate affairs), AstraZeneca: "Our biggest worry is the diversion of the drugs from the low-income countries to the developed markets." ■

P. HARI

For A Human Cause

The AIDS epidemic in Africa forces drug firms to rethink their strategies

P. HARI

WHEN the TRIPs agreement was signed in 1994, it was considered to be the final nail in the coffin of developing countries. In 10 years, TRIPs would have brought IPR laws in all signatories to the same level, and put the drug firms in charge of their products. The year 2005 is nearing, but the outcome is far from final.

The trigger is the AIDS epidemic in Africa, which is rewriting conventional approaches to disease control. There are drugs that reduce mortality and infection, but cost $12,000 per patient a year. Drug firms which made these drugs owned the patents as well, and charged whatever they liked. There was only one way out. Reduce drug prices.

Take the case of South Africa. The South African Patents Act 1978 afforded full patent protection to new drugs. In 1997, the government decided that it wanted to make medicines more affordable, which wasn't possible without amending the laws. The government passed the Medicines & the Related Substances Amendment Act No. 90. It had many controversial provisions — one was very interesting. In English, it meant that the health minister had the power to override patents and give anybody the right to make drugs or import them from sources other than the patent holder.

The country's pharma sector was the first to protest. For months it tried to persuade the department of health to change the amendment, failing which it filed a petition in the Pretoria High Court. The petition claimed that the amendment violated the country's obligations to TRIPs. South African courts decide fast in such matters, but the case was postponed *sine die*.

In 1998, the US placed South Africa on the Special 301 watch list. This was in response to representations by the pharma industry saying that South Africa didn't comply with TRIPS. But this was probably the last measure that the US took against the South Africans. Sympathy for AIDS patients began rising, and there were several signals that even the US government sympathised with the South African action.

AFP

There's still hope for patients in the developing nations

On 1 December 1999, president Clinton announced that the United States Trade Representative (USTR) and the Department of Health and Human Services (HHS) would develop a cooperative approach on health-related intellectual property matters to help poor countries gain access to affordable medicines. He also promised to ensure that the application of US trade law related to intellectual property, such as Special 301, remained sufficiently flexible to respond to legitimate public health crises. It was a major statement and a sign that the US recognised the importance of a different approach to AIDS.

On 27 January 2000, the US sent a letter to Thailand saying they would support the Thai use of compulsory licensing (overriding of patents) to increase access to AIDS drugs. It was another major statement, which meant that developing nations had the option of using this mechanism to dramatically cut drug prices. The letter read: "If the Thai government determines that issuing a compulsory license is required to address its healthcare crisis, the US will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO Agreement on TRIPs."

On 10 May 2000, came another significant order, called executive order 1355. The order speaks for itself: 'The United States would not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country: (1) promotes access to HIV/ AIDS pharmaceuticals or medical technologies for affected populations in that country; and (2) provides adequate and effective intellectual property protection consistent with the TRIPs Agreement. The US shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of, vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa'.

Even the pharma industry felt something had to be done. Pfizer, for instance, said that it would distribute medicines free in South Africa. Five drug firms including Merck agreed to cut AIDS drug prices for African nations. The biggest surprise came from Cipla, which said it would provide AIDS drugs for $350 a year. And the best news came on 19 April this year: all the pharma firms withdrew their petition against the government.

DILEEP PRAKASH

'Intellectual property rights in principle seeks to protect, promote and reward innovation. But it's skewed towards investment interest'

James Orbinski, director, Medicins Sans Frontieres

Is any of this feasible? Orbinski, who was president when MSF was awarded the Nobel Prize, is convinced that "the clear moral argument that appeals to human dignity and human values" will ensure the success of the access campaign. He finds that the three factors that propelled the campaign against landmines to victory are present in this case too: a strong coalition, a morally-compulsive argument and the political opportunity for wresting a bargain.

Orbinski's calculations may err on the side of naivete. Ranged against the access campaign and developing countries is a formidable opponent: an industry that makes no bones about its profit motive and its determination to increase those profits at all costs. This is not an accusation but a statement of intent that comes from the pharma industry itself. Its most influential spokesman is Philip Brown, publisher of the highly-regarded *Scrip* magazine, which reflects the views of the R&D-based pharma industry.

In a recent issue of *Scrip*, Brown says witheringly that "treating Third World illnesses is not the core business of the international pharmaceutical industry." He points out that for the industry, the market is the developed world where patent protection gives it "rights to charge the prices needed to sustain its activities." More important, its agenda is to treat the diseases of the western world — cardiovascular, neurological diseases, cancer and problems associated with the western lifestyle. AIDS, he argues, is a disease which spans both rich and poor countries and, hence, the problem. But primarily "pharma companies are businesses and not charities", says Brown. Thus, around 1.5 billion people benefit from its R&D; 4.5 billion people do not. Blunt and unpalatable as Brown's views may be, there's no debate on his most caustic observation: "The pharma industry is not a substitute for a country's national health service."

This is specially true of India. The government is yet to set out its public health priorities; the last policy was enunciated in 1983 under Indira Gandhi's premiership and some diseases mentioned in it have disappeared. Nor does the country have a drug policy or even a list of what it considers essential drugs. According to indications from the ministry of health, a draft national health policy is almost ready and is expected to be circulated shortly.

B.K. Keayla, a retired bureaucrat who has been spearheading the campaign for a fairer implementation of TRIPs through the formation of the National Working Group on Patent Laws (NWGPL), says India has failed to protect its national interest because it has not understood the correlation between the health and the drugs & pharma policies and the patent laws. The two, he argues, should be in place before enactments or amendments to patent laws are made to make them TRIPs-compliant.

But one should not be carried away by anti-TRIPs rhetoric, cautions Zafar Mirza, a doctor working with an Islamabad-based NGO. Mirza, who is in India to share Pakistan's experience post-TRIPs, says blaming TRIPS for each and every problem is passing the buck. The executive coordinator of Pakistan's Network for Consumer Protection points out: "TRIPs is an important factor in the health mess in developed countries, but there are hundreds of others. Government failure, for starters. We should not let our policy makers get away by blaming an international agreement for all the ills of our health system."

'The costs of drugs can be brought down if the drug development process shifts from developed countries to the developing countries'

R.A. Mashelkar, director-general, CSIR

DINESH KHISHNAN

For most crusaders though, the important issue now is to stay focused on the agreement. It isn't as if the MNCs have given up the fight. NGOs say the pharma giants will be putting pressure on their governments, most of all the US, to make it extremely difficult, if not impossible, for developing countries to use the exclusions and other safeguards in TRIPs. Therefore, 'the tremendous evocative appeal of the access campaign', should be used to delegitimise TRIPs. Their fear is that the pharma industry will try a damage-limitation exercise by making the AIDS campaign an exception; other essential medication would thus be left to the mercy of the patent regime.

Rapidly, however, the air is growing thick with talk of Article 8, 31, and the handful of TRIPs regulations that will be tested soon. It's the outcome of these legal battles that will determine the future of the global patent regime. Sen Gupta says there's no time to be lost. "The pharma industry has never been so defensive as it is now. Never before has public perception been so hostile to it, and never before has such a wide global unity been forged on the issue. Can we seize the moment?"

Can we indeed?

(With reports from R Hariharan)

DINESH KHISHNAN

'What TRIPs permits and what countries actually do are two different things. Ultimately, it is national law and practice that will be decisive'

James Love, director, Consumer Project on Tech.

AstraZeneca Steps Up

The first MNC to set up an R&D centre in India for a Third World disease

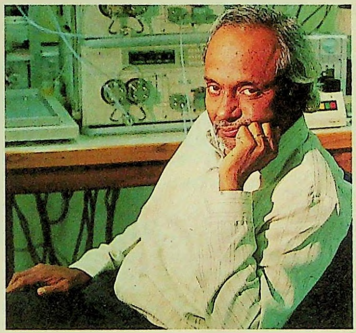
P. HARI

THE last thing you would associate the lush, tree-lined campus with is danger. But tucked away in a corner of the AstraZeneca R&D centre in Bangalore is one of the most dangerous places on earth. In a small building next to the main one, scientists wear special suits and oxygen masks while working. What's cooking?

In one of the rooms here, researchers spray the air with tuberculosis bacilli: the idea is to infect rats with TB of the lung. The sick rats become invaluable models to study the disease. AstraZeneca has invested $10 million in this facility, and plans to invest $5 million every year.

This is the first R&D centre set up by a pharma multinational in India to develop drugs for a disease of the developing world. Private companies have made some efforts on TB, the most notable being Glaxo Wellcome's Action TB initiative, where it pledged $32 million (to be spent in the UK, South Africa and the US) to develop a drug at an early stage of clinical trials by 2003, with a back-up molecule. But these are small efforts compared to the billions of dollars spent on diseases of the developed world. Hardly any company has set up an R&D centre in a developing country for a Third World disease.

In the next few years, about 60 scientists here will use cutting-edge technology to study the TB bacteria. They will use information from the TB genome (sequenced recently) to identify targets to attack in the bacterium. They will screen thousands of candidate molecules, using state-of-the-art, high-throughput techniques. The aim is to generate a few candidate drugs by 2005. Says T.S. Balganesh, AstraZeneca vice-president and head of research at the R&D centre: "The drug discovery process for TB is very old. We want to optimise it and get some new targets soon."



NAMAS BHOJANI

T.S. Balganesh, head of research at the R&D centre: joining the fight against the killer disease TB

An unfortunate paradox exists in drug research on TB, and it probably extends to any disease of the Third World. For a big multinational, developing new TB drugs do not make much commercial sense. The World Health Organisation estimates the TB drug market to be about $200-300 million. Most best-selling drugs have markets of a few billion dollars. The cost of developing a new drug can run into several hundred million dollars. Why should a private company invest so much?

Yet, the world urgently needs a new TB drug. The disease is the leading cause of death due to a single infectious organism in the world. There are 8-10 million new active cases of TB each year and approximately two million deaths. One-third of the world's population (1.7 billion individuals) harbours the bacterium, although not everyone develops the disease. TB is treatable, but world rates of tuberculosis are predicted to increase by approximately 50% each decade. Says Ashok Rattan, director of microbiology at Ranbaxy's new drug research programme: "What we need is a drug which can reduce the time of treatment from the present six months to about two months."

The TB bacillus is smart. It lies inside a type of cell called macrophage (it's supposed to defend us from intruders), which drugs can't reach easily. It isn't just inside the macrophage, it is inside a part of it called the vacuole. Since vacuoles are present inside most cells, it's a challenge to make a drug that can penetrate the vacuole, yet be non-toxic to everything except the TB bacteria.

There are other challenges. The bacterium divides every 23 hours, unlike 20 minutes for most other bacteria. This means that the drug has to be present in the body for a longer time. Most drugs have a half-life (the time it takes for 50% of the drug to be eliminated) of an hour, which is not adequate in this case. But a drug that is present in the body for a longer time has to be less toxic. This means that we need a drug which kills rather than inhibits the bacterium but works at very small concentrations. The drug researcher has to cleverly use cutting-edge science to take care of all these variables. To complicate matters, these efforts may not make the researcher much money, as the market is highly subsidised.

AstraZeneca's lab in Bangalore has earlier developed diagnostic kits for TB and malaria. So, when the company's management in the UK asked the lab to work on a developing country disease, it immediately chose TB. The Level-4 facility also helped. Most facilities in the world use injections rather than aerosol sprays, and the rats develop TB of the spleen instead of the lung. Since humans usually get TB of the lungs, using aerosol is a better way of studying the disease. In fact, observers say that the AstraZeneca facility is the place to watch for the development of next anti-TB drug. Let's.

The New Drug Policy

In August 1992 the Government, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilisers circulated a note to members of parliament regarding proposed changes in the 1986 Drug Policy. This was interpreted as an introduction to the New Drug Policy and was used by the industry to focus on its demands to fewer controls and higher margins of profitability. After more than two years the Government has finalised the draft for a new policy and has clearly decided to go along with demands of the industry.

With absolutely no change in the number of hazardous drugs in the market, no effort at ensuring unbiased drug information on ethical marketing practices and no improvement in quality control or drug legislation, the Drug Action Forum, Karnataka, All India Drug Action Network and National Campaign Committee for Drug Policy have felt the need to file a petition in the Supreme Court of India on behalf of all drug consumers of India. By this, the petitioners seek to enforce the fundamental rights of drug consumers under Article 21 of the Constitution for being protected against hazardous drugs and for information about hazardous drugs which are being manufactured and sold in India.

The petitioners have prayed to the court that it must give appropriate directions to the respondents to ensure that banned and harmful drugs are not manufactured or sold in India and that the consumers are properly informed and educated about them. The following are the details of the petition:

Petition

* issue appropriate writs and directions to the Respondents
* directing the union of India and the Drug Controller of India to make appropriate rules to ensure that the chemists and druggist prominently exhibit the list of banned drugs;
* directing the union of India and the Drug Controller to ensure that manufacturers of drugs print and attach with the product in vernacular language the caution statement and contraindications of the product;
* directing the Union of India and the Drug Controller to ensure that publishers of Current index of Medical Specialities (CIMS) and Monthly Index of Medical specialities (MIMS) publish the trade names of banned drugs and do not recommend banned drugs, and publish along with the products particulars and caution statement and contraindications;
* directing the Drug Controller of India to send all Medical Centers and Medical colleges in India notifications of banned drugs and caution statement and contraindications of such drugs notified by the Drug Controller;
* directing the Union of India to ensure that the electronic media such as TV and Radio broadcast periodically and as often as necessary information regarding banned drugs in generic names and in brand names;
* directing the Drug Technical Advisory Board to meet regularly to review and recommend the banning of drugs and make their reports public;
* directing the Union of India and the Drug Controller to implement the ban orders and prosecute those persons responsible for flouting the orders in a time bound manner;
* directing the Union of India to take immediate steps to get vacated any stay orders in other courts which is impleading the implementation of the ban orders of the Government;
* pass any other or further order/s as this Hon'ble Court may see fit and proper.

November 17 '94 hearing

The Bench comprising Mr.Justice J J Verma and Mr.Justice K S Paripoornan indicated that the court would like to appoint an expert committee of eminent and credible specialists to go into the whole question and make a report to the court. The next hearing has been fixed for the 9th of January '95. The proposed commission consists of Dr.N H Antia, Dr.Naresh Bannerjee and Dr.Nityanand.

Drug Action Forum, Karnataka

these laboratories. Separate vigilance cell should be created under Drug Control machinery to watch quality of medicines.

Irrational and Hazardous Drugs:

All irrational and hazardous drugs should be withdrawn. Registration system needs to be revamped. All drugs should be re-registered within a regular interval for establishing their therapeutic validity.

Research and Development:

Govt. should involve the research establishments of its own with adequate fund and encourage them for developing cost effective process technology. Any private company which develops new molecules should be encouraged for marketing their drug in the domestic market at cheaper price. Only with this condition, they may be given grants from

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the Govt.

Third Party Licenses:

The Govt. should abolish Loan/Third Party License system.

Prices:

All drugs under EDL shall be price controlled. Control of price of other drugs should also be covered and mark up shall be kept low based on the annual turnover

Providing of cost data by the manufacturers should be mandatory. Any violation of price fixed shall be entitled to sever punishment.

Prices of imported drugs should also be controlled based under the import price documents. Imported medicines may draw more duties than indigenously produced drugs.

Wholesale and retail margins should be determined by the Govt. which should be strictly followed. Like over pricing, under pricing should also be disallowed. Incentive, trade bonus should only be allowed in such a manner that would finally reduce prices to the consumers.

Prices of medicines should be net of taxes and shall be uniform all over the country.

Setup like NPPA should be strengthened with sufficient staff and statutory power.

Pharmacy Act:

Pharmacy Act should be amended so that each shop employ full time qualified pharmacist. More pharmacy colleges should be established to produce adequate number of qualified pharmacists. Preference should be given to qualified pharmacists for granting license to open retail chemist shops.

Pharmaceutical Authority:

A national Pharmaceuticals Athority should be constituted for monitoring production, selection of drugs, pricing, monitoring research, withdrawal of drugs. This committee should include experts from medical practitioners, industry, consumers, academics

From: "FMRAI" <fmrai@vsnl.net>
To: "Janswathya Abhiyan" <pha-ncc@yahoogroups.com>
Sent: Thursday, July 22, 2004 5:58 PM
Subject: [pha-ncc]

Dear All,

Giving below a scetch about our position on the drug policy which may be presented before the Ministry. This is a pruned thinking which may be remodelled based on the suggestions of JSA meeting and then it may be made specific on each points. This is being proposed for discussion in the JSA meeting at Bhopal.

Amitava

Pharmaceutical Policy:

Last couple of years Govt. has taken executive decisions in rapid successions for which the first Drug Policy, 1978 has been thoroughly changed. The political good will under which Drug Policy, 1978 was developed is wiped away making the basic tenant of the policy redundant. Present status of the policy reflects virtually scant Govt. control and add to this unwillingness of the past NDA Govt to implement whatever left in the policy has created an anarchy in the pharmaceutical field. It is , therefore needed to prepare and adopt anew policy in the new global regime keeping interest of the people in the foreground

Responsibility:

Excepting industrial part of the policy, all other area should come under the purview of the Health Ministry. Selection of drugs of National Essential Drug List (EDL), quality assurance, Drug Laws etc., should be the exclusive responsibility of the Health Ministry. Issues like drugs prices may be the concurrent responsibility of the Ministry of Chemicals and Fertilisers and the Ministry of Health.

Production:

Govt. used to monitor production of 93 bulk drugs. In order to ensure availability, the Govt. should monitor all drugs which come under national EDL. Govt shall publish production status of all these drugs at least once in a year. Govt. should also establish a cell to estimate need of all the drugs under EDL and should explore shortfall in indigenous production to determine import requirements or expansion of indigenous production. Public sector pharmaceutical units should be given priority for production and a policy to revive this sector should be developed.
A national authority should be constituted for developing policy and monitoring should be prepared which should be provided with statutory power.

National Essential Drug List:

The EDL shops should be prepared by an expert committee every after three years. Experts from different fields of medical profession, consumers, etc.

The list should be popularised with a guideline of use Standard Treatment Guideline) among the users. Its use should be mandatory among Govt., Public Sector Units and for use in reimbursement or for insurance coverage. Drugs under the list should be priced low. Industry should be given incentive for production of these drugs. Prescription of these drugs should be made in generic names.

Quality Control:

Drugs & Cosmetics Act should be amended to ensure quality control. Stringent punishment should be enacted for violation of quality norms. Drug testing laboratories should be established by the Govt. in each states. Consumers of Consumer organisations should be allowed to directly test any drug with doubtful quality with minimum charges in these laboratories. Separate vigilance cell should be created under Drug Control machinery to watch quality of medicines.

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