B-9/329(a)
MS:a 14.12.83

THE GAZETTE OF INDIA: EXTRAORDINARY (PART II-SEC3(i)

NOTIFICATION
MINISTRY OF HEALTH AND FAMILY WELFARE
New Delhi, the 23rd July, 1983

G S R 579(E)--- Whereas the Central Government is satisfied that the use of the drugs specified in the Table below is likely to involve risk to human beings or the said drugs do not have the therapeutic value claimed or purported to be claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification and it is necessary and expedient in the public interest so to do;

Now, therefore, in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture and sale of the said drugs, namely:-

TABLE

1. Amidopyrine
2. Fixed dose combinations of Vitamins with anti-inflammatory agents and tranquillisers.
3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
4. Fixed dose combinations of Strychnine and Caffeine in tonics.
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
6. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
7. Fixed dose combinations of Sodium Bromide/Chloral hydrate with other drugs.
8. Phenacetin
9. Fixed dose combinations of anti-histaminics with anti-diarrhoeals.
10. Fixed dose combinations of Penicillin with Sulphonamides.
11. Fixed dose combinations of Vitamins with Analgesics.
12. Fixed dose combinations of Tetracycline with Vitamin C.
13. Fixed dose combinations of Hydroxyquinoline group of Drugs except preparations which are used for the treatment of diarrhoea and dysentry and for external use only.
14. Fixed dose combinations of Steroids for internal use except combination of Steroids with other drugs for the treatment of Asthma.
15. Fixed dose combinations of Chloramphenicol for internal use except combination of Chloramphanicol and Streptomycin.
16. Fixed dose combinations of Ergot.
17. Fixed dose combinations of Vitamins with anti-TB drugs except combination of Isoniazide with Pyridoxine Hydrochloride (Vitamin B 6)
18. Pencillin skin/eye ointment
19. Tetracycline liquid oral preparations.
20. Nialamide
21. Practolol
22. Methapyrilene, its salts.

(No. X-11014/1/83-DMS & PFA)

S V SUBRAMANIYAN, jt Secy.

D-9/329(a)
MS;a.14.12.83

THE GAZETTE OF INDIA: EXTRAORDINARY (PART II-SEC.3(i)

PUBLISHED BY THE CONTROLLER OF PUBLICATIONS, DELHI-110054, 1983.

NOTIFICATION
MINISTRY OF HEALTH & FAMILY WELFARE.
New Delhi, the 23rd July, 1983.

G S R 577(E)-- Whereas the Central Government is satisfied that the use of the drugs specified in the Table below is likely to involve risk to human beings or animals and it is necessary and expedient in the public interest so to do;

Now, therefore, in exercise of powers conferred by section 10A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the import into India of the said drugs, namely:-

TABLE

1. Nialamide
2. Practolol
3. Amidopyrine
4. Phenacetin
5. Methapyrilene, and its salts.

(No. X 11014/1/83-DMS & PFA)

S V SUBRAMANIYAN, jt Secy.

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)
1981

findings on drugs and pharmaceuticals

THE INDUSTRY

THE TOTAL output of the industry increased a 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.

(11.03)

PATTERN OF DRUG PRODUCTION

THERE IS now an overproduction of drugs (oftenvery 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.

(11.05)

...2

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

(11.07).

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.

(11.14)

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.

(11.15)

PRICE CONTROL

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

(11.16)

.....3

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

(11.19)

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...

(11.19)

GENUINE 'BREAKTHROUGH' research has declined in recent times.

(11.19)

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.

(11.19)

PRICES ARE often inflated by the use of brand names....

(11.19)

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

(11.19)

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.

....4

QUALITY CONTROL

THE STANDARDS prescribed are unrealistic.. are mechanically copied from books. ....and not unformly 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 perpatient per year while in a Primary Health Centre, it is about 40 paise per patient per year...

(11.22)

.....

STATEMENT SHOWING THE CATEGORIES OF FIXED-DOSE COMBINATIONS RECOMMENDED BY THE SUB-COMMITTEE OF THE DRUGS CONSULTATIVE COMMITTEE FOR BEING WEEDED OUT

A. Categories of Fixed-Dose combi..ations to be weeded out immediately.

CATEGORY	REASONS FOR WEEDING OUT
1. Fixed dose combinations of Steroids	Fixed dose combinations of Steroids with any other category of drugs should not be allowed as they are considered harmful for the following reasons:- (a) The adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly with-drawn. (b) It is difficult to titrate the dose of the steroid when it is present in fixed dose combinations with other drugs.
2. Fixed Dose Combinations of Ami-dopyrine	Ami-dopyrine is considered toxic because:- (a) It causes high incidence of agranulocytosis. (b) In some individuals, it may cause a sharp fall of total leueocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of drug.
3. Fixed Dose Combinations of Chloramphenicol	Fixed Dose combinations of Chloramphenicol with any other category of drug is considered harmful for the following reasons and should not be allowed- (a) Chloramphenicol is the commonest drug which causes pancytopenia and peripheral blood changes including Leucopenia, Thrombocytopenia and aplasia of the bone marrow. This reaction is not related to dose and when done marrow aplasia is complete; the fatality rate is almost 100%. (b) Patients receiving chloramphenicol must be checked repeatedly for blood studies which is however generally done in the case of patients receiving fixed dose combinations of Chloramphenicol.

.....2/-

4. Fixed Dose combinations of Ergot

Fixed dose combinations of Ergot with Quinine, Ethinyl estradial, etc. should not be allowed. Such combinations are considered harmful for the following reasons:

(a) They may cause uncontrollable bleeding and may lead to serious consequences.
(b) They may cause many harmful s ide effects.

5. Fixed Dose combinations of Vits. with anti-inflammatory Agents & Tranquilizers.

Fixed dose combinations of Vits. with anti-inflammatory agents and tranquilizers should not be allowed. Such combinations are considered irrational for the following reasons:

(a) There is no definite role of Vitamins in the management of inflammatory disorders and therefore a fixed dose addition of vitamins in such preparations will be irrational.
(b) Similarly there is no rationale for adding Vitamins to tranquilizers.

6. Fixed Dose combinations of Atropine in Analgesic Anti-pyretics.

Fixed dose combinations of atropine in analgesic antipyretic should not be allowed as atropine may reduce efficacy of antipyretics by blocking sweating response.

7. Fixed Dose combinations of Analgin

Fixed dose combinations of any category of drug with analgin in oral dosage form are considered generally harmful as analgin is potentially a toxic drug and may cause agranulocytosis except for some combinations which may have therapeutic rationale e.g. with neurovitamins. However, fixed dose combinations with analgin in injectable form may be continued to be allowed as these are generally meant to combat an acute attack of pain, and injectables are less likely to be misused.

8. Fixed Dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.

Fixed dose combinations of Yohimbine and Strychnine in a formula containing Testosterone and Vit.B.12 should not be allowed. Such combinations are considered harmful and irrational for the following reasons:

(a) Yohimbine easily penetrates the CNS and can cause central excitation including rise of B.P. and heart rate, hyper-excitability and tremour.

.....3/-

(b) There is no convincing evidence regarding the aphrodisiac effect of Yohimbine and the drug has no proven therapeutic value.

(c) There is no rational basis for the use of strychnine in therapy and therefore no justification for the use of it in any proprietory medicine.

(d) There is a very narrow margin between the therapeutic dose and the toxic dose of Strychnine.

9. Fixed dose combinations of Iron with Strychnine, Arsenic, Yohimbine

Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine should not be allowed as there is no rationale of such combinations and such a combination can cause harmful side effects.

10. Fixed dose combination of Sodium Bromide/Chloral Hydrate with other drugs

Fixed dose combinations of sodium Bromide/chloral Hydrate with any category of drug are considered irrational and harmful for the following reasons:

Use of both Sodium Bromide and Chloral Hydrate have become obsolete, as there safer hypnotic drugs available today and their therapeutic concentration in blood is very close to their toxic levels.

11. Fixed Dose combinations of Tetracycline, Analgin with Vitamin C.

Fixed dose combinations of Tetra cycline, Analgin, etc. with Vit. C should not be allowed as there is no rationale of such combinations.

12. Fixed dose combinations of Ayurvedic drugs with modern drugs.

Fixed dose combinations of Ayurvedic drugs and potent allopathic drugs like Stilboestrol could be very harmful and there is no adequate evidence of safety of the interaction of drugs of these two systems of medicine.

13. Fixed dose combinations of Phenacetin

Fixed dose combinations of any category of drugs with Phenacetin should not be allowed, as the question of banning Phenacetin because of its potential toxicity (nephropathy, methemoglobinemea, hemolytic anemia as a consequenco of chronic over dosage) is under active consideration of the Government.

.....4./-

14. Fixed dose combinations of Chloramphenicol with Streptomycin	Fixed dose combinations of Chloramphenicol with Streptomycin should not be allowed as Chloramphenicol being potentially a toxic drug its use should be kept restricted to enteric fever only.
15. Fixed dose combination of Penicillin with Streptomycin.	Fixed dose combination of penicillin with streptomycin should not be allowed.
16. Fixed dose combinations of more than one anti-histaminics	Fixed dose combinations of more than one anti-histaminics in oral dosage form should not be allowed as the differences between their action is but marginal.

B. Categories of fixed dose combinations to be weeded out over a specified time.

Category	Reasons for weeding out
1. Fixed dose combinations of Anti-histaminics in anti-diarrhoeals.	Fixed dose combinations of sedative anti-histaminics in anti-diarrhoeal preparations may be permitted provided all ingredients are in adequate therapeutic doses.
2. Fixed dose combinations of Penicillin with Sulphonamides.	Fixed dose combinations of penicillin with sulphonamides are irrational for the following reasons: (a) The combination of penicillin a bactericidal drug and sulphonamide, a bacteriostatic drug may cause antagonism. (b) There is risk of development of bacterial resistance to both the drugs.
3. Fixed dose combinations of anti-histaminic with tranquilizer.	Fixed dose combinations of anti-histaminics having patent sadative preparations(for example, diphenhydramine dimenhydrinate, tripelennamines, pyrelamine, Antazolin methapyrilline etc.) with ranquilizers are considered irrational for the following reasons: Such combinations may cause enhanced sedation, which may interfere with the patient's day time activity and dull the mind and slow the reflex activity.

.....5/-

4.	Fixed dose combinations of tranquilizers, Anti-Histaminics and Analgesics.	Fixed dose combinations of Tranquilizers with anti-histaminics and analgesics in oral dosage form are considered irrational for the following reasons:- (a) Such combinations may cause a lot of unwanted sedation, which may interfere with the patient's day time activity and dull the mind and slow reflexes. (b) There may not be many clinical situations which would need a fixed dose combination of these 3 categories of drugs & there will be unnecessary drugging. However, fixed dose combinations of these drugs in injectable form may be allowed as injectables are not likely to be misused.
5.	Fixed dose combinations of Vitamins with Analgesics	Fixed dose combinations of high dose vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination.
6.	Fixed dose combinations of Paracetamol with Anti - histaminics and tranquilizers	Fixed dose combinations of Paracetamol with anti-histaminics and tranquilizers should not be allowed as there is hardly any clinical situation which should demand a fixed dose combination of anti-pyretic, an anti-histaminic and tranquilizer. However, fixed dose combinations of paracetamol with anti-histaminics and paracetamol with tranquilizers may be allowed provided the formula contains an adequate dose of such ingredient.
7.	Fixed dose combinations	Fixed dose combinations of Vitamins in prophylactic doses in anti-TB drugs should not be allowed as such combinations lack rationale. However, combinations having a therapeutic rationale such as INH+ B6 may be allowed.

***

notification to implement this policy was issued only in January 1981. Hoechst and Pfizer, two of the 'affected' MNC, went to the Delhi High Court and obtained a stay order. At present the Government is still debating whether this stay order should be contested.

(2) MNC continued to produce several non-essential drugs far in excess of the licensed capacity. In 1978, the Government decided that in such cases the capacities had to be 'regularised' and it was declared that the new licensed capacity would be fixed as the maximum production achieved in any one year during the 3 years preceding 1977. This effectively condoned and in fact provided legal approval for the unauthorised excess production. The MNC drug lobby which tried to extract further concessions has been demanding that the 'regularisation' should be at the level of production achieved in 1980. The Government has bowed to this demand and recently, in 1981, the Government has decided to regularise all capacities 'liberally' as of September 1981. Significantly, there has been no attempt on the part of the Government to force drug companies to produce at least the licensed capacity of essential drugs many of which are produced in quantities well below the licensed capacity*.

(3) Foreign companies were directed to reduce their foreign equity to 40%. But they were eligible to retain more than 40% foreign equity if they produced 'high technology' basic drugs or intermediates for the production of high technology basic drugs. To identify companies eligible for this concession, the Government appointed a High Technology Committee which submitted its report in 1979, The criteria for eligibility have been so broadly defined that almost any drug company can claim itself to be one employing 'High Technology'. For example, some of the criteria used are—use of toxic materials in production, use of different kinds of sophisticated purification and seperation techniques, etc. Based on such criteria the Government has permitted Hoechst, a leading MNC to manufacture drugs which are already being produced in the small scale sector. The Government has not only ignored the report of the 'High Technology Committee' but also stated recently that 'The need and scope for review of the findings of the Committee..... will be considered in the light of representations received from individual companies concerned'. This is only likely to enlarge the list of companies eligible for concessional treatment.

(4) The Drug Price Control Order of 1979 has resulted in a number of foreign companies reducing the production of vital drugs whose prices have been fixed by the orders**. Simultaneously, the production and prices of drugs not covered by the Drug Price Control Order have increased constantly. In fact diversification of production into areas of low technology, low priority consumer goods has been one of the routine

* For example, the production of the anti-tubercular drug PAS has declined from 482 tonnes in 1979-80 to 405 tonnes in 1980-81 due to under-utilisation of capacity. The demand for the drug continues to be much in excess of 482 tonnes

** The production of the anti-malarial drug Amodiaquin, anti-tubercular drug Thiacetazone and the anti-filarial drug DEC have all shown a decline in the year 1980-81 in comparison with the year 1979-80. One foreign drug company has closed down an entire department making a group of 6 formulations used in the treatment of TB, citing 'continued losses'.

responses of the MNC to any drug price control order. Thus, even earlier, Warner Hindustan had commenced production of chicklet chewing gum and Johnson & Johnson had started producing baby shampoo and baby powder.

The magnitude of the problem

To-day, nearly 7 years after the Hathi Committee produced its report, none of its major recommendations have been translated into practice. The feeble attempts towards a reform, represented by the Drug Policy of 1978 have been largely ineffective, thanks to subsequent reversal of policy by the Government itself and due to the manipulation of legal loop holes by MNC. Recent years have in fact seen a further deterioration of the situation with steep increases in drug prices and the dumping of hundreds of harmful drugs banned for use abroad, into India and several Third World countries.

The Third World countries have not succeeded in their attempts to control their drug industries and make them truly responsive to their people's needs. A striking recent example is the case of Sri Lanka. The Sri Lanka Government in 1971 set up a State Pharmaceutical Corporation (SPC) and implemented a new drug policy. The number of marketed drugs was slashed from 2100 to 600 and brand names were almost entirely (though not totally) abolished. The State Pharmaceutical Corporation took over the import of drugs and achieved 40% savings in just the first 6 months alone. When one of the multinationals, Pfizer, refused to fall in line with the new drug policy, it was threatened with nationalization. The United States ambassador intervened with the Government of Sri Lanka and, in turn, threatened to withdraw the U.S. aid. As a result, the Chairman of the State Pharmaceutical Corporation was asked to 'continue negotiating' with Pfizer and no action was taken against it. Later, when there was an epidemic of cholera, Pfizer was asked to make Tetracycline tablets but it delayed it for so long that the state had to purchase it from abroad at an enormous expense. Finally, the new government in 1977 once again allowed the private sector to import drugs and effectively neutralized the benefits of State Pharmaceutical Corporation.

Third World countries have also failed to support each other in their efforts to fight MNC. For example, India and other Third World countries have been silent on the recent Bangladesh ban order. Even the World Health Organisation has maintained a silence at the current efforts of Bangladesh Government to translate its (WHO's) own recommendations into action. Past efforts have shown that the MNC can bring several sorts of pressure to bear upon even the most committed Government. They can use threats and persuasions from abroad, get their home Governments, to support them, restrict future investments and, above all, use their powerful alliance with local doctors who are used to a powerful drug promotion system. In fact, the doctors and the local elite have accepted radical reforms only in response to popular movements or mass pressure, such as that which had installed a socialist Government in Sri Lanka in the election of 1970. In the case of Bangladesh, the demand for reform was spearheaded by the Gonoshasthya Kendra (Peoples' Health Centre), which in 1981 set up Gonoshas-

thya Pharmaceuticals Ltd. (GPL) and started production, of 2 of the 32 essential drugs, and by 1982, of 6 more drugs. GPL could sell these drugs at 50 - 65% of the prices charged by the MNC and still make a profit of 10-15%. The MNC responded by forming a cartel to undercut the GPL in its efforts to secure contracts to supply essential drugs to Government hospitals and clinics. By its new drug policy the Bangladesh Government has provided strong support to the Peoples' Health Centre and GPL. The policy contains provisions to protect local manufacturers and instructs MNC to "...concentrate their efforts and resources, on those items not easily produced by smaller national companies".

The Third World people are faced with a situation where, all the studies by their own Governments as well as the WHO, clearly point to a need for a drastic change in the drug industry. Nevertheless, the MNC still continue to impose on the Third World a pattern of drug production and consumption that is irrational, irrelevant and harmful. Any serious attempt at remedying this situation will have to address itself to the question as to what exactly is making us so totally dependent on the MNC, in the first place. One is then likely to be led to the discovery that the root of the problem lies in the fact of our having based the entire health-care system on the capital-intensive, high-technology, chemical-based modern Western approach towards medicine and health-care. As long as we are obsessed with such an approach, it is unlikely that we will ever be able to free ourselves completely from the tentacles of the MNC. And that could be realised only when we take a completely different approach to the entire philosophy and practice of medicine and health-care delivery—an approach that may have to learn much from our traditional systems of medicine. Even though this may be the only long-term solution to the menace of the MNC, a definite need nevertheless exists to initiate some immediate steps to curb the loot of health and wealth of our people by the MNC. Firstly, legislative action is crucial and needs to be fought for. However, this alone will not be effective, unless it is backed by a Peoples' Movement that can launch an educational campaign among the consumers and, more so, the doctors.

—Madras Group

99-1

Voluntary Health Association of India

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

Telegrams : VOLHEALTH
New Delhi-110016
Phone : 652007, 652008

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MS-cb/HCA-18/ 24th March,1982

Dear Friend,

SUB: LOW COST DRUGS

Ensuring availability of low cost essential drugs to all those who need is part of our responsibility as individuals and groups involved in 'peoples' health movement'.

Ensuring enactment of a Code of Conduct aimed at discouraging unethical marketing practices by profit oriented drug companies is part of this job.

Persuading the Government to enforce legislation to safeguard the consumers' rights to safe and low cost drugs is crucial for the efforts made in this direction.

Your participation is needed at this hour, to join in to demand an effective Code of Conduct for the Pharmaceutical Companies.

Please study the material being sent to you, with your colleagues and send in your responses and comments immediately , i.e. before 10th April 1982, so that it can be sent to Health Action International to deal with it, when they meet on the 15th April 1982.

On behalf of your friends in VHAI involved in Low Cost Drugs.

Dr Mira Shiva
Coordinator
Low Cost Drugs & Rational Therapeutics

Encl: 'Low Cost Drugs and Rational Drug Therapy, and You.' - International Codes

'Code of Pharmaceutical Marketing Practices' - IFPMA

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D-10/343

LOW COST DRUGS AND RATIONAL DRUG THERAPY
INTERNATIONAL CODES AND YOU !

Last year the WHO was instrumental in passing an International Code of Conduct of Marketing Practice of Baby foods.

This not only focussed the attention of the public, the health professionals on the baby food issue, but placed the concept of breast feeding from a 'rustic, old fashioned practice' to scientifically sound and recommended one. What this will do to the commercial interests of the milk food industry is anybody's guess? It is up to the aware public, the consumer associations, the journalists to ensure that the code of conduct of which India was a signatury - is firmly adhered to.

The contents of this code are being circulated for awareness and action of the health personnel and the public.

Along with it is a copy of the International Code of Pharmaceutical Marketing Practice, proposed by IFPMA (International Federation of Pharmaceutical Manufacturers Associations).

A copy of this provisional code was given to the participants of our Drug Workshop at Poona, for discussion and comments.

The code is being circulated along with extracts from the discussion document prepared by Health Action International on the code.

You are requested to read it carefully, share it with your colleagues and pass it on. Your comments and suggestions regarding the international code of pharmaceutical marketing practice are requested.

You are requested also to bring to our notice, cases of malpractice by drug companies which may be, by way of misinformation, selling of spurious drugs, unethical marketing practices, commissions for prescriptions, cut backs etc. Your participation is not only requested but is NEEDED for us and other groups and organisations to take any legal action, for malpractices to be curtailed before it is too late.

What is IFPMA ?

IFPMA is an International Federation of Pharmaceutical Manufacturers Association, a Zurich-based trade organisation, set up and supported by a number of national associations of manufacturers of prescription drugs. Altogether there are 30 affiliated national associations plus 12 affiliated through the Latin American Association of the Pharmaceutical Industry.

Why the IFPMA Code was introduced and what it aims to be?

"The Paris-based International Chamber of Commerce has published codes of advertising and marketing practice - which are meant to apply to business of all kinds. However, the IFPMA Code (which makes no reference to the requirements of the International Chamber of Commerce) is believed to be the first ever attempt to introduce an international code of marketing practice for pharmaceutical companies.

...2/-

2. to discuss briefly its significance in relation to controls that are needed and which might be applied; and

3. to suggest options for action by HAI participating groups. "

According to the discussion document, what are the three essential ingredients of any code of practice omitted in this IFPMA's Code?

1. Need for interpretation.

   Reference to the need to ensure that the industry makes products which have full regard to the needs of public health - appears a statement so vague that it is hard to accept it as anything much more than an advertising or public relations slogan.

2. Need for monitoring

   The question raised is 'what assurance is there, that the code will be adhered to?' Is the Code to operate on the basis of a complaints procedure? The mechanism for complaints handling and monitoring, which are fundamental to a code have not been referred to.

3. Need for enforcement

   What happens if the Code is violated?

   - who judges? industry (through its association or otherwise) or truly independent bodies.

   - whether enforcement decisions are published - or this is kept a secret? Could it be possible to establish, on the basis of past decisions, what practices are acceptable or unacceptable? And what is the record of individual companies where complying with the Code is concerned.

   - what sactions would be applied if companies break the provisions of the Code?

   - what incentive is there for firms to observe the requirement of the Code?

What are the implications and significance of this for the HAI groups?

This is useful to refer to the obligations of the industry identified by IFPMA;

Individual groups may think alternative or additional requirements which might be needed to control abuse in pharmaceutical marketing, and to consider how such requirements might effectively be enforced at both national and international level;

...4/-

D-10.341
SS:k/31.12.81

FROM : UHAI, Delhi

INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS (IFPMA)

CODE OF PHARMACEUTICAL MARKETING PRACTICES

Preamble

The Statute of the Federation article 3 states that one of the objects of the Federation is "to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntary agreed on and "to coordinate the efforts of its members towards the realization of the above objects".

It is believed that in keeping with the pharmaceutical industry's international responsibilities, the members of the Federation will be prepared to accept certain obligations, insofar as their marketing practices are concerned, and to ensure respect for them.

IFPMA recommends a Code of Marketing Practices to its member associations, recognizing the difficulty of setting out a simple Code which will be applicable in all parts of the world. It seems clear that national and regional conditions and legal restrictions will continue to vary to such an extent as to make a simple world Code impractical. Nevertheless, the Federation believes that it has a duty to encourage its member associations to either introduce such Codes of Practices or where such Codes already exist, to continually re-examine and where necessary revise them so that a voluntary system based on such a Code keeps pace with modern medical knowledge and changing health services and conditions.

It is recognized that many individual member associations of IFPMA have laid down their own Codes of Marketing Practices and this recommended Code is not intended to replace similar Codes or instruments already in force by members of the Federation. The following voluntary Code is therefore put forward as a model for IFPMA's member associations.

A Code of Marketing Practices of this sort should be the responsibility of member associations who should also provide guidance to their members on matters of compliance and interpretation.

Obligations of the industry

The obligations of the industry may be identified as follows:

The pharmaceutical industry, conscious of its special position arising from its involvement in public health, and justifiably eager to fulfil its obligations in a free and fully responsible manner, undertakes:

- to ensure that all products it makes available for prescription purposes to the public are backed by the fullest technological service and have full regard to the needs of public health;

- to produce pharmaceutical products under adequate procedures and strict quality assurance;

- to base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions of use;

.../-

7. Promotional communications should have medical clearance, or where appropriate, clearance by the responsible pharmacist, before their release.

II. Medical Representative

Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate and responsible manner.

III. Symposia, Congresses and other Means of Verbal Communication.

Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging such meetings, and entertainment and other hospitality shall not be inconsistent with such objectives.

IV. Printed Promotional Material

Scientific and technical information shall fully disclose the properties of the pharmaceutical product as approved in the country in question based on current scientific knowledge including:

- The active ingredients, using the approved names where such names exist.
- At least one approved indication for use together with the dosage and method of use.
- A succinct statement of the side-effects, precautions and contraindications.

Except for pharmaceutical products where use entails specific precautionary measures, reminders need not necessarily contain all the above information providing that a form of words is used which indicates clearly that further information is available on request.

Promotional material, such as mailings and medical journal advertisements, must not be designed to disguise their real nature and the frequency and volume of such mailings should not be offensive to the health care professionals.

V. Samples

Samples may be supplied to the medical and allied professions to familiarize them with the products, to enable them to gain experience with the product in their practice, or upon request.

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MULTINATIONALS IN DRUG INDUSTRY : A RETROSPECT OF THE HATHI COMMITTEE REPORT

On June 12th this year the Bangladesh Government promulgated an ordinance that prohibited the sale of over 1700 drugs. The drugs banned fell into 3 categories : (1) those deemed harmful and to be banned immediately by September ; (2) those requiring reformulation in accordance with new criteria and (3) those classed as being useless or of little therapeutic value, which are to be removed from the market at the end of 9 months. The decision was based on the report of an expert committee appointed by the Government of Bangladesh to evaluate the drugs currently in the market and to formulate a new drug-policy replacing the old one of 1940. The drug sales in Bangladesh are worth over $ 100 million a year and 75% of this is shared by 8 Multinational Corporations (MNC). (Pfizer dominates the market with over $ 10 million sales in 1981). This new drug policy has been a significant blow to the exploitative drug market in Bangladesh and the multinational drug corporations are bringing a considerable amount of pressure on the Bangladesh Government in an attempt to revoke the ban. The U.S. Government has urged the Bangladesh Government to reconsider its new drug policy and the U.S. State Department has admitted that this was in response to a request from the Pharmaceutical Manufacturers Association of USA. The Pharmaceutical Manufacturers Association has argued that blocking the flow of drugs from its member companies could open the market in Bangladesh to potentially 'impure' drugs from other sources. This should be viewed in the light of the fact that 70% of the drugs in the banned list are either banned in USA, or considered worthless—that is, described as being 'therapeutically useless' by the Federal Drug Administration of USA and the British National Formulary. The Bangladesh Government has already made some concessions in the face of mounting pressure and, in July 1982, it appointed a panel of military doctors to 'review' the ban.

Multinationals in the Indian Drug Industry.

The foreign investment policy of the Government of India was extremely 'liberal' right from its inception in 1949. This was being justified by the argument that such a policy would : (1) provide the technology for the production of basic essential goods ; (2) attract foreign investors and thus bring in foreign capital and (3) stimulate the transfer and growth of advanced technology in various industrial sectors. As a result, the first 25 years after independence saw the phenomenal growth of foreign companies in the Indian drug industry. The colossal profits repatriated by foreign companies and the inability of the Government to control drug prices was subject to heavy criticism in the Parliament and there was a demand for a thorough reform of the Indian drug industry. Hence, in 1974, the Government appointed a committee headed by Shri. Jaisukhlal Hathi to study various aspects of the Indian drugs and pharmaceutical industry.

*PRST BULLETIN , Vol. 5, No. 8 , November 1982

The Hathi Committee pointed out in its report that the Indian drug industry was heavily dominated by the Multinational Corporations (MNC). In 1973 they accounted for about 80% of the total drug market in India and held 85 - 90% of all drug patents. However, 80 - 90% of the production of several MNC consisted of simple household remedies like cough syrups, formulations with vitamins, tonics, etc. On the other hand, about 90% of the basic drugs* manufactured in the country were from the Indian sector (including small scale industries). In the case of many basic drugs-MNC, production was well below the licensed capacity**. However, the production by MNC of non-essential drugs like tonics and vitamins often far exceeded the licensed capacity***. In many cases where MNC did market basic or life-saving drugs, it was merely the packaging of the basic drugs imported from their own principals or subsidiaries, or the importation of the intermediate or penultimate product from abroad, with just the last stages being completed in India.

MNC spent a bare 1% of their annual turnover in R & D, in contrast to 12-15% spent on R & D in industrialised Western countries. This figure includes money spent on marketing-research and also sometimes the money spent on quality control. Of the 'new' drugs introduced by the MNC in the market 87% were imitation drugs (such as the sale of an already marketed drug under a new brand name by a different company) and 10% were improvements on the existing products ; only about 3% represented new drugs as such, i.e., containing new active ingredients. The Hathi Committee also noted that the MNC actively discouraged research by their Indian subsidiaries.

MNC were repatriating colossal amounts of foreign exchange by way of royalties, technical fees and dividends, often after paltry initial investment. Additional remittances were also made in the form of purchases of basic drugs and intermediates at prices dictated by their foreign principals. 'These prices', the Hathi Committee notes, bear no relation to either the cost of production or the international prices of the products.

Thus the MNC were making no significant contribution to the production of basic essential drugs and in fact chose to concentrate in the area of low technology, low priority consumer goods and formulations. Their contribution was negligible in terms of introducing new basic drugs. All the MNC were enjoying a privileged treatment under FERA (Foreign Exchange Regulation Act).

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* Basic drugs' is used to refer ro essential drugs, such as those used in the treatment of Leprosy, Malaria, Tuberculosis etc. 'Formulations' are those such as cough syrups, vitamin tonics, mineral tonics, digestion aids, etc. These are not essential drugs and in fact a vast majority of these are of little or no theraputic value.

** For example, the production of Dapsone, a drug used in the treatment of leprosy, was less than 50% of the licensed capacity in 1976-77 and this drug was unavailable in the market over a 6 month period due to shortage,

*** Between 1952 and 1965, 364 'Permission Letters' were issued to 15 leading foreign units. Only 4 of them were for basic drugs and the remaining were for formulations which included ointments, cough mixtures, etc.

It was in this context that the Hathi Committee made the following major recommendations about the drug industry:

(1) The MNC should be directed to reduce their foreign equity immediately to 40% and in course of time, to 26%. Those foreign companies that were marketing imported basic drugs should be directed to commence production of basic drugs by themselves. Further, any raw materials or intermediates required from abroad should be imported and distributed by the Government through a proposed 'National Drug Authority'.

(2) The Committee decided that there was a strong case for restricting the sale by generic name alone instead of by the brand name*. However it was considered 'inadvisable' to achieve this transition immediately. Hence, it proposed that as a start, the sale of 13 drugs could be restricted to sale by generic name. It was also suggested that the generic name could be displayed prominently on all drugs sold with the brand names also marked less conspicuously, if necessary.

(3) The Committee noted that, there were several thousands of drugs marketed in India, a vast majority of which were formulations sold by brand names. It drew up a list of 117 drugs, which were considered *sufficient* to meet the essential drug requirements of the country and suggested that the Government should concentrate on the production and distribution of these drugs**.

New drug policy of 1978 and the current position

For about 3 years after Hathi Committee submitted its report, the Government did not initiate any action on its recommendations. It was in 1978 that the Government announced its new drug policy and the following is a summary of some of the features of this policy and its current status.

(1) A list of 5 drugs was drawn up (out of the 13 recommended by the Hathi Committee) which could no longer be sold under brand names. However, the official

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* 'Brand' name is the commercial name under which a drug is sold, while 'generic' name is the common chemical name of the active ingredient in any drug. For example, a variety of headache 'remedies' such as Aspro, Aspirin, Anacin etc., have Aspirin as the active ingredient; thus Aspirin is the generic name of all these drugs. When a single active ingredient is marketed under a number of brand names, it increses the price of the drug considerably. Each company spends a fortune in trying to promote its own brand among doctors and consumers. It has been estimated that MNC spend about 17% of their turnover in marketing and advertisement (approximately 17 times the amount spent on 'Research'). In India, there is one medical representative for every 4 doctors while in most Western countries there is one medical representative for every 15-30 doctors. Doctors are 'encouraged' to prescribe specific brands by a variety of means such as giving commissions, gifts, handing out of free samples, etc. Hence, the sale of drugs by brand names was considered not in the best national interest and one that causes confusion among doctors and consumers.

** A World Health Organisation expert Committee in 1977 (and again in 1979) recommended that about 200 drugs are *sufficient* to meet the drug needs of the developing countries and suggested that it is advisable to market these drugs under their generic names.

2) Production of all new single ingredient drugs to be under generic names.

On what were these recommendations regarding generic drugs based?

The Committee found that 1) use of brand names led to unnecessary increase in cost because of costly promotional activities; 2) medical students were taught pharmacology using generic names.

What are the Drug Industry's objections against abolishing of brand names?

1. It is illegal and discriminatory because it contravened the protection afforded by the Trade and Merchandise Marks Act 1958 and there was no provision in the Drugs and Cosmetic Act 1945 to empower the government to abolish brand names for drugs.

2. Since prices are fixed under clearly defined formulae by the DPCO (Drug Price Control Order 1979), generic names will not reduce prices.

3. Standard medical text books use both brand names and generic names.

4. Trade marks guarantee ethics in manufacture and in the absence of brand names, customers cannot be sure of quality.

5. Generic names will lead to wrong dispensing of drugs with different pharmacological effects and harm patients' health.

6. The ban on brand names for single ingredient new drugs will completely stop introduction of new drugs in the market.

7. Drugs sold under brand names often have superior bio-availability than those marketed under generic names.

8. The use of generic names takes away the choice from the doctor to the chemist.

9. The general prescription is difficult to remember and reproduce, lengthy and cumbersome.

10. The Hathi Committee recommendations would have been quite different had it observed the results of the Pakistan experiment.

(Source: S. Viswanathan:
Business India - Sept.28
October 11)

What advantages are seen in having a planned generic policy?

1) It will eliminate monopolization because of brand names, and it will encourage healthy competition.

2) It will curb production of non-essential combination drugs which only add to the increase in price and have no additional benefit.

For example: Aspirin is marketed under two generic names:

- acetyl salycilic acid and aspirin
- 8 different brand names
- 7 brands marketing ASA and Caffeine
- 19 brands of ASA and Phenacetin and Caffeine

Effect on Costs:

Manufacturer	Content	Name under which drug is marketed	Price per unit(Paise)
Hoechst	Analgin (.5gm)	Novalgin	20.00
IDPL	Analgin (0.5gm)	Analgin	18.27
Haffkine	Analgin (.5gm)	Analgin	18.24
Nicholas	Aspirin (350 mg.) +Caffeine 30 mg.	Aspro	7.75
Sarabhai	Aspirin 350mg.	Kenalgesic	22.00
Boots	Aspirin 300 mg.	Aspirin	3.60
Haffkine	Aspirin 300 mg.	Aspirin	2.84

Source: Indian Pharmaceutical Guide 1980

Some more examples:

Anacin	Aspirin 389mg. Caffeine 16.2mg. Quinine sulfate 8 mg.	Anacin	8
Avedanplus	Aspirin 350 mg. Acetyl Aminophenol 125mg. Caffeine 30 mg.		8
Powerin	Aspirin 350 mg. Caffeine 65 mg. Codeine 8.125 mg. Paracetamol 65 mg. Salicylamide 65 mg. (Analysis of Painkillers done by Dr. Anant Phadke in his paper) Scientific Scrutiny of Over the Counter drugs)		20

What does WHO Expert Committee on selection of essential drugs (1st Report Technical series 615, 1977) recommend? It recommends Acetyl Salicyclic acid amongst the analgesics because besides being the cheapest it was therapeutically as effective as analgin (aspirin is 1/6) APC and multiple other combinations.

What are the loopholes being made use of in this generic policy by profit-motivated drug industry?

Since the use of generic named drugs applies only to the 5 single ingredient drugs it does not touch the COMBINATION DRUGS which anyway form the majority.

Drug companies will try avoiding the issue by producing more combination drugs and less single ingredient generic drugs.

Since BRAND NAMES is to be ABOLISHED for ALL NEW SINGLE INGREDIENT drugs, the drug industry will try introducing new drugs under BRAND NAMES with more than two ingredients. So not only the cost will go up because of the use of brand, but also because of addition of often unnecessary ingredients.

Since the government had emphasised that generic drug names should be displayed more prominently than brand names with effect from 1st August 1981, the drug companies complain of difficulties in making a long chemical name more prominent on small vials, ampoules and pleaded of accumulation of stocks inspite of 7 months' notice.

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What are the Drug Companies doing about this?

On 13th March, the industry's delegation met Mr. P.C. Sethi, Minister ofChemicals and Petroleum, under which the drugs come, having failed, Hoechst, Cynamid and Pfizer sued the Government in the Delhi. High Court against abolishing of brand names and have got a stay order.

What is the New Drug Policy?

Three years' debate following the Hathi Committee's recommendation ended with the New Drug Policy. (Presented in Parliament on the 29th March 1978 by Mr. Bahuguna, the former Minister for Petroleum, Chemicals and Fertilizers).

The NDP, the primary objectives were "to develop self-reliance in drug technology;" to provide leadership role to the public sector,"to foster and encourage the growth of the Indian sector", under NDP several limitations were imposed upon foreign sector drug companies. These included -

- the gradual reduction of the foreign share holdings of Multinational Corporations,
- no further expansion of capacity to foreign companies "engaged in the manufacture of household remedies".
- the grant of licences to manufacture formulations to foreign sector companies to be "linked with the production of high technology bulk drugs from the basic stage".
- the grant of licences for the manufacture of high technology bulk drugs to be conditional upon foreign sector companies supplying 50% of their production to "non-associated formulators".

(Source: Dilip Thakore - The Ethics of the Drug Industry Pg. 27 Business India : July 7-20,'80! Page 29.30)

If a multinational produced, say, Rs.100/- worth of bulk drugs, half of it had to be sold to the Indian sector and the remaining half used for formulating drugs under its own brand. The total turnover of drugs could not exceed three times the worth of bulk drugs, if produced, i.e., 100 x 3 = 300 lakhs.

What is the DPCO?

Drug Price Control Order, an offshoot of the New Drug Policy passed in 1979 is aimed to restrict prices of the bulk drug and formulations produced by any pharmaceutical company in the organised sector.

What are the stipulations under the DPCO?

Bulk or generic drug manufacturing companies are entitled to 12-14% return on net worth (capital + reserves) depending upon the complexity of the technology utilized in the production process.

Formulations (i.e. branded drugs) are divided into 4 categories

Category I - Life Saving Drugs
Category II -)
Category III -) in between
Category IV - Over the Counter Drugs.

"Mark ups" above the cost of production to the extent of 40%,55%, 100% are permitted by the Ministry of Petroleum, Chemicals and Fertilizers

production costs to be submitted by the manufacturing company.

What does the Drug industry have to say about it?

According to Dr. S.K. Bhattacharya recently elected President of the Organization of Pharmaceutical Producers of India (OPPI) (which constitutes of 62 big and 54 medium firms and produces 60% of that total bulk drugs and formulations in the country), the present drug shortage of commonly prescribed drugs is because of the New Drug Policy and the rigid price control and it will definitely get worse.

Which are the drugs which have had problems regarding availability?

Newsreports and A survey done by Medical Times (Glaxo's) Aug. '81 has revealed a shortage of painkillers

- antiepileptics
- anti-diabetics
- anti TB drugs
- sera vaccines
- Cardiac glycosides
- anti hypertensive

*Regarding prescription practices - surveyed by Medical Times (Glaxo's) use of brand and generic was concerned. Almost all the doctors seemed to use brand drugs. Reasons:

1) confidence in the brands
2) less chance of substitution by chemist
3) convenience in remembering

Any info what guides prescription practices?

A study done by NIN Hyderabad on drug utilization revealed that 14% of the population surveyed (1800 urban education population) was taking drugs on the basis of advertisements alone. Only 1.72% gave satisfactory replies on the proper use of drugs.

48% allopathy
18% homeopathy
14% naturopathy
11% ayurvedic
2% Unani

63% had erroneous idea about dosage schedules and mode of administration which could result in bioavailability and therapeutic problems.

What is OPPI paying to build up public opinion against the Government policies? OPPI has launched a Rs.24 lakh MEDIA CAMPAIGN in what is says is a bid to help avert more serious shortages in the future. (Source: Vanishing Drugs: Hindustan Times - April 27, 1980)

What is the situation regarding Drug Control?

The Drug Control situation in India is pretty bad. Only 3 (Maharashtra, Gujarat, West Bengal) our of 22 States in India have machinery to regulate the manufacture, distribution and sale of pharmaceuticals.

In Maharashtra, acknowledged to have the most effective drug control administration, there are only 96 drug inspectors and 1 drug testing laboratory for over 2000 manufacturers and 15, 000 shops.

(Source: Dr. S.K. Bhattacharya of OPPI in Medical Times - August 1981)

In Delhi for 5 million population there are 20 drug inspectors. In Uttar Pradesh for 100 million population there are only 24 drug inspectors.

(Source: Rajender Rainer : Delhi Reporder July 1981:Spurious Drugs dealing in Death)

At the time of the Hathi Committee Report (1975) the Total drugs Inspectors in the whole of India was 305. Current estimates are 500.

(Source: The Ethics of Drug Industry: Business India, July 7-20, 1980 - Pg. 33)

What percentage of drugs are considered sub-standard in the Indian Market?

Conservative estimates are 25-30%. The Drug Control authorities accept this figure.

(Source: Spurious Drugs: Delhi Recorder, July 8)

52% drugs are substandard according to a survey quoted by Anil Aggarwal in Drugs and the Third World. 2% drugs are spurious (According to the drug control authorities).

What are the reasons of such a high percentage of substandard drugs?

1) Inadequate drug control.

The centre can only lay down policies, state governments have control over manufacturers, sale and distribution (the inter-state barriers are fully exploited by trade in spurious drgs). Control, if any, is at the earlier stage of production into bulk form or later formulations, improper storage, etc. are not given that importance.

Shortage of certain brands of popular drugs gives an opportunity to spurious and substandard drug producers to take advantage of the situation. Linked to this is high demand of life saving and other common drugs.

- easy availability of drugs over the counter without preseription from a qualified doctor
- easier availability of drug selling licence
- ignorance about drug adulteration and substitution
- the increasingly prevailing habit of chemists to stock drugs of a company giving them commission in some areas
- the desire of the consumer to buy cheaper drugs because of the high cost of drugs (and his poverty in many cases)
- the buying of drugs by chemists without any bill to avoid payment of taxes
- only drug control authorities have been associated with checks and control unlike food adulteration where the consumer can play a role.

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What can consumers do to deal with this problem of substandard and spurious drugs?

1) Buy drugs only from licensed chemists.

2) Read the drug label carefully, verfy expiry date, price and seal before purchasing. Check with the price lists of manufacturers available with the chemists.

3) Ask for a cash memo-give the chemist enough time to fill entries of drugs bought, your address, etc.

4) Don't swallow all the claims made by the advertisers of the various drugs.

5) Avoid self medication by use of patent drugs, Don't medicate yourself with any drug you do not know about.

6) Follow instructions given by your doctor, pharmacist or on the medicine label regarding mode of administration of the drug dosage, frequency, etc., and duration. Check if in doubt specially if deasling with patent drugs.

7) Avoid using left-over drugs or drugs that change colour, taste, or look different. Keep drugs as advised - in a dark and cool place.

8) Keep drugs away from children's reach. Keep poisonous drugs separately.

9) Destroy old cartons, labels, containers to prevent misuse of spurious drug manufacturers.

10) If you feel doubtful about the quality of any medicine, contact the Drug Control Department.

11) If in Delhi, ring up 22 60 18 be4ween 9 A.M. - 6 P.M.. After office hours and on holidays ring up 63 33 00, 63 40 73 and 63 11 16.

The punishment provided in Sec. 27 and 27A of the 1940 Drugs and Cosmetics Act to safeguard the consumer is maximum imprisonment of 10 years, increased to life imprisonment by West Bengal.

What constitutes the public sector and how are they faring?

The public sector constitutes of -

IDPL - Indian Drugs & Pharmaceuticals Limited

HAL - Hindustan Antibiotics Limited

SSPL - Smith Stanistreet Pharmaceuticals Limited

BCPL - Bengal Chemicals & Pharmaceuticals Limited

IDPL and HAL incurred losses of almost 2 crores in 1979. Monthly losses of IDPL and HAL are 2 crores and 45 lakhs respectively.

(Source: Policy Pitfalls: Ranjana Kaul:
Hindustan Times, April 27, 1980)

Why are they running at a loss?

The reasons given are mismanagement, inefficiency, poor coordination, under-utilization of capacity, corruption, frequent machine breakdowns.

Probably, one acceptable reason is the refusal of the MNC and other private companies to go into production of essential and life-saving drugs of Category I & II which allow mark-up of only 40 and 55% respectively (as they can make up to 100% profit on non-[illegible] counter drugs) and the public sector

According to Mr. D.B. Telang, Financial Manager of the company for every kilo of streptomycin produced, a loss of Rs.25 is incurred. The more esssential drugs are produced the more are the losses incurred. Losses are due to increase in the price of raw materials, inflation - 35-40%; packaging 30%, power 30%, cost of transportation. A,, this in the presence of fixed drug prices apparently has caused the ever increasing losses in the public drug sector. IDPL, HAL, IDRI were instituted to break foreign monopolization and produce a reasonably cost essential drugs for the Indian public. But even today, 33 years we still import drugs for Kalazar, malaria, leprosy, diphtheria, TB. Losses can be made up by raising production or by asking government to alter the pricing structure.

How self sufficient are we regarding production of drugs? What do the MNC's and OPPI have to say about production of essential drugs?

Dr. Bhattacharya of OPPI says "We are business concerns. Why should we produce anything that will cause incurrence of loss." (which actually means less profits).

What is C.P.C.?

Chemicals & Pharmaceuticals Corporation is for channalizing drugs and regulating their availability in the country. The Corporation has had problems regarding availability and prices of imported ingredients. There are reports of essential bulk drugs not being lifted from the C.P.C. by the drug company on account of low profitability. On December 1, 1979, CPC had 4 crore worth of canalized bulk drugs in stock. These included essential drugs like tetracycline, streptomycin, doxycyclin.

Drug	Company	Licensed capacity in millions tons	Actual production in million tons
PAS	a) Biological Evans	120	56.06
	b) Warner Hindustan	300	135.82
INH	a) Biological Evans	10	0.13
	b) Ghas. Pfizer	1.6	0.06
	c) Warner Hindustan	90	6.08

What are the objectives of C.P.C.?

The basic objectives of CPC in canalizing import of drugs is as follows:

1. Bulk purchase for all manufacturing units gave bargaining power in world market so that concessional or low prices could be secured.

2. To prevent disturbance of indigenous production of drugs with a certain therapeutic value - introduce and regulate imports of newer, sophisticated drugs in a planned manner.

3. To protect the indigenous production of drugs, especially when the production is inadequate to meet internal demand.

4. To ensure the equitable supply of raw materials at uniform prices, eliminating middleman's profits, so that formulations from this are priced at a fixed uniform level.

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5. To help the small scale sector of the industry whose requirements are small and who would otherwise find it uneconomic and impractical to import.

6. To regulate the import of drugs whose indigenous production is substantial enough to warrant their being given protection so that their growth and utility are ensured with a view to achieving ultimate self-sufficiency.

7. To secure those drugs which have very few world manufacturers and monopolies at reasonable prices.

8. To regulate the import of drugs whose imports can cause public health problems, eg., addiction forming drugs, etc.

Loopholes points 4 and 5 were to avoid middlemen but unfortunately since small units have to give their REQUIREMENTS AND ADVANCE PAYMENT several months prior to time of supply (promptness of which is not assured), the small scale agencies are unable to take full advantage and it is the MIDDLEMEN who lift the STOCK, HOARD it and sell it at 25-30% higher than the usual rate.

10% foreign firms have not utilized 3 industrial licences and 7 letters of intent for the manufacture of 16 bulk drugs.

40 firms in the Indian private sector failed to implement the investment proposals with 31 industrial licenses and 27 letters of intent.

Of 32 items of bulk drugs covered by 13 licenses, 21 items were not produced by Glaxo laboratories for the last 5 years.

(Source: J.S. Mazumdar: Drug Industry Instruments of Policy)

And with all this, useless non-essential drugs are pumped into the market while essential drugs are not produced. Very obviously, profit is the motive of the drug production industry and not fulfilling of the country's need as is often alleged.

The small scale sector feels itself financially ill-equipeed to undertake any undue losses or profits and therefore also opts for non-essential drugs.

What does the 6th Five Year Plan require regarding drug production?

From Present	Bulk 226 crores	Formulation Rs.1150 crores
By 1984-85	to 665 crores	2450 crores.

VIth PLAN aims at:

1) Developing self-reliance in technology,

2) Ensuring availability of drugs with reasonable prices and inadequate amount

3) Dominant role of the public sector in the industry.

What's the situation?

Growth rate of bulk drugs has fallen from 13% to 6% and for formulations from 10% to 4%.

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IN THE FIRST YEAR OF THE PLAN, the foreign and big Indian companies are not interested in manufacturing the drugs that yield low profit margin. In fact, by cornering the already sanctioned licenses and letters of intent they are out to blackmail the government in order to secure substantial price rise - by starving the market of these drugs.

(Source: MNC's Fatten, Indian Die:
Dr. Pankaj Shah: Link, Aug. 2, 1981, Pg.10)

The Multinationals give the high prices because of the 'research' they apparently finance. What all constitutes research?

It includes
- basic research
- product development
- toxicity tests
- research on formulations
- mass production methods
- clinical trials, etc.

it also includes studies on colour design of product, its packaging to promote sales, general market studies, purchase of international patents, solely to extend the company's monopoly position abroad.

(Source: Link, Aug. 2, 1981, Pg.11
Dr. Pankaj Shah)

What percentage of their sales do they put into research? and what percentage in publicity?

Glaxo in 1979-80 spent Rs.1.52 crores on publicity - .. percent on tropical diseases.

Amount MNC's spend on research is <3% of their sales turnover compared to 14-15% in Developed countries. Even so research activities are seldom in tropical diseases but in diseases like cancer hypertension etc.

What are the country's health requirements based on priorities set by Alternative Strategy: ICMR/ICSSR Study

Measures against
- Communicable Diseases
- Nutritional deficiencies
- Family Planning, Fertility rate,
- Basic health care

Some of the figures that indicate the seriousness of the problem

*IMR in 1976 129/1000 live births (when Sri Lanka's is 45:1 in '72 (pg.129))

*Maternal mortality 163 in 1976 (Percentage Distribution (pg. 125)

*Birth rate - 33.3% per thousand per annum in 1978 (Pg.13)

Health Budget set aside for the VIth Five Year Plan - 182.05 Crores

50% of the Health budget earlier has been spent on curative care.

40% in construction and capital expenditure and only 10% on preventive health care(Health Statistical Intelligence Report)

50% of under fives and pregnant mothers are found to be anaemic

60-80% are clinically malnourished.

50% of Indian children get ½ the calories that they require.

40,000 children become blind each year because of Vitamin A deficiency

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*27,08,222 get malaria every year and 147 die of malaria in 1979 (Pg.82)
Incidence of T.B. is 2%, i.e., 8 million people. About 2 million have open TB.

*Incidence of leprosy is 25,59,566 cases on Record - Mar.'80
21,58,822 cases under treatment on Record - Mar.'80 (Pg.89)

(India harbours 1/3 of the world's leprosy, malaria cases).

(*Source: Pocket Book of Health Statistics '80, CBHI, New Delhi)

The incidence of malaria - even Falciparum - Filaria, polio, Kalazar, Japanese 'Becephalitis has shown an increasing trend.

The above becomes extra significant when we focus on the percentage of people below or bordering the poverty level - a figure that is also showing a rising trend. 60% Indians are below poverty line (assessed in relation to average caloric requirement).

What is the production of drugs like in relation to these health requirements:

Out of Rs.636.9 crores of drugs sold in 1980

19% were anti-biotics
10.21% vitamins
4.41% tonics
4.241% anti-anaemic preparations
4.71% cough and cold (increase in growth within the last 5 years has been 70%).

Talking in absolute figures 137 crores worth of vitamins were sold in the year 1980.

Break-up of the above available in Dr. A. Patwardhan's paper 1,2, and 3.

All modern drugs are available to economically well off 5%.

Basic drugs available to another 20%.

Percentage of people denied availability of essential modern drugs is 75%.

This is when our population is 65 million.

With annual expenditure of 636.9 crores.

By 2001 the population will be 950 millions.

Amount required for drugs with inflation, increasing prices of raw material, etc, etc., will be .....

Our National Formulary has over 60,000 drugs and chemicals. (15,000 brand drugs)

68% are obsolete and useless (only about 5000 are useful and 2500 of marginal use)

The Hathi Committee has identified 117 as essential drugs and WHO about 200 drugs which would take care of the 90% of the EXISTING HEALTH PROBLEMS.

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Regarding essential drugs production what is happening?

Out of Rs.1260 crores worth of drugs manufactured in 1979-80 essential and life saving drugs accounted for Rs.350 crores only - the rest were tonics, digestive enzymes, formulations of medicines with marginal benefit.

MANY VITAL BULK DRUGS IN HUGE QUANTITY HAVE BEEN WASTED WHICH COULD HAVE BEEN UTILIZED FOR MANUFACTURE OF ESSENTIAL DRUGS.
(Source: Drugs : Industry Instruments of Policy - J.S. Majumdar)

	1977		1978	
Anti-T.B. Drugs	Installed capacity Tonnes	Production tonnes	Installed capacity Tonnes	Production Tonnes
INH	509	57	539	94
PAS and its salts	1170	56	1290	558
Theacetazone	153	25	153	13
Streptomycin	257	194	257	225
Anti-Leprosy				
DDS and its derivatives	26	17	38	17
Anti-filaria DEC citrate	56	18	56	23
Anti-typhoid Chloramphinicol	128	95	128	95
Anti-Dysentery				
Halogenated Quinolines	587	157	590	195
Metronidazole	137	16	170	55
Anti-malarials				
Chloroquin	156	34	176	45

Pfizer Ltd.

Products	Licensed capacity	Production during 1978	1979
INH	80 metric tonnes	45 MT	52 MT
PAS and its salts	110 " "	90 MT	54 MT
Terramycin	14 " "	53 MT	54 MT
Protienex	110 " "	269 MT	290 MT

Burrough's Welcome	Licensed annual capacity	Production 1980-81
Septran	26 million tablets	187 million tablets

Similarly, Glaxo's production of Betamethazone has been increasing while production of antibiotics - penicillin, streptomycin, serra and vaccines is much below licensed capacity.

Make-up of Drug Industry at a glance?

*5000 pharmaceutical units
*1500 units based on loan license system
*45 Multinational drug companies which have foreign equity more than 40%
*3500 manufacuring units
* 118 companies in the organised sector
* Of the 20,000 formulations in the market - 78% formulations in the hands of Multinationals, 16%

99.18

VOLUNTARY HEALTH ASSOCIATION OF INDIA

D-10:343
MS:k:5.1.82

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THE DRUG SITUATION IN INDIA

The causes of the problems and the solutions of the present day drug situation differs markedly when seen from the eyes of the drug industry especially OPPI, the Drug Controller, WHO, IMA, groups and organizations who see everything in terms of what is socially just or not, and the consumer.

Many significant changes have occurred in the past few years which are bound to have far reaching effects. It is important for all of us to be familiar with the problem, with the loop holes, with the different versions of the various groups involved.

THE FACT THAT THE SOLUTION OF THE MAJORITY OF THE HEALTH PROBLEMS IN INDIA DOES NOT LIE IN MORE PILLS, MORE DOCTORS, MORE HOSPITALS, BUT IN SOCIO ECONOMIC & POLITICAL POWER RELATIONS IN SOCIETY IS W. BELIEVED ACCEPTED BY MOST OF US HERE.

The need for greater social awareness is not only relevant for the villager who gets deprived of his right to the least basic needs, basic health care, but also for those involved in health work (whether it is in a community health programme, a dispensary, hospital or even a teaching hospital).

Knowing about drugs is not limited to their brand names, dosages, side effects, but also their COST and their AVAILABILITY.

The various factors influencing these need to be analysed.

We will highlight some of the more important aspects which will strongly influence our search for solutions.

Here are some questions that arise and need answers. How much is our health budget for the 6th Five Year Plan? and how much of it goes on drugs as a total percentage and what is the per capita expenditure on health? (Medical & Public Health & Family Welfare)

a) 1821.05 Crores (1980-85) Centre/State &/Union Territory
Source : (6th Five Year Plan - Pg.382)

b) Traditional System of Medicine - Centre 29 Crores
Source: (Planning Commission - N.D.)

c) Rs.15.05 (+ Rs.1.51 for Family Welfare) in 1977-'78
Source: (Pocket Book of Health Statistics of India - 1980 Pg.37)

What percentage of the Indian population utilizes the benefits of modern drugs:

- about 20%; according to some estimates only 10%

How self-sufficient are we in producing this?

We still import 50% of the raw material at stupendous rates inspite of our Pharmaceutical industry being 33 years old and the biggest in the Third World.

What is happening to drug imports?

Our imports tripled between 1963-64 to 1973-74 from Rs.13.11 crores to Rs.37.50 crores — within next year it increased to Rs.47 crores this constituted 35% of the bulk drugs utilized in formulations.

According to Dr. S. S. Gothoskar, the Drug Controller of India "The last 3 yrs have witnessed a steady increase in the requirements of imported raw materials by nearly 100 percent. Thus while our

production increased by only 50% from 1976-77 to 1978-79 the expenditure incurred on import of bulk drugs, intermediates, solvents etc. rose by nearly 80%.

The break-up of the drugs in the market is:-

Foreign Multinationals	.. 78%
Public Sector	.. 6%
Indian Private Sector	.. 16% (Source: Dr. Pankaj Shah:Link - Aug. '81) Pg. 12.

In 1978-79 MNC's produced .. 28% Bulk drugs (Basic drugs)

.. 44% Formulations

(Source: Dr. Thakor - Businss India, July 1980, Pg.26)

What are the allegations against Multinationals?

According to the Hathi Committee Report in 1975 the Multinationals:

- block others from producing drugs for a period of 16-20 years by invoking patent production,
- din the brand names into the minds of the medical profession by employing a large force of medical detailers,
- resort to high pressure sales techniques, and,
- rig up prices to levels which have no relation to the cost of manufacture of products or international prices.

What were the Hathi Committee's major recommendations?

1) Nationalise the Drug Industry,
2) Foreign undertakings operating in the country should be directed to bring down their equity to 40% with progressive reduction to 26%**

(Under the New Drug Policy it was added that Multinationals maintain a ratio of 1:5 for production of bulk drugs to formulations)

**In the US more than 10% share by a foreign undertaking classifies the company as foreign.

What were the Hathi Committee's recommendation regarding generic drugs?

1) Abolition of brand names in a phased manner, beginning to be made with 13 single ingredient drugs:

- analgin
- aspirin
- piperazine
- ferrous sulfate
- chlorpromazine
- chloramphenicol
- streptomycin
- Tetracycline
- reserpine
- tolbutamide
- INH
- INH & thiacetazone

Recommendations made in 1975. In Jan. 17th 1981 decision was taken to abolish brand names for 5 classes of drugs:

- analgin
- asprin
- chlorpromazine
- ferrous sulfate
- piperazine

../-

99.12

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July 17, 1984.

ESSENTIAL DRUGS

A DEMAND FOR PRIORITIZATION

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

Background paper
for
Drug Action Network
Core Group Meeting
Wardha

30 - 31st JULY 1984.

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VHAI:pt:19.7.'84

ESSENTIAL DRUGS - A DEMAND FOR PRIORITIZATION

- Dr. Mira Shiva, VHAI.

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3. ensuring placing essential drugs before inessential drugs

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

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

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I. ESSENTIAL DRUGS

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

II. COURAGEOUS EFFORTS - A Brief Review

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

CHILE:

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

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

SRI LANKA:

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

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

PAKISTAN:

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

INDIA:

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

MOZAMBIQUE:

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

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

W H O:

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

BANGLADESH:

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

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

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

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

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

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ZIMBABWE:

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

III. OUR INITIATIVES IN PROMOTING AWARENESS OF ESSENTIAL DRUGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dealing with Resistance:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Criteria for selection of essential drugs:

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

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

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

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

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

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

Selection of Dosage forms:

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

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

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

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

Provision of information on essential drugs:

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

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

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

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

3. Clinical information:

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

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

4. Pharmaceutical information.

V. THE RATIONALE OF ESSENTIAL DRUGS

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

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

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

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

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

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The following figures speak for themselves:

Table

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

Source: FMRAI News
July 1984.

The production of category I drugs i.e. essential and life saving drugs and Category II drugs (essential drugs) is showing a declining trend according to Ministry of Petroleum and Chemicals and Fertilizers.

Production of antimalarial, anti-TB, antifilarial and anti-leprosy drugs have been trailing far behind the estimated demand and while demand has increased the actual production has been falling. In fact, production of the antimalarial Chloroquin, and the anti tuberculosis PAS, INH and thiacetazone fell short of estimated demand by about 84, 50, 4', and 70% respectively in 1979-'80, except for a small increase in INH production for all those drugs decreased further in 1980-'81.

	Estimated demand	Production in tonns MT		Estimated Production	
	1979-80	79-80	80-81	81-82	82-83
Antimalarial					
Chloroquin	250	35.16	34.62	58.96	70.00
Amodiaquin	40	38.49	23.15	26.02	33.00
Antitubercular					
PAS & Salts	600	481.78	405.46	261.97	290.00
INH	200	112.43	129.20	110.40	128.00
Thiacetazone	40	12.55	8.44	13.98	25.00
Streptomycin	300	220.16	227.33	255.45	266.00
Antifilarial					
DEC	30	21.57	18.99	16.43	13.00
Antileprosy					
DDS	28	16.20	21.05	25.61	30.00

Ref: Dr. W.Y. Rano - Why don't our drugs match our diseases - Science Today - October 1982.

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Demand Projection for Bulk drugs for the period 1979-80 to '84-'85

	Base year	Estimated Requirement				
	79-80	80-81	81-82	82-83	83-84	84-85
Antimalarial						
Chloroquin	250	275	300	335	365	400
Amdiaquin	40	46	53	61	70	80
Anti Tubercular						
PAS	600	630	660	700	730	770
INH	200	240	290	360	415	500
Thiacetazone	40	42	44	46	48	50
Streptomycin	300	330	363	400	440	485
Antifilarial						
DEC	30	33	36	40	45	50
Anti leprosy						
DDS	28	32	37	45	50	56

Ref: The Indian Pharmaceutical Industry Problems and Prospects P.L. Narayan, NCAER Study National Council of Applied Economic Research - January 1984.

- ICMR and ICSSR study on Alternative Strategy had indicated the grossly inadequate drug production for TB and leprosy which happen to be our priority health problems. With half of the TB patients of the world in India our production of INH was less than 1/3 of the minimum requirement.

- The Malaria deaths in Rajasthan were not merely due to drug resistance and cerubral malaria, but due to non-availability of chloroquin even at certain government PHCs. The estimated requirement and the actual production are getting further apart and reliance on imports is resulting for drugs that are so routinely needed.

Chloroquin imports in tons

1979-'80		1980 - '81		1981 - '82	
Production	Imports	Production	Imports	Production	Imports
35.2	52.8	34.6	71.8	59	166.3

Ref:* NCAER Report - The Indian Pharmaceutical Industry.

National Council of Applied Economic Research.

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- There are an estimated 60 million iodine deficiency cases of goitre in India. It is known that children of iodine deficient mothers are known to be born as cretins, deaf, mutes and mental subnormality.

  The simple technology of production of iodized salt is known. Merely 50 paise worth of iodized salt can make all the difference between a child being normal and subnormal.

  We still produce only 20% of the iodized salt required.

Required amount of iodized salt is	- 7 lakh tons
Amount produced	- 2 lakh tons
Amount sent to Nepal	- 1 lakh tons
Amount left for utilization for the 60 million goitre cases	- 1 lakh tons

When adequate production of an essential low cost item like iodized salt for a National Goitre Programme cannot be assured, what happens to production of the essential drugs for non priority national programmes can very well be imagined.

In Kenya, in a pilot project funded by DANIDA and SIDA, supplies of drug kits containing 39 drugs in 15 rural districts has increased the accessibility of essential medicines for the rural population from 10% to 40%.

B. DPCO and its negative impact on Production of Category I and II drugs

Under D.C.O (Drug Price Control Order) the mark up on Category I drugs is limited to 40% and that on Category II is 60%. Producing category IV drugs because of the high mark up allowed are therefore definitely most profitable.

For the decreasing priority being given to essential and life saving drugs DPCO is therefore blamed. With the decontrol of prices of 75% of the drugs as is being recommended by the drug lobby and its supports, a further switch to production of more profitable unessential drugs is imminent. If government is serious about ensuring that essential drugs are sold at a reasonable price - this can be done by doing away with taxes.

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

The outright, calculated neglect of the priority drug needs of the majority is well known. The following table speaks volumes. (See Annexure II - Production of Essential Drugs by Multinationals and Organised Sector)

D. Dilution of FERA Companies - an invitation to more formulations:

With the dilution of foreign equity shares to 40%, various concessions are being granted to the FERA companies so that bulk to formulations ratio will be increased from 1:5 to 1:10. With the drug production pattern as it is, we can look forward to more formulations and more unessential drugs irrelevant to our people's health need. Bulk production by foreign sector for 1982-'83 was Rs. 55 crores worth; the formulation turnover according to 1:5 ratio should not have exceeded Rs. 275 crores, however, Rs. 515 crores worth of formulations were produced i.e. more than 1:10 ratio when only 1:5 was allowed.

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E. Rational use of scarce resources:

i) Wastage of scarce foreign exchange: India with its level of indebtedness to IMF World Bank, IDA etc., can hardly afford to squander its scarce foreign exchange for importing inessential drugs.

ii) Inessential vs basic health needs: Worse still is the enforced wastage of scarce resources of the poor on useless nonsensical drugs, when they can hardly afford adequate food and clothing and bare essentials. When the percentage of people, below or around the poverty line happen to be around 60 - 70% of a country's population - the very production and heavy promotional of costly irrational and hazardous drugs is criminal. A strong public opinion alone can ensure withdrawal of such drugs, with priority being given to essential and life saving drugs.

iii) Inessential vs essential drugs: Often inessential drugs are bought at the cost of specifically needed essential drugs. For the ignorant majority, the difference between the therapeutic value of a costly tonic, vitamin, digestive ensymes, antipyretic and much needed specific drug eg. antiasthmatic, antibiotics etc. all written in the same prescription - does not exist. This was shown by Veena Shatrughana's study of Prescription writing and drug consumption. By ensuring priority, availability and prescription of essential drugs, we would be contributing to preventing the wastage.

iv) Economics of scale increased: If essential drugs were given priority in production, through sheer economics of scale, the production cost would decrease for the manufacturer and thus the consumer.

v) Bulk purchase: An essential drug list can ensure bulk purchase of selected essential drugs, which can cut down drug costs.

F. Influencing market demand and thus the Drug Production pattern in favour of essential drugs:

If the concept of essential drug list was widely propagated, accepted by choice or by legislation, this would necessarily influence the prescription pattern and hence the drug demand in the market. This would definitely alter the drug production pattern towards essential drugs.

G. Decrease drug misuse and over use:

This can be done with identification of drugs which are - therapeutically effective, safe, easy to administer, and of appropriate cost preferably single ingredient well tried drugs. The use of drugs which are of doubtful value, costly, irrational and hazardous drugs should be avoided. Majority of the drugs available are combination drugs. This increases costs as these drugs are often in subtherapeutic and irrational dosages. According to Halfden Mahler, 90% of drugs in the developing countries are non essential.

H. Preventing Iatrogenesis (Drugs induced health hazard):

As long as potentially hazardous drugs with very high risk (compared to) benefits ratio are misused and overused, unwarranted high incidence of iatrogenesis is bound to occur.

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In USA where the drug control and the prescription practices are much better controlled, the incidence of iatrogenesis is very high. One in 5 hospital admissions are known to be due to iatrogenesis. In India we have such a high degree of self prescription, prescription writing by unqualified health personnel and by qualified personnel who are made highly biased by drug representatives. This along with poor drug controls ensures drug misuse, overuse and iatrogenesis. Most cases of iatrogenesis are not diagnosed in India. This of course does not imply that they don't exist.

Most of the combination drugs have 2 or more ingredients. It is known that with consumption of over 6 drugs compared to 2, chances of drug interaction increase by 40% as compared to 5%.

I. Drug Information for health personnel and consumers possible:

With 30,000 drugs in the market it is impossible not to be confused about them. A doctor may be familiar with the drugs he or she uses routinely. Unfortunately he or she cannot be so with the various brands used by others. Their prescriptions are often taken from one doctor to another by critically or chronically sick patients.

Confusion abounds, since majority of the health personnel have no access to pharmaceutical index to figure out what drug has been given. Majority of the drugs in the market, are combination drugs. Lack of familiarity with the contents and their dosages makes matters worse. If prescription practices for the majority of the health problems could be based on essential drugs? Relevant drug information about their relative cost, dosages, indications, contraindications, side effects and toxicity could be made available to health personnel and consumer caution be ensured?

Studies also indicate that it is impossible to remember details of even 100 drugs in routine practice. Ensuring that these prescribed drugs are the ones that people need and not what are most heavily pushed by the drug companies because of their profitability, is our responsibility. Focussing on all aspects of essential drugs and rational drug use in medical education would ensure their better use which would be better for the nation and the patients.

J. Ensuring better quality control:

There are 30,000 formulations in the market. Most of them are combination drugs and one in 5 drugs in the market is substandard. With a lesser number of drugs in the market which are single ingredient drugs quality control can be better streamlined. Making profits by promoting unessential drugs is crazy, but to make inadequate number of essential drugs available, with even these being substandard, is really unacceptable.

K. Ensuring generic prescribing:

Generic prescribing is recommended by WHO itself as it cuts down drug costs.

Pharmacology input during medical education, nomenclature used in medical literature and medical journals is based entirely on generic names.

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With a restricted essential drug list generic prescribing can definitely be ensured. The pharmaceutical industry and government drug control authorities would have to take greater responsibility to ensure quality control AT ALL LEVELS. Brand name prescribing is no solution for substandard drugs. Brand names do not prevent spurious drugs entering the market as most spurious drugs are imitations of well known brands. Name of the specific drug house can be written if it is felt absolutely necessary. Generic prescribing is possible with single ingredient essential drugs which are quality controlled.

L. Subsidizing costs of essential drugs:

With restricted list of drugs meant for the health needs of the majority, subsidizing is possible by removing sales tax, excise duty and octroi for these. Any loss in the taxes can be compensated by increasing taxes on cigarettes, alcohol and other such anti-health products or more so on luxury items meant for the rich. In conclusion, demanding an essential drug programme is aimed at focussing attention and giving priority to health needs of the majority.

CONCLUSION/SUMMARY

Demanding priority production and distribution for essential drugs is accompanied by demand for a just health care delivery system. We know that a just health care delivery system cannot exist in isolation in a socially unjust system. Demand for essential drugs before unessential drugs is accompanied by demand for employment, fair wages, food, water, sanitation and all that goes to ensure good health. Our fight for essential drugs and health care as a fundamental right of every Indian, specially the deprived sections is a fight against the injustice of the present socio-political system, which in reality accepts this deprivation of health and basic health care as a normal phenomenon.

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Annexure III

PRODUCTION OF ESSENTIAL DRUGS BY MULTINATIONALS AND ORGANIZED SECTOR

Name of the firms	INH	PAS	THIACITAZONE	ETHAMBUTOL	RIFAMPICIN	STREPTOMYCIN
Abbott	Nil	Nil	Nil	Nil	Nil	Nil
ACCI	Nil	Nil	Nil	Nil	Nil	Nil
Hoechst	Nil	Nil	Nil	Nil	Nil	Nil
S.K. & F.	Nil	Nil	Nil	Nil	Nil	Nil
Searle	Nil	Nil	Nil	Nil	Nil	Nil
Sandoz	Nil	Nil	Nil	Nil	Nil	Nil
Roche	Nil	Nil	Nil	Nil	Nil	Nil
Parke-Davis	Nil	Nil	Nil	Nil	Nil	Nil
Sarabhai	Yes	Nil	Yes	Yes	Nil	Yes
Boehringer Knoll	Nil	Nil	Nil	Nil	Nil	Nil
Glaxo	Nil	Nil	Nil	Nil	Nil	Yes
E. Merck	Nil	Nil	Nil	Nil	Nil	Nil
Ciba-Giegy	Nil	Nil	Nil	Nil	Nil	Nil
Pfizer	Yes	Yes	Yes	Nil	Nil	Yes
Warner	Yes	Nil	Nil	Nil	Nil	Nil
Burrough Wellcome	Nil	Nil	Nil	Nil	Nil	Nil
German Remedies	Nil	Nil	Nil	Nil	Nil	Nil
Cynamid	Nil	Nil	Nil	Yes	Nil	Nil
Ethnor	Nil	Nil	Nil	Nil	Nil	Nil

SOURCE: A Study on Preventive Disease in India, by J.S. Majumdar; prepared for the Drug Workshop in Jaipur, organized by VHAI.

For sharing this endeavour, we are grateful to the following for their help and moral support in compiling the Essential Drug Ligt.

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  ii) for providing the PGI drug formulary
  iii) for being with us at Pune Workshop -January 1982 where Pune Drug List was finalized.
- Dr Qasem of Gonosasthya Kendra, for having kindly complied to our request to send the graded Bangladesh drug list.
- Dr Joel Fernando, Medical School, Sri Lanka for providing the Sri Lanka drug list.
- Friends in Echo and Action Medeor who sent their lists.
- Late Mr John Agacy, Secretary Low Cost Drugs and Rational Therapeutics, who tediously typed the first draft of the Comparative Essential Drug list in alphabetical order.
- Alphonse our Secretary of Low Cost Drugs and Rational Therapeutics for typing this comparative drug list based on WHO format.

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Graded Essential Drug List

Explanatory Note:

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

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

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

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

EMRO(Eastern Mediteranean Regional Office)- WHO

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

Bangladesh drug list:

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

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

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

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

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

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

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

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

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

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

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

NOTE:

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

Numbers in the Paren thesis following the drug names indicate:

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

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

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

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

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

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

7. Antimigraine drugs
8. Antineoplastic and immunosuppressive drugs
9. Antiparkinsonism drugs
10. Blood, drugs affecting the
    - 10.1 antianaemia drugs
    - 10.2 anticoagulants and antagonists
11. Blood products and blood substitutes
    - 11.1 plasma substitute
    - 11.2 plasma fractions for specific uses.
    - 11.3 plasma substitute.
12. Cardiovascular drugs
    - 12.1 antianginal drugs
    - 12.1 antiarrhythmic drugs
    - 12.3 antihypertensive drugs
    - 12.4 cardiac glycosides
    - 12.5 drugs used in shock or anaphylaxis.
13. Dermatological drugs
    - 13.1 antifungal drugs
    - 13.2 antiinfective drugs
    - 13.3 antiinflammatory and antipruritic drugs
    - 13.4 astringent drugs
    - 13.5 keratoplastic and keratolytic drugs.
    - 13.6 scabicides and pediculicides
14. Diagnostic agents
    - 14.1 opthalmic drugs
    - 14.2 radiocontrast media
15. Disinfectants
16. Diuretics
17. Gastrointestinal drugs
    - 17.1 anacids and other antiulcer drugs
    - 17.2 antiemetic drugs
    - 17.3 antihaemorrhoidal drugs
    - 17.4 antispasmodic drugs
    - 17.5 cathartic drugs
    - 17.6 diarrhoea, drugs used in
    - 17.6.1 antidiarrhoeal (symptomatic
    - 17.6.2 replacement solution. drugs.
18. Hormones
    - 18.1 adrenal hormones and synthetic substitutes
    - 18.2 androgens.
    - 18.3 estrogens
    - 18.4 insulins and other antidiabetic agents
    - 18.5 oral contraceptives.
    - 18.6 ovulation inducers
    - 18.7 progestogens
    - 18.8 thyroid hormones and antithyroid
19. Immunologicals
    - 19.1 Sera and immunoglobulins
    - 19.2 vaccines
    - 19.2.1 for universal immunization
    - 19.2.2 for specific groups of individuals.
20. Muscle relaxants (peripherally acting) and cholinesterase inhibitors.
21. Ophthalmological preparations.
    - 21.1 antiinfective agents
    - 21.2 antiinflammatory agents
    - 21.3 local anaesthetics
    - 21.4 miotics
    - 21.5 mydriatics
    - 21.6 systemic preparations
22. Oxytocics
23. Peritoneal dialysis solution
24. Psychotherapeutic drugs
25. Respiratory tract, drugs acting on the
    - 25.1 antiasthmatic drugs
    - 25.2 antitussives
26. Solutions correcting water electrolyte and acid-base disturbances.
    - 26.1 oral
    - 26.2 parenteral
27. Vitamins and minerals.

Comparative Essential Drug List

Main List	Complementary List	Route of administration dosage forms and strengths	List A Emro	List B Emro	CMC	Low Cost	PU	PG	SL	G	E	AM	A B C	I	II
	1. Anaesthetics														
	1.1 General anaesthetics and Oxygen														
ether, anaesthetic (2)		inhalation					•			•			C		
thiopental (2)		powder for injection, 0.5g, 1.0g (Sodium salt) in ampoule											C		
	1.2 Local anaesthetics														
*Lidocaine		.5% inj, 1,2 (hydrochloride) in vial inj.1%, 2% + epinephrine 1:10000 in vial					•		•	•	•		B		•
		topical forms 2-4 (hydrochloride)													
	2. Analgesics, antipyretics, Nonsteroidal antiinflammatory Drugs and drugs used to treat Gout.														
	2.1 Non-opioids														
acetylsalicylic		tablet 100-500mg, suppository, 50-150mg poed Aspirin	•	•	•	•	•	•	•	•	•	•	A	•	
*ibuprofen		tablet 200mg					•	•							
indometacin		capsule or tablet 25 mg						•				•			
paracetamol		tablet 100-500mg, suppository 100mg + syp	•	•	•	•	•	•	•	•	•	•	A		
	2.2 Opioid analgesics and antagonists														
(Phenylbutazone)/Oxyphenbutazone													A		
morphine (1)		inj 10mg (sulfate or hydrochloride) in 1 ml ampoule					•	•	•	•					
pethidine Hcl 5ml/ml							•	•	•	•					•
	3. Antiallergics														
*chlorphenamine		tablet 4mg (maleate)					•	•	•	•			A		•
		inj 10mg in 1ml ampoule					•	•	•	•					
epinephrine		inj 1mg (as hydrochloride in 1ml ampoule					•	•	•	•	•		A		

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

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

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

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

Main list	Complementary list	Route of administration dosage forms and strengths	list A	List B	CM	low Cost	P	U	P	G	I	SL	G	E	AM	A R C	I	II
*isosorbide dinitrate		tablet(sublingual)5mg																
*propranolol		tablet 10mg,40mg(hydrochloride) inj 1mg(hydrochloride)in 1ml ampoule							•	•						C		•
*verapamil		tablet 40mg,80mg(hydrochloride) inj 2.5mg/ml(hydrochloride)in 2ml ampoule														C		
	12.2 Antiarrhythmic drugs																	
*procainamide		tablet 250mg,500mg(hydrochloride) inj 100mg(hydrochloride)/ml in 10ml ampoule																
	12.3 Antihypertensive drugs																	
*hydralazine		tablet 50mg(hydrochloride)II							•							C		
*hydrochlorothiazine		tablet 50mg							•							B		
*propranolol		tablet 40mg,80mg(hydrochloride)							•	•						C		
	*reserpine(A)(7)	tablet 0.1mg,0.25mg inj 1mg in 1ml ampoule							•	•		•		•	•			•
	12.4 Cardiac Glycosides								•									
digaxin(4)		tablet 0.0625 mg,0.25mg oral solution 0.25 mg/ml inj 0.25mg/ml in 1ml ampoule							•			•	•	•	•			
	12.5 Drugs used in shock or anaphylaxis																	
epinephrine		inj 1mg(as hydrochloride)in 1mlampoule							•	•		•	•	•		B		
inj mephenteramine sulphate		15mg/ml																
inj noradrenalin(Hathi)		1mg/ml							•	•						C		
	13. Dermatological drugs																	
Benzoic	13.1 Antifungal																	
acid + salicylicacid			•	•	•		•					•				B		
Whitfield ointment(Hathi)																B		
	13.2 Antiinfective drugs																	
neomycin+bacitracin		ointment 5mg neomycin sulfate+500IU bacitracin zinc								•					•			

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

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

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

Main list	Complementary list	Route of administration dosage forms and strengths.	List A Emrp	List B	CMC	Low cost	PU	PG	I	SIG	E	AM	A B C	I	II
21.1	21.4 Miotics														
pilocarpine		solution(eye drops)2%,4%(hydrochloride or nitrate)					•	•							
	21.5 Mydriatics														
physiostigmine(Hathi) homatropine(A)		solution(eye drops)2%(hydrobromide)													•
	22. Oxytocics														
*ergometrine		tablet 0.2mg(maleate)		•	•	•		•	•	•	•	•		•	•
oxytocin		inj 0.2mg(maleate)in 1ml ampoule imj 10 IU in 1ml ampoule					•								
	24. Psychotherapeutic drugs														
*chlorpromazine		tablet 100mg(hydrochloride)					•	•	•	•	•				•
		syrup 25mg(hydrochloride)/5ml													
		inj 25mg(hydrochloride)ml in 2 ml ampoule													
*diazepam		tablet 5 mg					•			•	•				
	25. Respiratory tract, drugs acting on														
*aminophylline	25.1 antiasthmatic drugs	tablets 200mg	•		•	•	•	•	•	•	•	•	B		•
		inj 25mg/ml in 10ml ampoule		•											
epinephrine		inj 1mg(as hydrochloride)in 1ml ampoule													
*salbutamol		tablet 4mg(sulfate)		•		•	•	•		•	•		C		
		oral inhalation(aerosol)0.1mg per dose													
		syrup 2mg(sulfate)/5ml													
adrenalin tartarate maliate in 1000							•	•		•	•		C		•
P E T- phenobard 5mg, ephedrine 10mg, theophyline 125?(Hathi)													B		
noscapine(cough suppressant)	ephedrine(A)	tablet 30mg(as hydrochloride)				•				•			B		,

Drugs in Small Rural Hospital
: A repliminary study

Note: Tick where indicated

A. General Description of hospital

1. State in which hospital located:

2. Bed strength: <25 ≥25 ≥50

3. Staff position (specify number and grades):

   a. Medical Officer

   b. Nurses

   c. Others

4. Facilities available

   a. Laboratory b. X-ray

   c. Pharmacy d. C.T.

5. Patient load - numbers seen in last year.

   a. Out-patients:_____ b. In-patients:_____

6. Commonest disorders seen (top 5 only)

	Medical	Obst & Gynae	Paediatric	Surgical
OPD				
IPD				

B. Drug Availability (range and type)

7. How many drugs are available in your pharmacy?

   a. tablets/capsules:

   b. Injections:

   c. Syrups/liquids:

   d. Skin/eye/ear: _____

   e. Total _____

p.t.o....2

8. What are the brands you stock in the following categories? (Mention brand names (company names in brackets) eg., Baralgan (Hoechst))

   a. Antibiotics

   b. Analgesic/antipyretic

   c. Anti-inflammatory

   d. Antidiarrhoeals

   e. Steroids

   f. Hormonal preparations

   g. Psychotropic drugs

   h. Anti-histaminics

   i. Cough syrups

   j. Tonics/Vitamins

   k. Skin preparations

   l. Non-allopathic drugs (or combinations)

   m. Food substitutes

   n. Eye/ear preparations

9. What fixed-drug combination drugs do you stock in the following categories?

   a. Antibiotics

   b. Vitamins with other drugs

   c. Steroids with other drugs

   d. Antihistaminics with others

.....3

C. Drug selection/Purchase/Pricing

10. Who selects drugs in your hospital?

11. What are all the criteria for selection?

12. Do you purchase -

a. whole sale; retail; through medical representative

b. by generic names or brand names?

13. Do you purchase any drugs in bulk? Specify.

14. Do you prepare any medicines/mixtures/ointments in the hospital? Specify.

15. Do you get drugs donated from abroad? (Mention names and sources).

16. How do you price your medicines? (What percentage formula over wholesale-retail price)

a. Injections:

b. Tablets/capsules:

c. Vaccines:

d. Samples:

e. Foreign drugs:

D. Dispensing/Prescribing

17. What categories of staff in your hospital -

a. prescribe? b. dispense?

18. Do you have a trained pharmacist?

19. Does your hospital dispense drugs in any of the following situation? If so, in each one (a) who prescribes? (b) who dispenses? (c) is there a standardised list for each level?

a. Mobile clinics

(a)

(b)

(c)

b. Village Health Centre/Sub-Centre

(a)

(b)

(c)

c. School/Hostel/infirmary

(a)

(b)

(c)

d. Rehabilitation Centre

(a)

(b)

(c)

20. What is the regime you follow in your hospital for the treatment of (specify brand names of drugs) -

a. Malaria

b. Tuberculosis

c. Diarrhoea in children

21.a Do you have any policy about use of expired drugs?

b. If you use some beyond the expiry date, which are these?

c. For how long beyond expiry date do you use them?

22. Do you use any drugs as Placebos? Yes/No

If yes, which are the commonest and for what situation?

23. Are you aware of the drugs banned by the Government in July 1983?

Do you have a banned brand list?

Have you weeded these drugs out of your hospital?

E. Drug information

24. How do you/your staff get information on drug indications/ doses/side effects.

a. Product literature - Yes/No

b. Drug company handouts - Yes/No

c. Any other sources

25. Do you have in your hospital -

a. formulary;

b. list of minimum/essential drugs; and

c. standardised drug regimes?

F. Adverse Reactions

26. Have you had any adverse reactions with drugs in your practice in the last one year? YES/NO
If yes, specify:

G. Drug Budget

26.1 What is the annual expenditure on drugs in the last financial year?

26.2 Did the pharmacy run at a loss or a profit? LOSS/PROFIT
If so, how much during that year?

H. Additional Information

27. Have you taken any initiatives in recent times to rationalise the prescribing/dispensing practices in your institution?

What are they? How successful have you been?

28. If there are any other problems/issues that you have come across with your hospital, please mention them here.

29. Have you identified any forms of irrational prescribing, over-prescribing, under-prescribing or wrong prescribing of the medical practitioners in your area through prescriptions your patients may have brought with them? Give details.

.....7

30. Are there any pressing drugs issues on which you would like reliable information?

31. Do you have any suggestions for issues/problems that should be discussed/considered at the workshop? Mention.

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DR 1

Drugs in Small Rural Hospital
: A repliminary study

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   i. Cough syrups

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(b)

(c)

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(a)

(b)

(c)

c. School/Hostel/infirmary

(a)

(b)

(c)

d. Rehabilitation Centre

(a)

(b)

(c)

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99. 16.

VHAI

Drug Workshop I
Pune
Mira Shiva

MS-cb/D-10:343/ Some Instances of 'Drug Dumping'

For any drug promotion FDA in USA insists on four requirements

1. There must be enough information in the advertisement to enable the patient to use the product properly with side effects, precautions, contraindications etc. included in the information.

2. All such information must also be on the product label.

3. Good and bad aspects of the label should be given equal emphasis.

4. Brand name should be followed immediately by generic names.
Medical professionals can atleast demand compliance with the above in India too.

They can point out outrageous nonsensical bombastic claims.

They can check out the references to so called medical authorities which give a positively biased picture of the product.

They can share valuable information with others.

Kefanver Committee was set up in States one decade ago to deal with the problem of unethical practices of pharmaceutical industry. The Committee concluded that:

'The high margin and profits in the drug industry result from monopoly control of the market excercised by larger firms through monopoly grants that come from patients, through extraordinary high expenditure on promotion and advertising and their success in brainwashing doctors into writing prescriptions in terms of brand names, rather than generic names.'

What is happening to drug imports?

These tripled between 1963-64 to 197 -74 from 13.17 crores to Rs.37.50 crores - within next year it increased to Rs. 47 crores this constituted 35% of the bulk drugs utilized in formulations.

According to Dr S S Gothoskar, the Drug Controller of India, "The last three years have witnessed a steady increase in the requirements of imported raw materials by nearly 100%. Thus while our production increased by only 50% from 1976-77 to 1978-79 the expenditure incurred on import of bulk drugs, intermediates, solvents etc. rose by nearly 80%

The question is with this dependence on foreign imports in which the multinationals have the trump card can one really expect them to comply with drug legislations which may have the interest of common man in mind but which may curtail their high profits.

Double Standards.

1. Ancoloxin marketed by Glaxo, information is altered according to the strictness of regulatory agency.

In America doctors are warned not to prescribe to pregnant women as experiments with rats have shown to endanger the unborn child.

In Britain whilst drug therapy is undesirable during the first trimester of pregnancy the administration of Ancoloxin may be warrned if vomiting is severe. In U.K. M.I.M.S. there are no warnings against the use of drugs in pregnancy.

In Africa, India and other Third World Countries - Ancoloxin specifically recomm recommended for treatment of morning sickness during pregnancy as assessed from information material issued to doctors chemists and in the prescribing guides used in the Third World.

...2/-

2. Melsedin (a hypnotic) produced by Boots. According to Physicians Dest Reference 1977

'PREGNANT WOMEN AND CHILDREN SHOULD NOT USE THIS DRUG'
But two out of three, Third World prescribing guides had 'DOSES SPECIFICALLY SUGGESTED FOR BABIES.'
(Boots were under the impression it had been withdrawn worldwide in 1973 - 74 Social Audit purchased a sample from India in 1978. Boots subsequently confirmed it was being made in India)

3. Migrél (for Migraine) produced by Englands Wellcome.

In U.S.A. maximum dose set by Wellcome five tablets (10 mg) A WEEK with adequate warnings about side effects.
England maximum dose - six/weeks.

India - maximum 12 tablets per week. One serious side effect m like headache, for which they may take more MIGRIL.

Wellcome aware of these discrepencies says that differences reflect "current medical opinion" in the countries concerned.

4. Hydroxyquinolines (vioform lioquinol) available in India as Mexaform, entero Vioform has been banned in Japan as it was associated with numerous cases of neurological toxicity causing partial or severe blindness which left 10,000 patients with permanent disability. This drug is sold freely over the counter with warning of ocular toxicity written nucroscopily in English which anyway very small percentage of population can read.

5. (Metronidazole) Flagyl too has been under severe attack in the West. Because of association of cancer in rats when given in large doses. In India with so much amoeibiasis its use has continued.

6. Bismuth Salts used for digestive upsets have been found to be connected with more than 1,000 cases of encephalitis in France.

7. Lomotil (Diphenoxylate/atropine)
Lomotil Banned abroad for infants is used indiscreminately in India for paediatric age groups.

. Selected Drugs banned in the US but marketed in the Third World.
(Continued on the next sheet)

VHAI
MS-cb/D-10:343/

Selected Drugs Banned In The U.S. But Marketed In The Third World

Drug	Drug Company and FDA Status	Reason for banning or special warning
Dipyrone	Not marketed in the U.S. A.M.A. has justified it only as a last resort	Drugs containing Dipyrone can cause a fatal blood disease known as agranulocytosis (a disease in which a sharp drop in bacteria fighting white blood cells leads to drastic decrease in immunity to infection.
Alginodia	Upjohn	
Beserol	Winthrop/Sterling	
Conmel	Winthrop/Sterling	
Coricidin S/A	Schering	A paper published in 1980 by the Regional Office of the International Organisation of Consumers Unions in Penang Malaysia reported 20 preparations containing Dipyrone and related compounds on the market in 28 similar preparations are listed in the amain prescribing guide with little or no mention of the dangerous side effects.
Corilin	Schering	
Diprona MK	McKesson/F McK	
Dolopirona	Winthrop/Sterling	
Dorflex	Merrel/Richardson-M	
Genservet	ICN	
Stegalgina	Searle	
Valprione	Endo/Dupont	
Optalidon	Sandoz	
Doloneurobion	Merck	
Novalgin	Hoechst	
Cibalgin	Ciba-Geigy	
Depo Provera	Upjohn Not Approved by FDA	Upjohn has been trying for more than ten years to get FDA approval for this 3 month injectable contraceptive. Reported side effects include: breast nodules, cancer of the reproductive organs of test animals, irregular ~~to~~ bleeding, reduced resistance to infection, long term or permanent sterility. If injected into a pregnant woman, it can cause birth defects, especially congenital heart defects. The drug should not be used in lactating women. Source: AFSC Women's Newsletter Summer, 1980

Sources: Multinational Monitor, 8/80 and Interfaith Centre on Corporate Responsibility in New York

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Clinoquinil two Ciba brands sold in Southeast Asia: Entero-Vioform and Mexaform	Ciba-Geigy US and several countries have banned the drug	Clinoquinil and its derivatives have been associated with sub-acute myelooptic neuropathy, a crippling, sometimes fatal disease of the nervous system. The directions given for these drugs in Malaysis and Thailand suggest their use for"non-specific diarrheal disorders and also as a prophylactic".
Chloramphenicol (Chloromycetin) Wintetil Chloramfenicol Chloroptic	Parke Davis Parke Davis Winthrop/Sterling McKesson Allergan	While Chloramphenicol is clinically useful, it should be reserved ONLY for those serious or life-threatening infections caused by susceptible organisms for which less potentially hazardous therapeutic agents are ineffective or contraindicated.
Ambra-Sinto Chloroptic I.S.O.P. Econochlor Opthochlor Opthocort	Dow Allergan Alcon Parke Davis Parke Davis Status: should carry warning regarding severe and often fatal occurence of aplastic anemia.	Both the Physician's Desk Reference in the U.S. and the British text, Martindale's Extra Pharmacopeia provide warnings about the drug causing severe irreversible aplastic anemia. This warning is often not provided in the drug inserts in the developing countries. Sources: Multinational Monitor, 8/80, Physician's Desk Reference, 1980, and Intergaith Center on Corporate Responsibility New York.

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Tetracyclines		
Bristacycline	BristolMyers	As a group, Tetracyclines have relatively low toxicity but can have potentially very serious side effects that can also become life-threatening. Liver damage can occur with certain people. The drug should not be used in children under eight years or in women during the first half of pregnancy due to the drug's tendency to permanently stain children's teeth and to retard fetal bone development.
Tetrex	Bristol/BM	
Bristacin	Bristol/BM	
Achromycin	Lederle/AmCy	
Achrostati	Lederle/AmCy	
Cyclopar	Parke Davis/WL	
Kesso-Tetra	McKesson/FMC	According to the International Organisation of Consumer Unions, of the 42 tetracycline preparations in the 1979 Drug Index for Malaysia and Singapore, only two contained a caution notation.
Panmycin	Upjohn	
Comycin	Upjohn	
Robitet	Robins	
SK Tetracycline	Smith Kline	Sources: Multinational Monitor, 8/80, and ICCR, New York
Sumycin	Squibb	
Tetracycline	Philips Roxanne	
Tetracycline	Wyeth/AHP	
Tetracyn	Pfipharmecs/Pfizer	
Tetrastatin	Pfipharmecs/Pfizer	
Topicycline	Proctor and Gamble	
Mysteclin	Squibb	
Aueromycin	Lederle/AmCyan	
Ledermicin	Lederle/Am Cyan	
Vibramicin	Pfizer	
Terramicin	Pfizer	
	Status: All of the above tetracyclines should provide a caution in the drug insert warning the physician not to use the drug in women who are in the first half of pregnancy or in children under eight years of age.	

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Lincocin Cleocin	Upjohn Upjohn	In 1973, the British medical journal Lancet published an article linking Lincocin and Cleocin with a high incidence of intestinal disorders, diarrhea, and occasional deaths. The current U.S. PDR does offer sa warning regarding these side effects, however, this warning may not be present in the third world countries.
MER-29	Richardson/Merrell Inc. Status: banned in U.S.	This is an anticholesterol drug which was taken off the U.S. market in the mid 1960s after it was found to cause cataracts, baldness and impotence.
Sintex	Richardson/Merrel Inc.	In 1978 the company had to recall and reformulate their Sintex nasal spray after the company found that in contained resistant bacteria. Source: Everybody's Business, The Irreverent Guide to Corporate America, Moskowitz, Milton, et.al., 1980, New York.
Selacryn	Smith Kline Status: U.S. Justice Dept. is investigating the company and may bring criminal charges against the company for failing to report adverse reactions to the FDA. Banned in West Germany, Mexico, the Philippines, and Switzerland	According to a report by Dr Wolfe of the Public Citizen Health Research Group, as of November, 1980, the FDA had received 1,100 adverse reports including 600 cases of liver toxicity and over 60 deaths, as a result of Selacryn's eight month tenure on the U.S. market as a antihypertensive. Source: Multinational Monitor, July, 1981

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1	2	3
Stanozolol (Winstrol)	Winthrop/Sterling FDA Status: 1980 PDR states, "Final classification of less than effective indications requires further investigation	Stanozolol is a steroid hormone chemically and pharmacologically related to methyltestosterone. The actions of this drug are similar to those of the male sex hormones with the possibility of causing serious disturbances of growth and sexual development. Source: Interfaith Center for Corporate Responsibility, New York.
Indomethacin (Indocin)	Merck, Sharp and Dohme	Indocin's precise mode of action is not known. It relieves symptoms, but does not alter the progressive underlying disease. Careful instruction to the patient is essential. Source: ICCR, New York
Res-Q-Aire resuscitator	Banned in the U.S but exported to Africa	Ineffective as a respirator; failed to revive the Kenyan politician Tom Mboya when he was shot some 12 years ago.
Dalkon Shield IUD		This device has geen linked with the deaths of 17 women in the U.S., however hundreds of thousands of Dalkon Shields have been sent to third world countries. Source: Mother Jones, May 1981

RESOURCES

Interfaith Center on Corporate Responsibility New York
C/o Father Michael Crosby, OFMCap
3900 North Third Street
Milwaukee, Wisconsin, USA 53212

Depo-Provera Campaign to block FDA approval:

Judy Norsigian
Boston Women's Health
Book Collective
Box 192
West Somerville Massachusetts, 02144

Multinational Monitor
P O Box 19312
Washington, D.C. 20036

Circle of Poison, Pesticides and People in a Hungry World, David Weir and Mark Schapiro, published by the Institute for Food and Development Policy, 1981

Institute for Food and Development Policy
2588 Mission Street
San Francisco, California, 94110

MULTI-NATIONALS IN THE INDIAN DRUG INDUSTRY*

- Anant Phadke**

Introduction

THE Pharmaceutical industry all over the capitalist world is controlled by a few giant multi-national corporations (MNC). These corporations can apply the latest fruits of scientific and technical research because they have the resources to do so. They can also set aside large sums of money to do the research required for identifying newer and better drugs. However, since their primary motive is to maximise their profits, this potential is not realised adequately. Instead their strength is used mainly to manipulate the system to serve their narrow profit-interests. This is clearly seen in their role in a developing country like India.

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* This article is modified from the original which appeared in the medico friend circle bulletin in January-February 1982.

** Anant Phadke is the Convenor of the medico friend circle--a socially conscious group of individuals which is working to evolve a pattern of medical education and methodology of health care relevant to Indian needs and conditions. Also actively involved with the Lok Vidyan Sangathana, Maharashtra, Anant has been writing on health related issues in English and Marathi.

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The following facts highlight the monopolistic structure of the MNCs in the world and in India.

* In 1974, the top 30 multi-national firms accounted for 52 percent of the total sale of pharmaceutical products in the world (2).

* In 1973, the top 20 firms accounted for over 75 percent of the total ethical drug sales in the USA and the UK (2).

* In 1973, according to Roche Company's own estimates, their two main tranquilizer formulations--LIBRIUM and VALIUM--held more than a third of the entire world tranquilizer market (2).

* In India, while the value of drug production has increased from Rs.10 crores in 1948, to Rs.445 crores in 1973 and Rs.1376 crores in 1979-80, the share of MNC subsidiaries and minority ventures still remains substantial (3).

* In India in 1973-74, 60 firms with foreign shares accounted for 70 percent of the country's total drug sales. The remaining 30 percent was shared by 116 large and 2500 small manufacturing companies (3).

THE pharmaceutical industry in India has been dominated by the giant foreign companies in the 30 years after independence. Since most of the research in Pharmaceuticals in the commercial sector of the capitalist world is undertaken by MNCs and since the industry is protected by

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patent laws, 90 percent of patents in the pharmaceutical industry in India are also held by these foreign controlled corporations. What is the role and the effects of this commercial, profit-oriented, giant monopolistic sector?

(1)
Emphasis on Drug Formulations and its social cost

PRODUCTION of bulk drugs requires setting up complex manufacturing units here in India. However, foreign companies, which started here as marketing subsidiaries of their giant parents are not interested in this. They have beenforced by circumstances into manufacturing activity. This mainly consists of importing bulk drugs from parent companies and merely mixing them together in various proportions to make various formulations with particular brand names.

* In 1978-79 out of a total production of Rs.220 crores of bulk drugs in India, the foreign sector accounted for 16.7 percent, whereas out of Rs.1050 crores of drug formulations, it accounted for 43.8 percent worth of formulations(4).

  This affinity for formulations exists because formulations means more profit.

* The average profitability (pre-tax) of four foreign companies during 1974-77 was 7 percent for bulk drugs and 21.8 percent for formulations(3).

ONE of the main reasons given for allowing the foreign companies to operate in India is that these companies will bring their complex technology with them and thereby help setting up a modern manufacturing drug industry in India. Though this has happened to a certain extent, the main effect has been to thwart the development of a modern drug industry in India. Since the foreign companies are the prime movers in the drug industry in India, private companies of Indian origin also indulge mainly in production of formulations.

* In 1978-79, private Indian companies accountedfor 22.3 percent of bulk drug production and 32.4 percent of formulations. The public sector, however, produced 14.6 percent of bulk drugs and only 5.7 percent of drug formulations(4).

IT is well known that many of the formulations in the market are not useful on account of one or more of the following factors--unnecessary ingredients, wrong ingredients, sub-therapeutic dosages and wrong combinations. The WHO, the Indian Medical Association and the Hathi Committee have recommended respectively 200, 156 and 116 essential active substances as essential drugs. The WHO has, in addition, recommended 30 complementary drugs for treating rare disorders. To this list could be added a few more rational drug combinations. As opposed to the fact that we need about 250 or so drugs as calculated above,the situation in India is very different.

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About 15000 formulations are being marketed under different brand names--most of these being repetitive.

* Out of Rs.1260 crores worth of drugs manufactured in our country in 1979-80, essential and life saving drugs accounted for Rs.350 crores only; the rest were pick-ups, tonics and formulations of marginal value(4).

* An analysis of 289 manufacturing units (accounting for over 85 percent of drug production) showed that in 1972, these units were marketing 244 multi-vitamin C preparations, 262 Vitamin-B complex tonics and 126 cough syrups(3).

  Most of these formulations and brand products are not very different from one another and therefore the main technique of selling them is through high-pressure advertising and marketing. This advertising pushes up the price to be paid by the consumer.

* As much as 18 percent of turn over on an average is spent by Pharmaceutical firms on sales promotion in India(2).

* In a study of 24 foreign drug companies over head costs (including sales promotion expenditure) amounted to 33.32 percent during 1974-77 as opposed to an average of 20 percent in other industries(3).

  These expenses are a huge social waste. They are, however, necessary for the drug companies

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formonopolistic competition among themselves.

(2)
Irrational combinations

TO justify a different brand name, drug companies many times add some ingredients to the essential drug. Most of the times these additions are irrational. A sub-committee under the Drugs Consultative Committee stated that of the 34 categories of fixed combinations examined, 23 categories were to be weeded out. The medical profession are aware of many examples of irrational combinations but it would not be out of place to quote examples of a couple of scandalous combinations.

* Analgin causes serious blood dyscrasias as well as gastric ulcers. Phenylbutazone and oxyphenbutazone are equally hazardous drugs. But a combination of Analgin and Phenylbutazone achieves a record sale of over Rs. 2 crores within a year of its introduction (6).

*Amidopyrine is a very toxic drug that is banned the world over; but most of our antispasmodic combinations contain Amidopyrine. In 1979-80, we imported 95 tonnes of Amidopyrine (6).

Because of their monopoly-control leading manufacturers can dump these products into the consumer's body; the doctors virtually acting as agents of these companies.

(3)
Drugs--Not for the Poor

MOST of the combinations and formulations of drugs in India are too costly for the vast majority of our population because of the brand-names, advertising, unnecessary ingredients and high-profit margins. The drugs that the poor need - drugs against tuberculosis, leprosy, malaria etc., and also vaccines are under-produced because those who need these do not have the money to buy them. Tables (1) and (2) show the discrepancy between installed capacity and actual production of some of these drugs in 1978 and between targetted and actual production of vaccines in 1980-81.

Table (1)[5]

1978

Name of drug	Installed capacity (tonnes)	Production (tonnes)
1. Isonex	539	94
2. PAS and its salts	1290	558
3. Thiacetazone	153	13
4. Streptomycin	257	225
5. Chloroquin	176	45
6. DDS and its derivatives	38	17

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Table (2)[7]

1980-81

Vaccine against	Target (lac tonnes)	Production (lac doses)
1. Diphtheria, Pertussis Tetanus	400	145
2. Diphtheria-Tetanus	250	120
3. Tetanus	110	70
4. Poliomyelitis	60	20

EVEN amongst the same class of drugs: for example - the Vitamins, a similar pattern is seen between what the poor need and what the rich can afford.

* Vitamin B Complex preparations of various sorts consisting mainly of irrational combinations consumed by the rich account for 5.5 percent of total drug production. However, Vitamin-A (the deficiency of which is extremely widespread amongst the poor and turns 12000 children blind every year) accounts for mere 0.3 percent of total drug production[6].

As against this, the drugs consumed mainly by thewell-to-do, eg., high protein concentrates and drugs prescribed by doctors for their own interests: eg., injection terramycin are produced much beyond their licensed capacities. Table (3) highlights the discrepancy between such products and much-needed anti-tuberculosis drugs.

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Table (3)[5]

Product	Licensed capacity (metric tonnes)	Production during 1979 (metric tonnes)
1. I N H	80	52
2. PAS and its salts	110	94
3. Terramycin	14	54
4. Protinex	110	290

DRUG firms obtain licenses and letters of intent for bulk drugs and formulations but do not use them when they find that the profitability is less.

* Of 32 bulk items covered by 13 licenses, that 21 items were not produced by Glaxo Laboratories for a period of five years has been reported[5].

(4)
Very little research for the poor

OUT of a total world production of drugs of 50 billions, the developing countries in 1974, imported about 2.1 billions worth ie., about 4.2 percent. But out of an estimated annual research bill of 2 billion only 30 million ie., 1.5 percent was spent by the companies on the tropical diseases which constitute one of the most pressing health problems in developing countries. This amount according to W.H.O. is equivalent to the cost of building a few miles of motorway and less than one fiftieth of the annual expenditure on cancer research[1]. Whatever research

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is done by Western agencies on tropical diseases, takes place in developed countries and is focussed mainly on problems which they are concerned with. For example, the U.S. Walter Reed Army Research Institute is the only Western agency doing systematic research in Malaria. It got interested in malaria because of the U.S. involvement in Vietnam where malaria caused more American casualties than did the Vietcong army[1].

MNCs and their subsidiaries in India show the same pattern in research.

* In India out of 45 foreign companies identified by the Hathi Committee, under the Foreign Exchange Regulation Act, FERA, only 7 companies performed R & D in the manufacture of basic drugs[8].

* An analysis of 20 MNCs in India showed that during 1974-75, the R & D expenditure of these firms ranged between 1.5 to 2.5 percent of their sales turn over, whereas their parent companies in the West spend typically between 5 to 15 percent of their annual turn over on R & D[8].

* The Sandoz group as a whole spends nearly 9 percent of its world wide turnover on R & D while its Indian subsidiary spent only 1.4 percent of its turn over on R & D in 1975[3].

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THE reasons for this pattern is obvious. The MNCs cannot afford to spend on research on drugs to be used by the poor, the poor being unable to pay for this research through higher prices for new drugs. This state of affairs will not change unless human needs take a priority over the profit-motive of the drug industry. It costs around 50 million to develop a new drug . In case of drugs for tropical diseases it may even be more, since a lot of ground work needs to be done initially. The MNCs are not going to change their research strategy unless strong public pressure forces them to do so.

(5)
Are MNCs needed on Technological grounds?

ONE of the important arguments in favour of allowing the MNCs to continue their operations in India is that they bring new and better drugs into the country. Recent studies and reported facts show this to be no longer a valid supposition.

* A study on MNCs in India showed that the time-lag between years of production of a drug abroad and in India was 7-16 years showing that fruits of research done in the West do not percolate quickly through MNC subsidiaries in India(9).

* Out of 138 drugs listed as major pharmaceutical innovations from 1950 to 1967 in the West, only 20 were being manufactured in India in 1973(9).

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Now in the West in spite of growing expenditure on drug research, less and less genuinely new drugs are being innovated since the scope for newer drugs is becoming less and less for the developed societies.

* Out of the 1500 drug patents field in 1972, only 45 (3 percent) were genuine new drugs, 150 (10 percent) were major modifications and the remaining 1305 (87 percent) were purely imitative drugs(1).

This means that the post-war period of explosion of new better drugs is over.

THE second argument usually presented is that the Indian drug industry is not yet technically competent to produce most of the drugs needed in the country. The situation in recent years makes this argument equally untenable.

IN 1977, there were 64 foreign controlled firms of which only 38 produced bulk drugs, numbering 207. Out of these 207 bulk drugs, 93 were exclusively produced by foreign companies, the rest being also produced by the Indian sector--both public and private included. Out of these 93 drugs only 29 drugs were high technology drugs, the production of which could probably not be taken up by the Indian sector for lack of know-how(6). The Indian sector had the technology to produce the remaining 64 drugs being produced exclusively by the foreign sector at that time. Among the 29 high technology drugs, some may be chemical analogues that are closely related and hence the total number of drugs that the Indian

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industry could not produce because of lack of know-how would be a very small number. Even in the case of such drugs Indian companies could enter into technological collaborations (as they have been doing currently) with foreign companies.

THUS on technological grounds it is not at all necessary to allow foreign companies (MNCs) to operate here.

(6)
Economic effect on Industry

QUITE apart from the above mentioned facts of the MNC operations in India, a very crucial problem is the long-term deleterious effects they have on our industrial economy--through the practices of pumping money out of India through repatriation of profits and 'transfer pricing'.

* A case study of 42 foreign drug companies showed that during the period 1968-69 to 1977-78, these companies repatriated Rs.45.11 crores out of India in the form of profits, dividends, royalties, office expenses etc (3).

IT is clear that though most of the MNCs operating in India earn huge profits by exploiting cheap labour in India, they do not re-invest all of it here.

REPATRIATION of profits is only one of the mechanisms. The other mechanism is 'transfer pricing'. The subsidiaries of multi-nationals import raw materials from parent companies at rates higher than the prices in the international market. This raises the prices of the final products andthereby pumps off money from the pockets of our people into the coffers of

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the parent companies.

* A systematic study of 29 foreign companies showed that in 1977 the out-flow through transfer pricing was an estimated 20 to 40 percent more than the out-flow through repatriations[3].

* A foreign subsidiary charged Rs.60000/kg for dexamethasone (steroid) which was later reduced to Rs.16000/kg at the intervention of the Controller of Imports[2].

* Gentamycin (an antibiotic) was being imported into India by a multi-national subsidiary at the rate of Rs.45000/kg. When import of some drugs was channelised through a government agency, the price was lowered to Rs.10000/kg. Similarly the price of Doxycycline (another antibiotic) was brought down from Rs.3000 to Rs.1500/kg.[2]

Conclusion

MULTI-NATIONALS in India, because of their profit-motive, monopolistic form, inter-company competition especially product differentiation through brand names, high-pressure advertising and other such characteristics, are primarily interested in manufacture of fancy formulations for the well-to-do at the expense of essential drugs for the vast majority. For the same reasons they are not interested in research areas vital for our people's health. Their presence

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in our country cannot be justified on technological grounds. Moreover they have been responsible for exploiting the cheap Indian labour and pumping out large sums of money into the coffers of their parent companies. By their own performance in the last few decade they have demonstrated their irrelevance to the Indian drug Industry and the Indian people.

A foot note

The functioning of the Indian private and public sector also need to be analysed, in order to get a better understanding of the important obstacles to the evolution of a rational drug policy. Even at a glance, however, the Indian private sector will show that it is dominated by monopoly profit motives while the public sector has been unable to reverse the basic trends towards irrelevance in the drug industry in India. Both of these, however, are outside the scope of this article

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2-8 are papers presented at the Seminar

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Annexure III

PRODUCTION OF ESSENTIAL DRUGS BY MULTINATIONALS AND ORGANIZED SECTOR

Name of the firms	INH	PAS	THIACITAZONE	ETHAMBUTOL	RIFAMPICIN	STREPTOMYCIN
Abbott	Nil	Nil	Nil	Nil	Nil	Nil
ACCI	Nil	Nil	Nil	Nil	Nil	Nil
Hoechst	Nil	Nil	Nil	Nil	Nil	Nil
S.K. & F.	Nil	Nil	Nil	Nil	Nil	Nil
Searle	Nil	Nil	Nil	Nil	Nil	Nil
Sandoz	Nil	Nil	Nil	Nil	Nil	Nil
Roche	Nil	Nil	Nil	Nil	Nil	Nil
Parke-Davis	Nil	Nil	Nil	Nil	Nil	Nil
Sarabhai	Yes	Nil	Yes	Yes	Nil	Yes
Boehringer Knoll	Nil	Nil	Nil	Nil	Nil	Nil
Glaxo	Nil	Nil	Nil	Nil	Nil	Yes
E. Merck	Nil	Nil	Nil	Nil	Nil	Nil
Ciba-Giegy	Nil	Nil	Nil	Nil	Nil	Nil
Pfizer	Yes	Yes	Yes	Nil	Nil	Yes
Warner	Yes	Nil	Nil	Nil	Nil	Nil
Burrough Wellcome	Nil	Nil	Nil	Nil	Nil	Nil
German Remedies	Nil	Nil	Nil	Nil	Nil	Nil
Cynamid	Nil	Nil	Nil	Yes	Nil	Nil
Ethnor	Nil	Nil	Nil	Nil	Nil	Nil

SOURCE: A Study on [illegible] India, by J.S. Majumdar; prepared for the Drug [illegible] in Jaipur, organized by VHAI.

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THE MEDICINE MEN

Following the tricky footwork of the multinational drug companies calls for an eye skilled in pharmaceutical and financial choreography-even the most sophisticated health services have been confused into paying exorbitant prices. So what chance do the developing countries stand ? Not much according to a forth coming report* by the Haslemere Group. Gross overpricing inadequate labelling and the restrictive use of patents are just some of the disturbing features of the drugs trade revealed in the extract below.

If there is one industry that's given multinational companies a bad name it's the pharmaceutical business. The subject of constant investigations in both Europe and North America on charas of everything from selling useless drugs to unethical/clinical trials - the industry continues nevertheless to increase its profits resist its critics and even to counter-attack with its own propaganda. Indeed, UK judge Lord Justice Diplock has remarked, "We are might be pardoned for supposing that we were witnessing a contest between rival philanthropists, as to which of them might be permitted to confer great benefit on the public".

The industry is strength which has enabled it to escape most government attempts it to control drives from two facets of its operations which are closely related its multinational character and its monopoly trading position. Since the 1950's the pattern of development has been increasingly that of mergers and takeovers so that the larger national companies rapidly grew into multinational giants and smaller companies were gradually swallowed up or beaten out of the market.

OBSCURE ACCOUNTS

The swiss drug companies keep the economics of their operations a tightly guarded secret, under the protection of swiss law they are financially answerable to no one save their shareholders. The published accounts of most British companies give little more useful information, profits from drug sales are carefully concealed among those from their other diverse interest in foods, drinks, fertilisers and cosmetics.

American law, however forces all publicly owned drug companies to disclose their accounts in some detail. From these it is evident that profitability of the drug companies is nothing short of staggering. The average return on capital around 18% compared with only 11% for all other types of manufacturing industry. The situation has been so throughout the history of the drug industry, and the high returns have only been topped by the soap and cosmetics industry which in many cases is linked with pharmaceuticals.

When considering the giant nationals, however even these average figures make the true enormity of their profits. Merck, Sharpe and Dohme, for example, the second largest drug maker in the USA, showed a 50% return on capital in 1973, and other manufactures all show well above average returns.

Such high returns are not less true for operations in the developing countries. In India for example, the 33 foreign controlled drug firms supplying 65-75% of the total maker showed returns on capital of 30% in 1970, and recorded profits of over 20% in every single year between 1968 and 1970. There is no doubt that in India the foreign drug companies are not only the most profitable of manufacturers, but also of all the foreign controlled businesses generally.

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HIGH PRICES

In view of the enormous profits, it will come as no surprise that the pricing of individual drugs relates less to the cost development production and promotion than to what the market will bear.

In 1960, Scherings anti-inflamatory drug, predisolone cost them 1.6$ per tablet to produce. It was sold to the pharmacist for 17.9$, who sold it to the patient for 28.8$ a mark-up of 1,118%. On a drug for which this firm did not even have to do the research, profits were even more astronomical. Schering purchased oestradiol, a sex hormone, from the french firm Roussel, and sold it under the Schering lable at a mark-up of 7,079%.

But if prices are high in the developed world, when we come to consider Third World countries, they are, as David Warburton, General Secretary of the General and Municipal Workers' Union put it near criminal'. This view was recently endorsed in a confidential report of the WHO in Geneva. For, whereas Britian pays American firms $2.40 per kilo for vitamin 'C'. India has to pay nearly $10 per kilo. The tetracycline antibiotics, costing $24.30 in Europe are being sold to India, Pakistan and Colombia for between $100 and $270 and one of the most popular semi-synthetic penicilline, Bristol's Polycillin, has been sold for $41.95 per hundred tablets in Brazil, when the same product in the US was only $21.84.

Although it is American prices which have been most closely scrutinised through senate comittee hearings, it is clear that some European drug multinationals operate equally exploitative in the absence of effective policies in the absence of effective machinery for price control in most developing countries. A particularly disturbing feature of pricing in the Third World is that the cost of well established drugs. Whose patients ran out years ago, continues to rise, whereas in the developed countries it typically declines. In India a survey of 8 long established drugs showed that their price had risen by 42% between 1961 and 1970.

RESEARCH COSTS

Drug companies are always quick to point out that the unparalled profitability of the pharmaceutical industry is offset by the cost of research and development, which in this filed is uniquely high and unduly risky.

There is no doubt that the fundamental research necessary for real innovation, the safety testing of new drugs and the development of formulations suitable for marketing is a costly business. But on average, research and development expenditure comprise only 10% of income, while advertising and promoting take up more than 20%. And even the term 'research' may be deceptive. It not includes fundamental research into formulations and methods of production. And therapeutic research (clinicaltrial in man). But may also includes such items as development of more pleasing colours, tastes and packing for drugs, expenses for employees to attend conferences at home and abroad, as well as general market research aimed at improving sales and profits, and the purchasing of international patents whose purpose is merely to extend the monopoly position of the firms.

A "HIGH RISK" INDUSTRY

And what are the risks we are always hearing about ? At first sight, the cost of developing individual drugs in relation to possible risks, seems quite high: for example, in the field of contradiction, so extensive are the requirements for safety evaluation that it has been estimated that the cost of developing a new type of pill would be of the order of £10 million.

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However, very few drugs will be major innovations, estimated at only 4 to 7 a year from the whole industry. Most of these potential drugs already in existence that require no major development in such chemical synthesising techniques, or in subsequent screening procedures.

The industry certainly seems to have few qualms about marking useless drugs. In 1971, an investigation of 2,000 products by a panel of the American Food and Drug Administration, found 60% lacked evidence for their therapeutic claims. Some of these were ordered off the US market, but most have found ready market elsewhere, in Third World Countries, where regulations governing toxicity and efficacy of drugs may be non-existent or rudimentary. The drug dithiazanine iodide (netocyd) active against certain types of worms was voluntarily taken off the market by one US manufacturer, Eli-Lilly, because of toxic effects that emerged with its use, Pfizer, however continued to market the drug in areas not under the control of the American FDA, and in 1973 it could still be brought in Panama with a package insert discribing the drug as a "significant" advance in the treatment of the most common kinds of parasitic infestation", with no attempt to restrict its use.

NEGLECTED AREAS

It is clear that the industry does not invest in what would seem to be genuine high-risk areas. There is almost no research into drugs for rare disease, where there is little prospect of things high returns. Ronald Edwards, former chairman of Beecham, recently suggested that the government should finance such research. Presumably the industry should continue to reap its high profits on more commercial enterprises, vastely over-priced to cover those 'high risks'.

The drug industry is equally neglectful of research into drugs for tropical disease, many of which are wide spread throughout the developing world, and would lend themselves to international co-operation in research. The multinational pharmaceutical industry with its highly developed research and production facilities spread throughout the world, is ideally placed to tackle such problems, but chooses not to. For although the potential sales at first sort of money the drug companies would want them to pay in neglect of Third World health problems, the pharmaceutical industry not alone; only 1% of all money spent by industry government and charities on medical research is devoted to the major disease problems of the developing countries.

Because the pharmaceutical industry is geared not only to the needs, but also to the petro-chemical resources of the industrial world, there is no research done into the possible alternative resources for pharmaceuticals within Third World countries themselves. It has been suggested for example that agricultural by-product should be utilized for the manufacture of pharmaceuticals in Tanzania. And a group of Chinese experts have identified some fifty species of plant growing in Tanzania, extracts of which are used in current Chinese medical practice. Not only does the western pharmaceutical industry not investigate these possibilities it actively discourages them, preferring to sellintermediate ingredients to subsidiary companies.

UNUSED PATENTS

Pharmaceutical companies maintain their position of their power through a patent system designed originally to ensure remuneration for the time, physical and intellectual energies, and costs that were put into the development of the idea. Drugs, however are patented not by industries, giving manufacturers of new drugs sole rights over production, and in the absence of any competition, save that from drugs already market for the same therapeutic indications, the right to name its price.

In developing nations generally, 90% or more of the patents are held by foreign ownership is increasing. In Chile for example, 98.4% of chemicals and drugs patents are foreign owned. Concentration of these patents in the hands of very few is also evident: In Colombia in 1970, 60% of drugs patents were held by only 10% of all the foreign patent owners. In effect, there is a ruthless exercise in monopoly power by the multinational pharmaceutical companies for once a patent is registered neither a national nor a foreign competitor can enter the production market it covers, even if it is not being exploited by the patent holders.

The fact is that foreign-owned patents are almost totally un-exploited. In Colombia and Peru less than 1% of drugs patented are actually produced in those countries the function of the patent is to preserve secure import markets for foreign companies, without necessitating investment, and to block potential competition from other close substitutes.

DANGEROUS LABELLING

The fact that drugs available only on prescription in the west, are obtainable over the counter in developing countries makes adequate labelling and warnings all the more important. A recent survey of the situation in Latin America showed that companies frequently minimise risks and exaggerate claims for their own drugs in the way they are not permitted to do in the U.S. Drugs are recommended for a wider variety of conditions than allowed in the U.S., and warnings on restrictions of use and adverse reactions are incomplete or entirely absent. According to one drug company spokeman, "Product documentation will sometimes vary in individual countries to reflect local needs economics, health conditions and government regulations", Clearly, for some companies, absence of government regulations on the inclusion of warnings means that such for warnings become unnecessary.

One drug which may have caused unnecessary death is Raudixin, originally introduced as a major tranquilliser and still to reduce high blood pressure. The frequent tendency of this drug to cause severe depression, occasionally resulting in suicide, led to abandonment of its use as a tranquilliser some years ago in the west however, a package insert obtained in Brazil in 1974 still described the drug as "the ideal medicine, for the treatment of emotional disturbances" and the drug of choice in daily practice". A spokeman for the manufacture squibbs, said that the package insert had been written twenty years ago, but that it still conformed with Brazil's present drug regulatory requirements. As of last autumn it had still not changed the package insert. Once again we see that it is sales, and the letter of the law, which concern the drug companies.

Along with the rest of Western medical practice, we have exported to third world countries our own mistaken believes in efficacy of chemical intervention in individual sufferers for endimic disease. Third World countries continue to deploy large amounts of their scarce resources on buying drug from Western countries, often as we have seen at higher absolute cost than in industrialised countries where health and social welfare bedgets are low, the high cost of medicines puts them well out of reach of the much of the population. Where governments do pay for drugs, the cost takes up a dis-proportionately high amount of the total money available for health, to the detriment of preventative medicine schemes.

....5.

PROPOSALS FOR CHANGE

The particularly vulnerable position of third world countries in their relationship to the international pharmaceutical industry has been noted in a recent report published by the UN conference on Trade and Development.

The report proposes certain immediate measures that poor draw up a list of essential drugs, that brand names used, and that drugs be purchased through a centralised distribution agency, supplied by small producers in both developed and developing countries. It also advocates the third world countries should co-operate in the manufacture on pharmaceuticals and the setting of technology centres to conduct research and development and diseminate information on drugs, thereby facilitating the transfer of pharmaceutical technology to the developing countries.

Many of these ideas have been advocated before. The reduction of the national pharmacopeia to a few dozen items was advocated in Chile by its late president Dr. Salador Allende, himself a physician, but the majority of Chilean doctors were opposed to his ideas. It remains to be seen whether a co-operative effort on the part of third world countries, both to restrict the import of non-essential drugs and to establish their new pharmaceutical manufacturing industry, can succeed in breaking the monopoly power of the multinational pharmaceutical companies.

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SIGNATURE CAMPAIGN

A note to demand for a People Oriented Drug Policy.

Dear Friend,

This signature campaign is against misuse of drugs. It is against continued sales of hazardous, irrational and banned drugs, against allowing sales of substandard and spurious drugs

It is a demand for streamlining production, distribution of drugs that are needed for the health problems of the majority. More than that, it is a demand for dealing with those conditions that ensure ill health.

Please go through the text of the memorandum which summarizes the basic demands of the organizations mentioned below it.

Name	Address	Your Organizations Name	Your job- If possible please give the capacity in which you are working there

If you feel strongly about the injustice in the healthand drug scene, circulate this to others and obtain signature of others supporting the demands.

If you wish to be involved in the Drug Campaign join the Drug Action network which is part of an emerging 'People's Health Movement'. If you would like the name of your organization included in the list of organizations who are taking a strong stand against the drug misuse, let me know. Please also specify the responsibilities you would be willing to take and contributions you would like to make in Drug Action.

Within two months the New Drug Policy would have been passed. The time to express our concerns, to make our demands and suggestions is now. Probably what the most important need of the moment is to be able to organize ourselves around

this issue, whether we are health groups, Consumer groups, legal aid groups or involved in Community Organization or People's Science movement. Public pressure is crucial to prevent vested interest from getting away unchecked with anti-people, policies stands.

The signature campaign is to
- urge you for your support
- it is to build a network of groups to act as the watch dogs on behalf of the people
- it is to build pressure to demand public accountability from our drug industry health personnel and policy makers.

Only a very small minority feels concerned about issues of social justice. To demand any People Oriented policy whether it is related to human rights, enviornmental issues or health we have to support each other. Since health and survival are everybody's concern and not the pregorative of those involved in health work alone, we hope you will join hands with us.

Looking forward to your support, and solidarity.

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

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FROM : VHAI, Delhi

D-10.341
SS:k/31.12.81

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INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS ASSOCIATIONS (IFPMA)

CODE OF PHARMACEUTICAL MARKETING PRACTICES

Preamble

The Statute of the Federation article 3 states that one of the objects of the Federation is "to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntary agreed on and "to coordinate the efforts of its members towards the realization of the above objects".

It is believed that in keeping with the pharmaceutical industry's international responsibilities, the members of the Federation will be prepared to accept certain obligations, insofar as their marketing practices are concerned, and to ensure respect for them.

IFPMA recommends a Code of Marketing Practices to its member associations, recognizing the difficulty of setting out a simple Code which will be applicable in all parts of the world. It seems clear that national and regional conditions and legal restrictions will continue to vary to such an extent as to make a simple world Code impractical. Nevertheless, the Federation believes that it has a duty to encourage its member associations to either introduce such Codes of Practices or where such Codes already exist, to continually re-examine and where necessary revise them so that a voluntary system based on such a Code keeps pace with modern medical knowledge and changing health services and conditions.

It is recognized that many individual member associations of IFPMA have laid down their own Codes of Marketing Practices and this recommended Code is not intended to replace similar Codes or instruments already in force by members of the Federation. The following voluntary Code is therefore put forward as a model for IFPMA's member associations.

A Code of Marketing Practices of this sort should be the responsibility of member associations who should also provide guidance to their members on matters of compliance and interpretation.

Obligations of the industry

The obligations of the industry may be identified as follows:

The pharmaceutical industry, conscious of its special position arising from its involvement in public health, and justifiably eager to fulfil its obligations in a free and fully responsible manner, undertakes:

- to ensure that all products it makes available for prescription purposes to the public are backed by the fullest technological service and have full regard to the needs of public health;

- to produce pharmaceutical products under adequate procedures and strict quality assurance;

- to base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions of use;

.../-

- to provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contra-indications, tolerance and toxicity;

- to use complete candour in dealings with public health officials, health care professionals and the public.

Suggested Code of Marketing Practices

We hereby declare our intention to voluntarily conform to the following Code of Marketing Practices:

I. General Principles

1. The term "pharmaceutical product" in this concept means any pharmaceutical or biological product intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, which is promoted and advertised to the medical profession rather than directly to the lay public.

2. Information on pharmaceutical products should be accurate, fair and objective, and presented in such a way as to conform not only to legal requirements but also to ethical standards and to standards of good taste.

3. Information should be based on an up to date evaluation of all the available scientific evidence, and should reflect this evidence clearly.

4. No public communication shall be made with the intent of promoting a pharmaceutical product as safe and effective for any use before the required approval of the pharmaceutical product for marketing for such use is obtained. However, this provision is not intended to abridge the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media, nor to restrict public disclosure to stockholders and others concerning any pharmaceutical product as may be required or desirable under law, rule or regulation.

5. Statements in promotional communications should be based upon substantial scientific evidence or other responsible medical opinion. Claims should not be stronger than such evidence warrants. Every effort should be made to avoid ambiguity.

6. Particular care should be taken that essential information as to pharmaceutical products' safety, contradictions and side effects or toxic hazards is appropriately and consistently communicated subject to the legal, regulatory and medical practices of each nation. The word "safe" must not be used without qualification.

7. Promotional communications should have medical clearance, or where appropriate, clearance by the responsible pharmacist, before their release.

II. Medical Representative

Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate and responsible manner.

III. Symposia, Congresses and other Means of Verbal Communication.

Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging such meetings, and entertainment and other hospitality shall not be inconsistent with such objectives.

IV. Printed Promotional Material

Scientific and technical information shall fully disclose the properties of the pharmaceutical product as approved in the country in question based on current scientific knowledge including:

- The active ingredients, using the approved names where such names exist.
- At least one approved indication for use together with the dosage and method of use.
- A succinct statement of the side-effects, precautions and contraindications.

Except for pharmaceutical products where use entails specific precautionary measures, reminders need not necessarily contain all the above information providing that a form of words is used which indicates clearly that further information is available on request.

Promotional material, such as mailings and medical journal advertisements, must not be designed to disguise their real nature and the frequency and volume of such mailings should not be offensive to the health care professionals.

V. Samples

Samples may be supplied to the medical and allied professions to familiarize them with the products, to enable them to gain experience with the product in their practice, or upon request.

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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 mill 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 digestant mostly consumed by the relatively well-fed urban population. Twenty percent is covered by antibiotics, only 1.3 percent by sulphonamid

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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.

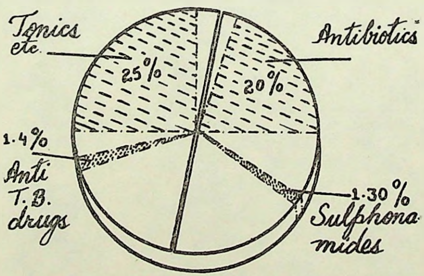
Source:
Health for All - An alternative Strategy :: report of a study group set up jointly by the Indian Council of Social Science Research (ICSSR) and the Indian Council of Medical Research (ICMR).

drug colonialism

A new type of colonialism—drug colonialism is oppressing us. Long after the other type of colonialism had left the stage, the poor countries of the world continue to be oppressed by the exploitative practices of multinational drug companies. In this game of drug colonialism, the privately owned Indian companies also join in. For both are in search of quick profits with little concern for the real drug needs of the country.

Consider the facts:

* 80-90% of the output of some major foreign owned drug companies in India consists of simple household remedies like cough syrups and vitamin preparations. But life-saving drugs account for only 30% of the total value of the formulations sold by the major foreign companies.



* In 1976, the total production of drugs was Rs. 700 crores. Out of that amount, 25 percent was taken by vitamins, tonics, health restoratives and enzyme digestants, 20% by antibiotics and only 1.3% by sulphonamides and 1.4% by anti-TB drugs. Obviously, the pattern of the drug production is irrational and irrelevent to our health needs.

* Look at the box item on INH and dapsone. The estimations calculated in the box are based on the assumption that we are endeavouring to treat all patients of TB and leprosy and giving them a complete course of treatment. Even if we put a conservative estimate of half the requirement against what is calculated in the box, our industry still remains far behind the target. Because of this a drug like dapsone is difficult to obtain and there was a period of six months when none was available due to stoppage of production.

* For many important drugs, installed capacities are far below licensed capacities. Even in the case of insulin, only 50% of Installed capacity is being used in the country.

For nonessential items like vitamins and tonics, production in several firms exceeds licensed capacity. Much of drug promotion money, goes into convincing the doctor to prescribe and the patient to buy such socially useless drugs.

* Although malaria is a major disease in India, primaquin and trimethoprim are not produced locally at all and imports of chloroquine exceed production. The production of cholera vaccines in India cannot meet needs in times of epidemic, even though production was started 40 years ago. Vaccines against influenza, mumps, measles and poliomyelitis are not produced in India at all.

* Although India has the third world's most sophisticated drug industry, out of 51 major drugs sold against infections and parastic diseases, respiratory ailments and diseases of the central nervous system, 28 are being imported.

* There is a marked resistance from the drug industry and the medical profession against using generic names instead of brand names, and against having an essential drugs list for the country (See other articles in this issue).

* A variety of sharp marketing practices and false advertisements have been used by drug companies to increase the drug dependency, and promote fancy formulations and costly drugs (see article on advertisements and marketing in this issue of *Health for the Millions*).

Estimated Requirement of Two Essential Drugs

Drug	Licensed capacity in MT	Production 1976-77 in MT	No of cases	Daily dose for one patient	Total requirement for all patients in a year in MT
INH	538.56	79.21	2.2 million Sputum positive	300 mg drug regimes	240.1
Dapsone	37.8	16.42	2.5 million (detected)	75 mg in all types	68.45

Both health professionals and the public are also responsible for giving in to this hard-sell.

brute power

The major accusation against the multinational drug companies is their misuse of their brute market power. They sell drugs to especially third world countries at terms very unfavourable and suicidal to the buyer. Tied purchase clauses force the local company to import its raw materials, intermediate products, equipment and spare parts from a specific foreign company usually the parent company. And these are usually priced at a highly inflated rate. An UNCTAD survey in 1975 reported 30-500% overpricing of imported inputs for pharmaceutical firms in Chile, 20-300% in Peru, 40-1600% in Mexico and 100-800% in Spain. In the case of diazepam, Colombia imported from the parent company paying to the extent of 6,478% overpricing (See box below).

In the Columbian case, the actual returns by the subsidiary to the parent company 100% = Reported Profits for Tax Purposes 3.4% + Royalties 14% Overpricing 82.6%. This figure is an average. The case gives an idea of how repatriation of profits occur directly and indirectly. There is enough other evidence to indicate that such overpricing and tied purchase clauses are damaging to the development of countries like India, for they occur with Indian imports too.

* In India, the 33 leading foreign controlled drug firms were always more profitable than the 6 main local ones. They also make more profits than all other types of foreign controlled enterprises.

* 85-90% of drug patents in developing countries are estimated to be held by foreign companies. Only 5-10% of foreign held patents are ever used in local production. Patents are used to secure import monopolies and more to prevent local production rather than protect their own local manufacture (as happened in Latin American countries when they attempted to begin manufacturing their low-cost antibiotics).

Product	Multinational price of importation to Colombia (FOB) US$	Range of other quotations to more developed countries in the world market (FOB) US$	Percentage overpricing
Chlordiazepoxide	1,250.00	18.90-20.00	6,155
Diazepam	2,500.00	30.00-45.55	6,478
Ampicillin	420.00	162.50-200	136.5
Tetracycline base	250.00	23.5	948.0
Erythromycin	275.56	132.00	108.7
Oxytetracycline	147.00	31.75	387.5
Promethazine	140.00	19.70	654.3
Triamcinolone	24,000.00	6,600.00	233.3
Neomycin	53.00	37.7	40.6
Dihydrostreptomycin	29.00	27.50	5.4
Chloramphenicol	27.00	13.5	100.0
Dexamethasone	27.50	7.10	267.0
Methyldopa	80.00	18.48	333.0
Indomethacin	640.00	72.5	611.0
Hydrochlorothiazide	90.00	5.20	1,530.7
Guanethidine	920.00	190.80	382.0
Metronidazole	390.00	11.15	3,398 0
Penicillin G	0.03MU	0.018MU	66.7

* The expecation of the country from the

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table-A

Imports of selected pharmaceuticals by the State Pharmaceuticals Corporation (SPC) of Sri Lanka, 1974. Comparison of actual cost with cost of traditional supplier.

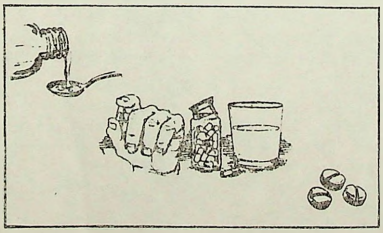
(Dollars)

	Drug	Traditional supplier	Cost	New supplier	Cost	Savings	Savings as percentage of original cost
1.	Benzyl penicillin	Hoechst	45 999	Sarabhai	33 166	12 833	27.9
2.	Chloramphenicol inj.	Carlo Erba	926	Ranbaxy	555	371	40.1
3.	Methyldopa	Merck, Sharp and Dohme	15 208	Medimpex	10 866	4 342	28.6
4.	Nalidixic acid	Sterling	9 072	Medimpex	6 871	2 201	24.3
5.	Nitrofurantoin	Smith, Kline and French	7 611	Unique	1 485	6 126	80.5
6.	Phenylbutazone	Ciba-Geigy	30 088	Ranbaxy	1 710	28 378	94.3
7.	Benzhexol	Cyanamid	5 433	Aktielskabet	1 503	3 930	72.3
8.	Balladonna a phenobarbitone	Sandoz	23 126	Wockhardt	1 997	21 129	91.4
9.	Chlorpromazine	M and B	16 179	Unique	1 521	14 658	90.6
10.	Diazepam	Roche	19 583	Ranbaxy	790	18 793	96.0
		Total	1 73 225		60 464	1 12 761	65.1

Source: S. Bibile, The State Pharmaceuticals Corporation of Sri Lanka, Colombo, 1976

what is transfer pricing

In 1973, the Sri Lanka, SPC took over the purchase of some of the raw materials required by privately owned drug factories. The following table shows the prices paid by the SPC in 1973,



compared to the prices paid in 1972 by multinational subsidiaries for the same supplies bought from their parent companies. This illustrates the widespread phenomenon of "transfer pricing".

Raw material	Private sector supplier 1972	SPC supplier 1973	Private sector transfer price (A)	SPC purchase price (B)	B as % of A
Tolbutamide	Hoeschst W Germany	Hoeschst W Germany	40.62	19.24	47
		Polfa Poland	40.62	2.52	6
Paracetamol	Sterling UK	R. Poulenc France	3.24	2.76	85
Chloro-propamide	Pfizer USA	Pliva Yugoslavia	126.21	9.46	8
Tetracycline	Pfizer USA	Hoeschst W Germany	98.87	19.72	20
Aspirin	Glaxo UK	Polfa Poland	1.16	0.99	85
Ampicillin	Beecham Singapore	Beecham Singapore	569.90	95.11	17

The Joint Mission Hospitals Equipment Board Limited (ECHO) in England, whose sales have grown tenfold in the last ten years, services more than 1000 mission and charity hospitals in 80 developing countries. "Manufacturers come running to us because of our large orders", says Dr James Burton of ECHO.

Spokesmen of both ECHO and IDA, the Netherlands-based International Dispensary Association, claim that their prices are generally 30-40% cheaper than their individual clients would be able to obtain for themselves.

At the request of WHO, ECHO has recently prepared a list of standard equipment required for a rural health centre (which would include accommodation for minor operations and lab work) and for a small village clinic. By bulk purchasing drugs and other items, ECHO is now providing a completely pre-packed kit for a rural health centre and for a small village clinic. ECHO recently supplied prepacked kits for 10 rural health centres and 50 village clinics to Vietnam.

action
medeor

Action Medeor is Europe's largest mail order dispensary solely and exclusively intended for the developing countries. They supply medicines to nearly 4,000 institutions in the Third World. The brain child of Dr Ernst Boekels "a country doctor"—who continues to be the chairman of its Board of Directors, MEDEOR has an assortment of 95 medicines which can be ordered at the cost price.

Medeor buys the basic ingredients for the medicines needed in the Third World from the pharmaceutical industry. These ingredients are used to manufacture, under medical supervision, medicines according to the standards set by the scientific community against cholera, scabies, leprosy, malaria, tuberculosis and other prevalent diseases existing in tropical and subtropical countries.

The pharmacy stocks about 100 million tablets and has an yearly turn over of 2 million dollars. "There are two kinds of difficulties in supplying drugs to India," says Mr Beckers the Managing Director, who is also the mayor of the town.

(1) The Indian institutions cannot make payments in dollars or Deutsch Marks

(2) Difficulties at customs in spite of the fact these drugs are imported under the Indo-German Agreement.

Action Medeor would welcome if an organization could unify and systematize their supply in India.

medeor in action

The UN Children's Fund (UNICEF) is another organisation that bulk-buys drugs for developing countries. It buys all its drugs as generics. As its orders are quite large, manufacturers are willing to label these drugs in the way UNICEF asks them.

UNICEF drug prices are often half the market prices and sometimes as low as one quarter. Even some rich countries like Iran order certain drugs through UNICEF. In 1977, UNICEF distributed drugs and vaccines worth about $15 million, most of them as gifts.

What does this mean? It is obvious that even if groups of voluntary institutions in India get together, and do bulk purchasing of formulations and/or bulk drugs, enormous savings can be effected. Who will bell this cat?

99-26

Council on International and Public Affairs

(Formerly Conference on World Affairs, Inc.)

777 United Nations Plaza
New York, New York 10017
(212) 972-9877
Cable: COUNINTERP NEW YORK

Please reply to above address unless otherwise noted.

March 29, 1982

MEMORANDUM

TO: Coordinating Committee on Toxics and Drugs

FROM: Ward Morehouse

SUBJECT: Pharmaceuticals in India

As most of you know, I have been for the last six weeks in India, where I was in contact with a number of environmental, consumer, public health, and other voluntary social action groups. I enclose a brief note on health care and drug companies in India, growing out of discussions with these groups. I hope shortly to prepare a similar note on pesticides and industrial chemicals, where the problems and what can be done about them are somewhat different.

I discussed with several persons the concerns of our Committee and how we might work most effectively with similarly concerned groups in India and have the following suggestions to put before the Committee for its consideration:

1. Dr. C. Sathyamala of Health Action India (and VHAI) will, working with other concerned health care professionals, pick some drugs (such as the Oestrogens mentioned in the attachments to the note) which they consider to be high priority and gather documentation on labeling practices, content and distribution of explanatory literature, how sold (i.e., over-the-counter or through prescription), etc. This documentation can then be forwarded to us, so that those on the Committee working especially on pharmaceutical questions can take up specific products with individual U.S.-based multinationals.

2. Both Dr. C. Sathyamala of Health Action India/Voluntary Health Association of India and Dr. Anant Phadke of Medico Friends Circle need the latest version of the U.S. Physician's Desk Reference. (Dr. Phadke has the 1981 PDR.) I took it upon myself to promise that one way or another we would see that they received the latest PDR edition.

3. I think we should make an effort to bring someone from Medico Friends Circle or Health Action India to educate us on the nature of health care problems in India and what needs to be done about them. By "us", I mean not just the Coordinating Committee but also our respective constituencies.

4. If we really mean what we say about avoiding a "top-down" approach in working at the international level with NGOs in the Third World, I think we need the benefit of an external observer undertaking a critical examination of who we are, what we do, and how responsive we are to Third World concerns. (The reverse occurs all the time - witness my recent trip to India.) My candidate is Anil Agarwal, the founder of the Centre on Science and the Environment, former Assistant Editor of Earthscan in London, and a well-known, serious, and careful investigative science journalist.

I am sharing copies of this memorandum and the attached note with some of the people with whom I discussed these matters in India by way of keeping them informed. I hope we can give some serious attention to these suggestions at our next meeting.

WM/mbi
cc: Anil Agarwal
Dr. C. Sathyamala
Dr. Anant Phadke

Attachment: Note on Health Care and Drug Companies in India

March 26, 1982

A Note on Health Care and Drug Companies in India

Some Key Actors

Among the groups involved in the struggle for more socially relevant health care in India are:

Voluntary Health Association of India, an organization of doctors, hospital administrators, and others engaged in community health work, which grew out of the joining together of two associations of Christian hospitals in India.

Medico Friends Circle, a small but strongly committed group of doctors, mostly young, who are working in a variety of rural and urban community health projects around the country.

Centre for Science and Environment, a non-profit "public interest" research agency which conducts investigative reporting of economic and social issues which are science and technology-related.

Health Action India, not a formal organization as such but simply those individual health care professionals willing to engage in common action on specific health care issues.

A list of addresses and contact persons is attached.

The Problem

Drugs are not the main issue in working toward a more socially responsive health care system in India, let alone pharmaceutical multinationals. The main issue would appear to be the Indian medical profession, which is maldistributed in relation to the population (80% of the doctors are in the cities while 80% of the people are in rural areas), socially irrelevant in terms of much of the technique they use, and motivated more by their own greed rather than their patients' need.

Chemists or druggists certainly aid and abet a health care system largely irrelevant to the health care needs of most of the people but they are not the prime problem. Indeed, most of the population has no contact with chemists, who are overwhelmingly concentrated in urban areas - thereby suggesting that one pharmaceutical MNC argument is spurious, at least in India (i.e., in poor countries, chemists frequently substitute for doctors).

To the extent that drug companies are a significant part of the problem, India may be atypical among Third World countries because

a substantial part of that problem is Indian, not foreign - i.e., Indian drug companies producing and marketing drugs for the domestic market. (A glance at the "Dear Doctor/Chemist" letter attached indicates, using the case of Oestrogen-Progesterone drugs, that a significant proportion of the companies making and marketing the offending product are Indian companies, not Indian subsidiaries of MNCs (although the latter are involved as well).)

There is some government regulatory machinery, including a Government of India Controller of Drugs. While this machinery is not totally ineffective, it is far from being as efficacious as it should be.

Of course, at a more fundamental level, the problem of inadequate and misdirected health care is both a manifestation and a cause of widespread poverty, illiteracy, infant mortality, malnutrition, and the other social ills of Indian society.

The Remedy

There is, naturally, no single remedy for such a deep-rooted and pervasive problem. But if the foregoing summary of the nature of the problem is near the mark, much of what needs to be done must be done by concerned individuals, including health care professionals, and groups within India. Concerned persons and organizations in the North, can at best be helpful at the margins of the problem and should tailor their efforts so as to be responsive to priorities determined by those working toward a more socially responsive health care system within India.

The most essential need is obvious but, because it is so massive, elusive--greater public awareness and understanding of patterns of morbidity which afflict them and what can be done about them. Steps are being taken through a number of community health projects at the local level throughout the country. At the national level, one of the more important has been to bring out an Indian edition of Where There is No Doctor, first in English and Hindi, and in time, in other Indian languages.

The need for educating, and ultimately changing the behavior patterns, of health care professionals is obvious. One small step in that direction is reflected in the Oestrogen/Progesterone campaign described in the attachments ("Dear Doctor/Chemist" and "Dear Sister").

Drugs are a small part of the total problem in India but not an unimportant one. Some action is beginning to move forward by groups such as those mentioned above. The Oestrogen/Progesterone campaign is one example. The Medico Friends Circle recently held a workshop

on drugs. And the VHAI has produced a special issue of its bimonthly magazine, Health for the Millions on the subject.

Ward Morehouse
Council on International and
Public Affairs, Inc.
777 United Nations Plaza
New York, NY 10017
(212) 972-9877

Attachments: List of health care organizations and points of contact in India; "Dear Doctor/Chemist," and "Dear Sister" (letters on misuse of Oestrogen/Progesterone combination drugs); Counterfact Health Cell Feature ("Abuse of Female Hormone Drugs," Centre for Education and Documentation, March 8, 1982); description of Medico Friend Circle of India; subject index of back issues of MFC Bulletin.

March 29, 1982

List of Health Care Organizations and Points of Contact in India

Voluntary Health Association of India
C-14, Community Centre
SDA, New Delhi 110 016
INDIA
(Dr. C. Sathyamala)

Health Action India
C-14, Community Centre
SDA, New Delhi 110 016
India
(Dr. C. Sathyamala)

Centre for Science and Environment
807, Vishal Bhawan
95, Nehru Place
New Delhi 110 019
INDIA
(Dr. Anil Agarwal, Director)

Medico Friends Circle
50 LIC Quarters
University Road
Pune 411 016
INDIA
(Dr. Anant Phadke)

Pune Journal of Continuing Health Education
1913 Sadashiv Peth
Pune 411 030
INDIA
(Dr. A.R. Patwardhan)

Alternative Drug Policy — Some Criteria

Amitava Guha

Profit cannot be the only motive force for the development of Drugs & Pharmaceutical Industry.

"Committee on Drugs & Pharmaceuticals"

In the recommendations of the Hathi Committee are the first ever attempt was done to-wards a real development of drug industry in our country. Almost all recommendations of the committee including the nationalisation of multinational drug companies (TNCs) are vitally required for our country. Few relevant issues needs to be taken up afresh. The Committee did not considered distribution system in their report.

Dilution of foreign equity :

Recommendation of the Committee in this respect is to taper down the foreign equity to 26%. In fact it should be brought down to 10% within a span of 3 years and no company having any amount of foreign equity should be considered as 'Indian Company'. No company should be given the status of Indian company unless the plant and machinaries are installed on turn-key basis and no stipulation is put for import of raw materials from the parent company.

Transfer technology should be guided under UNIDO recommendations. Only latest technology can be imported on the basis of global tender from all the developed countries. Preference should be given to the countries whoever accept "Rupee" as transfer currency and indegenous plant and machinaries are accepted.

Petrochemical industry in our country is mainly oriented for heavy chemicals, detergent, paints synthetic fibres, etc. There should be adequate stress for orientation of Petrochemicals for production of raw materials for fine chemicals and phyto-chemicals.

Production capacity of the plants producing basic drugs of essential nature should be increased. No intermidiaries for essential drugs should be imported.

Export of raw harbs and alkalids should be banned.

"Committee for Rational Drugs"

There has been various development after the report of the Hathi Committee was published. Patern of the industry has been changed and large scale manufacturers have made up lee ways to make the recommendations futile. Therefore it has become most important to constitute another Committee for rational drugs where doctors from research centres, people from health institutions and drug action groups should be included (and none from the manufacturers). Objective of the committee shall be -

1. To prepare a 'List of Essential Drugs' (WHO guideline), including the drugs needed for tropical diseases.

2. To prepare an overall study report on the production of drugs and pharmaceuticals, requirement and production pattern for essential drugs.

CONTD... 2

3. National survey on disease pattern and drugs needed thereto.

4. Weeding out of the harmful/banned/habit forming drugs and drugs having doubtful action. Survey for substandard drugs and their sources.

5. To judge the applicability of the drug policies of different countries including the countries under socialist block.

6. Reduction of the number of formulation and ~~introduction~~ abolition of brand names.

7. To bring effective check on the expensive and unethical sales promotion.

8. Develop drug distribution system under total government control.

9. Develop drug information machinery.

For the consideration of the said Committee the following notes may be placed.

Manufacturing :

*TNCs should not be allowed to manufacture common formulations (essential drugs) household remedies, cosmetics.

* Suitable change in the Drugs & Cosmetics Act & Rules so that small scale industries do not suffer (schedule 'M' of the Rules, etc.).

* Stringent laws on quality control is required. Quality control laboratories are to established by the Government in all manufacturing centres all over the country, to facilitate tastes at cheaper cost and to maintain uniform standard.

* No import of machinaries directly or without the guarantee from the end-users.

* No import of machinaries, if the similar machines are indegenously available. Import of the machines for filling, sealing, labelling, caping, packing, etc. should be banned.

* Open General Licence system is to be abolished. There should be raw materials pool in each state for inform pricing of raw-materials. A Bulletin is to be published informing availability and prices of the raw materials every month. Prices of raw materials should be uniform all over the country.

* A standard has to be fixed for packing of fixed dosage forms - uniformity in bottle size, strips, shippers, etc. No fashionable packs like tonic bottles, blister pack, etc. should be allowed.

* All taxes should be abolished and Subsidy should be provided for transport of essential drugs and raw materials.

* 'Leader price' system is to be ~~changed~~ abolished and maximum price of each drugs is to be calculated on the basis of BICP data. The basis of this calculation and all BICP data about drugs and pharmaceuticals should become public document.

CONTD... 3

*Loan Licence system is to be totally withdrawn.

* Product-mix and production capacity has to be determined by the Committee and it should be distributed to the manufacturers for essential drugs which should form the minimum base line for capacity utilisation.

* No COB licence or production over the licenced capacity should be allowed.

Quality Control:

.. Taste Laboratories are to be established in each districts 0.1% surcharge can generate adequate finance for the purpose.

.. All complaints regarding harmful effects of drugs are to be entertained. Analysis should be conducted at least in three taste labs. on the basis of double blind study.

Efficient Regular sample survey throughout the nation should be done.

.. Special statute and judicial set-up should be made to check production and sales of harmful and substandard drugs. Compensation should be extracted from the convicted producers.

.. In arrangement with the leading institutions in four zones of the country trial and study has to be made for each new drugs before its introduction.

- Informations regarding banning, withdrawal of drugs from the market has to be published in news papers and mailing to the retailers& medical profession

.. Drugs should be immediately replaced to the buyers if any doubt is expressed even if a part of the pack is used.

.. Cosmetics, OTC drugs, household remedies cannot be sold from the shop where pharmaceuticals are sold in the cities and towns.

* Sales Promotion :

There should be a parmanent National Organisation for information on drugs and therupy. Informations are to be circulated by the organisation every month through a journal. A full fledged machinary has to be established by the Govt.

In sales promotion activity only scientific information can be circulated by the manufacturers. All sales promotion informations/advertisements has to be checked by the national net work of information education and communication on medicines.

Physician sample of new medicines can be given for three years after introduction. For all other drugs, samples required to treat one patient for a particular drug can be provided on written request from the physician.

No literature can be published without mentioning full indications, contra-indications, side effects, drug interaction and antidotes.

No gifts of any form shall be allowed to be given to the medical profession/& retailers

No seminar, scientific session can be held without written permission from the National Net-work.

Bonus/incentive system on sales of the products by the distributors or retailers has to be abolished.

All manufacturers shall inform their yearly sales promotion strategy to the National Net work for approval. Expenses equal to the sales promotion has to be contributed for research by the MRTP companies. All research and development centres are to be run jointly by the private and Govt. sectors.

Each pack of neutrients and food products should bear the mark "it is not a substitute to normal food".

MEMORANDUM

We, the health personnel and citizens of India recognize health as a fundamental right of the people in this, our welfare state. We recognize and strongly believe that the health status of our people is more dependent on their access to adequate food, safe and adequate water, proper sanitation and clean environment.

While we support the overall perspective and approach of the new National Health Policy Statement and demand its proper implementation, we believe that a 'Rational Drug Policy' is an integral part of a good National Health Policy.

We therefore, demand the following:

1. We have a right to safe, essential, quality drugs which are in keeping with the health needs of the people, at costs which the majority can afford.
2. We urge our government to accept and implement the Hathi Committee Recommendations which are also in keeping with the WHO Guidelines for a Rational Drug Policy.
3. Further the national drug formulary should be revised and compiled by an expert multi disciplinary committee keeping the following criteria in mind;
   - Essentiality
   - Efficacy
   - Safety
   - Cost
   - Ease of administration
   - Availability
   - Potential for misuse.

   Such evaluation of the drugs in the market and revision of the lists should be done periodically.
4. The Essential Drugs Policy should be adopted for all health services, government and private, and priority in production, distribution and dispensing should be given to these essential drugs.
5. The public sector should produce essential and life saving drugs on a priority basis at the national level.
6. Drug production by multinationals and private manufacturers in India should also be aligned with national health priorities.
7. Bulk procurement of essential and needed drugs should be through world-wide competitive tenders and rationalization of drug purchases should govern both the public sector as well as private health sector.
8. Imports and production of non essential, specially hazardous drugs, should be strictly curtailed.
9. Drugs which have been banned from sale after being marketed for some time in one country may not be submitted for clinical trial or marketing in India. The onus of proving why a non-essential drug should be introduced or allowed to continue on the market should be with the manufacturer and such introduction should be preceded by adequate trials and evaluation by Drug Control Authorities.
10. Comprehensive drug legislation which covers areas such as price control at different levels, patents, and marketing practices should be incorporated to serve the objectives of the national drug policy and there should be no levies, sales tax or excise duty on any pharmaceutical product in the essential drugs list by the Central or State governments.
11. No technology transfer agreement shall be legal and binding which contains restrictive practices, disproportionate and unnecessary use of imported intermediaries or obsolete technologies or unfair arrangements with respect to prices, payments or repatriation of profits.
12. The National Drug Policy should state clearly the steps towards a complete abolition of brand names and as a first step use of generic names should be made compulsory in medical education, prescribing and labelling of drugs. Generic names should appear more prominently on all packagings

13. It shall be the primary responsibility of the manufacturer to ensure the quality of drug products. However, it shall be the statutory responsibility of the Drug Control Authorities to monitor the standards and ensure a minimum uniform level of government control. Consequently, the government shall take all necessary measures to enable the Drug Control Authorities to function in an effective manner and discharge the statutory duties cast upon them.
14. It shall be the statutory duty of the drug control authorities to inform health personnel and consumers of the essential drugs lists, policies, categories or brands of drugs banned for manufacture or sale, through publication in the national newspapers, magazines, medical journals with adequate explanations and details.
15. Availability of drugs required in the Government's National Programmes should be ensured on a priority basis to the government as well as voluntary and private health institutions. Quotas for anti TB, anti leprosy, anti malarial drugs, iodized salt etc should be made easily available with regularity of supply to the voluntary health institutions wherever possible, specially when their performance, in health care delivery is known to be effective.
16. In all review committees, statutory bodies and other such bodies, there should be adequate representation of consumer groups and voluntary health sector.
17. Drug companies should follow ethical marketing practices, and this should be ensured by their own organizations like OPPI, IDMA, IFPMA. We deplore the tendency of these companies and associations to get around every progressive measure of the government through recourse to technicalities of the law and through the courts.
18. The marketing code drawn up by HAI(Health Action International) should form the basis for a National Code for Marketing Practices. This should be accepted by our government and should be suitably implemented through legislation.
19. The government of India should take a lead and endeavour to influence the WHA and WHO to adopt the Code in the interests of the other developing countries and their peoples.

(IFPMA and HAI Code attached).

- Voluntary Health Association of India
- Centre for Science and Environment
- Centre of Social Medicine and Community Health-Jawaharlal Nehru University.
- Kerala Sahitya Shastra Parishad
- Medico Friends Circle
- Arogya Dakshata Mandal
- Lok Vigyan Sanghatana
- Consumer Guidance Health Services
- Consumer Education Research Centre
- Federation of Medical Representatives Association of India.

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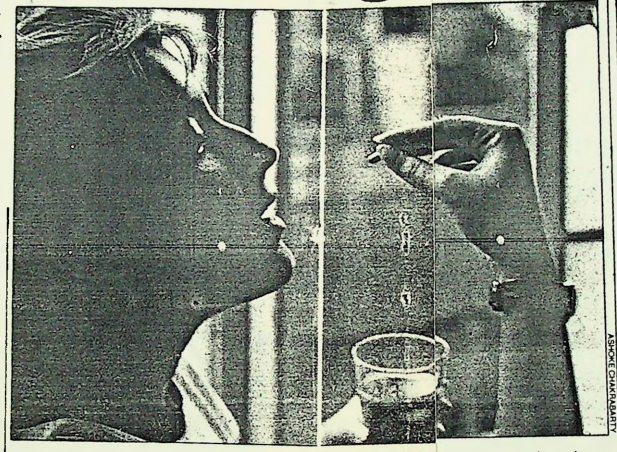
Who's winning this war?

With the increasing use — and abuse — of antibiotics, bacteria are learning to fight back against the deadly drugs

Dr Tilak Kumar, GP

"It is unfair to blame the GP alone for increasing antibiotic resistance. Patients should be educated against self-medication"



ASHOKE CHAKRABARTY

You have the sniffles, you are running a temperature and your headache won't let you think. Your doctor sympathises with your desire to be back to normal for tomorrow's crucial event and prescribes an antibiotic. You wince at the price, but the next day, there is good news because you are already feeling fine. Good doctor, you think indulgently and spread the word to your friends.

Now for the bad news: the antibiotic could *not* have made you better. An antibiotic takes more than a day to even begin to effectively cure you — at least for most common infections.

Perhaps you didn't need the antibiotic anyway as you probably had a viral infection. And though doctors never bother to explain this to patients, antibiotics have no effect on viruses.

The truth is that antibiotics are among the most used and most abused of drugs today. By some estimates, more than ten per cent of all drugs prescribed in India are antibiotics. And because they are expensive; they account for almost half the value of all drugs sold in the market.

So what, you shrug, perhaps I took the wrong medicine. But I got better, didn't I?

Maybe you did. But maybe you also helped create more antibiotic resistant germs (pathogens) within your body. That could mean that someday, when your body really needs an antibiotic drug to fight a serious illness, the drug won't have the desired effect.

Antibiotic resistance

The more you take, the less it works

It goes back a little to the days when Alexander Fleming discovered penicillin, which led finally to the use of the first antibiotics in the Forties. Mass production of the first antibiotics, penicillin and streptomycin, began during World War II. Penicillin opened the flood gates to a variety of antibiotics that worked very effectively against disease-causing bacteria.

Since it was relatively cheap and easy to administer, and since they worked miraculously on the then life-threatening diseases like tuberculosis, typhoid and venereal disease, the use of antibiotics spread like wild fire.

Even today, newer antibacterials (for the purposes of this article, antibacterials and antibiotics are being used synonymously in terms of their action, i.e. inhibiting bacteria) are being created regularly by drug designers with a little tinkering of the organic chains of older drugs, or with other chemical jugglery. The potential for new drugs seems limitless.

Except for one thing. Even five decades after the first antibiotics were introduced, bacterial diseases remain a major cause of illness, and even death.

Ram Shah, pharmacist

"Bacteria evolve much faster than human beings. The only way out against them is to keep one step ahead through technical innovation"

Did you know? ◇ *Some little-known facts about antibiotics*

The beginning

Mass production of the first antibiotics began during World War II, when penicillin was found to have reduced a great number of amputations and casualties.

Then, since it was relatively cheap the use of antibiotics spread like wildfire.

Oh, what a lovely war!: the beginning of penicillin

And now...

Take a look at these figures. Incredible as it may sound, today, the Indian drug market has 70,000 formulations available to doctors and patients — even though the World Health Organisation lists only 250 essential drugs.

With so many antibiotics in the market today with so many variations, this leads to the dangerous abuse of drugs by an unsuspecting public.

SUDIP KOLANTY

On the market: more than we need

Suffer the little ones

The overuse of antibiotics is particularly shocking when it is extended to children, who can develop resistant strains of bacteria in their systems which they pass on to other children. These children can then develop diseases for which commonly prescribed antibiotics provide no cure.

VIVEK DAS

The vulnerable ones: not all pediatricians care

Good news for the manufacturer

The economic problem has not stopped pharmaceutical companies from pumping a lot of money into the antibiotics research market.

Cynics would say it is with good reason. The

Although this has something to do with poverty and the lack of medical care, it also has a lot to do with the problem of *resistance*.

As bacteria are bombarded with the antimicrobials (another term covering antibiotics) designed to kill them, they do their best to fight back, to develop armour against the deadly drug. And they use formidable and cunning methods to do so. The bacteria, microscopic as they are, are diabolically clever. Their very simplicity allows them to evolve easily to win the war against the enemy.

Among the many methods used by micro-organisms to develop resistance to a drug is genetic mutation. The gene of the bacteria which is supposed to be sensitive to the antimicrobial factor mutates and the antibiotic proves useless in attacking the micro-organism.

Worse (for us, not for the bacteria), they can transmit the acquired resistance, called the R-factor, to other bacteria. And worst of all, there is then a selective multiplication of antibiotic-resistant strains. These are the supergerms, which can laugh into the face of the doctor's prescription and continue to wreak havoc in your body, in defiance of many of the multi-coloured tablets in the market.

When in doubt, prescribe

Indian doctors love antibiotics

Resistance to antibiotics develops mainly because of their inappropriate and irrational use. Survey after survey reveals that antibiotics are being widely misused, especially in India, where drug laws even if stringent, are rarely implemented.

One survey conducted by the Christian Medical College and Hospital at Vellore found that in common infections like fevers of short durations, antibiotics are not indicated in 78 per cent of the cases in which they are prescribed.

What do these specialists mean when they say that your trusted family doctor is responsible for widespread resistance to antibiotics?

General practioners can prescribe antibiotics for relatively minor ailments or by prescribing them when they are not required at all. Such shotgun therapy leads to an overusage of antibiotics, which then makes bacteria more quickly resistant. Doctors sometimes also prescribe the wrong doses.

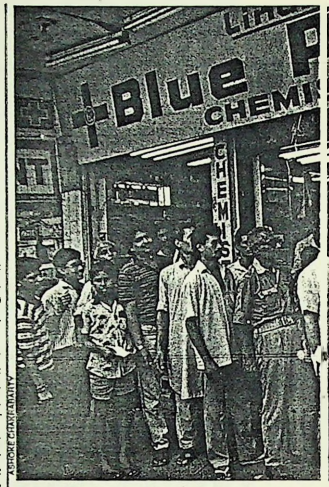
If a patient is underdosed, some bacteria in the body could remain active or through some method of mutation could actively thrive. Equally, overdoses have their own problems: they make the bacteria more aggressive.

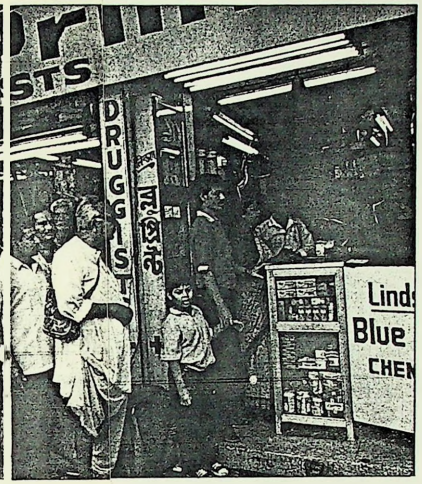
All doctors are well-acquinted with these facts. So why is there so much abuse of antibiotics?

Well, there are many reasons. One, doctors have a mandate to give the patient relief. And they cannot wait for the sensitivity tests (which tell you which antibiotic will work on your infection) to start medicating a patient because that will push recovery further away.

What is the impact of these malpractices on the community as a whole? The frightening truth, as a handbook on antibiotics says, "One clinician's bad prescribing can directly affect patients of colleagues via selection of the cross-infection by antibiotic-resistant micro-organisms. Furthermore, the profligate use of antimicrobials in one locality may result in resistant organisms with the potential to spread widely and rapidly."

To all of us it means that if your friends Sheela and Ramesh take their children regularly to a physician who often and wrongly prescribe antibiotics for every small ailment like upper respiratory viral infection or fever, then the bacteria in the kids' bodies may become resistant to the drug. And when you meet those cherubic kids at the next neighbourhood party, it is just possible that your kids could bring home the antibiotic-resistant infection. And you, model parent as you are, with little or no antibiotic exposure for your kids, will still find that the commonly prescribed antibiotic does little to cure your children quickly. Individual abuse leads directly to collective resistance.





There is no need for any knee-jerk reaction to antibiotics either. Modern societies could not survive without antibiotics, which are marvellous agents of recovery

But in fact, it is often patients themselves who are responsible for misusing antibiotics. Two days into an antibiotic course, when one of the milder side effects of the antibiotics are becoming bothersome (perhaps gastro-intestinal problems) and you are otherwise recovered, you may be tempted to stop the medicine. That's when you are tempting fate. Because you have allowed some active bacteria to remain within your body. And the bacteria need just that oppurtunity to develop mechanisms to resist the drug next time around.

Sometimes, however, it is also the economic factor which precents a patient from completing his antibiotic course. "Often, my patients, especially the poorer mothers, say they gave their children only as many tablets as they could afford, or as many as their husband bought," says Dr Nalini Shenoy, a pediatrician in Bangalore.

Given this patent misuse among the general public, Dr Tilak Kumar, a family physician, thinks it is unfair to blame the GP alone for increasing antibiotic resistance. "If we abolish quackery, where allied medicine doctors wrongly prescribe antibiotics, if we get druggists to dispense antibiotics strictly against prescriptions only, and if we educate patients against self-medication or incomplete medication, there will definitely be less of a problem," he says.

Even if there was no misuse on the part of doctor or patient, however, bacteria would still someday beat the drugs meant to destroy them. Says Ram Shah, proprietor, Tilrode Chem, with a PH.D in pharmacy from Belgium, "It is a purely evolutionary process. Bacteria evolve so much faster than human beings. Some bacteria could have a life span of half a day. So the evolution time scale is much smaller. In a matter of time, a strain of bacteria would develop natural resistance to a drug."

So how do mere human beings win the war against deadly bacteria? Ram Shah displays the same insouciance shared by many others in the pharmaceutical industry. He keeps faith in the endless innovation of medical technology. "The only way out is to keep one step ahead through technical innovation," he says.

One of the ways of tackling resistance, for instance, is to develop missiles that penetrate the shields that bacteria develop around them.

This brings up the question: Is it infinitely possible to create new antimicrobials? Can we have newer and newer generations of cephalosporins etc.?

Technically, the answer is yes. "We would hate to think that there could be a limitation," says K.S. Chandraprakash, senior product manager at the Bangalore Pharmaceutical and Research Laboratory (P) Ltd (BPRL).

Even so, it still begs the next question. At what cost? And there's the rub. "The future is limitless so long as money is limitless," explains Ram Shah. "With faster obsolescence of drugs, more and more money has to be pumped in all the time (to create newer generation antibacterials) and then you get into an economic problem." So far, the economic problem has not stopped pharmaceutical companies from pumping a lot of money into the antibiotics research market.

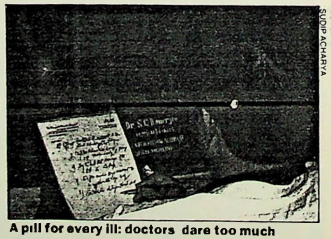
Cynics would say it is with good

Did you know? ◇ *Some little-known facts about antibiotics*

spiralling prices of newer drugs that are entering the market each day also mean better bottom lines for the drug industry.

The doctor isn't God

Don't be afraid to question your doctor when he prescribes antibiotics. They will not cure you if, for instance, you have a viral infection. Ideally, antibiotics should only be given after a culture/sensitivity test determines what will be effective.



SUDIP ACHARYA

A pill for every ill: doctors dare too much

At the Bangalore Laboratory: the search goes on

Once you are convinced of the need to take an antibiotic, inform yourself about the correct dosage and duration of the medication — *and keep to them.*

Never self-medicate, re-use old prescriptions or old antibiotics lying around the house. It may tempt you to take non-optimal doses.

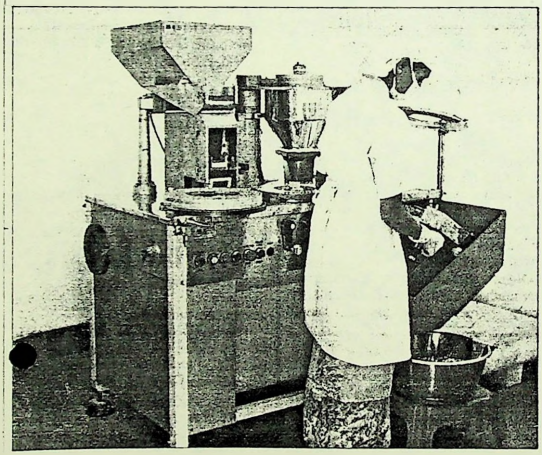
Remember that prevention is better than cure. Antibiotics are no substitute for good sanitation and personal hygiene.

son. The spiralling prices of newer drugs that are entering the market each day also mean better bottom lines for the drug industry. And the obsolescence of older, cheaper antibiotics is only good news for pharmaceutical companies. As doctors prefer to, or are forced to use higher order antibiotics to kill simple ailments, the bills that go up are the patients'.

Take a look at these figures. The Indian drug market has 70,000 formulations available to doctors and patients when WHO lists only 250 essential drugs and even the Hathi committee which went into the issue found only 116 drugs essential for India. The mind-boggling figure of 70,000 preparations includes many unessential and sometimes dangerous drugs that are in fact banned in many other countries.

antibiotics. Millions of dollars are spent to research, produce and market each new-generation antibiotic drug. And the pharmaceutical companies have to pass on the cost to the consumer. Which they do. That is why a newer antibiotic, such as Ceftum (which is a new antibiotic drug called cefuroxime) from Allenbury's costs around Rs 41 for one 500 mg tablet, whereas the middle-range antimicrobials like cephalexin costs Rs 9.50 for a 500 mg tablet. Compare that to sulphonomides, or cotrimoxazoles like Septran, which costs between 75 paise to Rs 1.50 per tablet depending on its strength.

And these are only the more common antibiotics. Some of the higher-order injectable antibiotics can cost upto Rs 350 per dose, whereas the higher-order tablets can reach upto Rs 90 per tablet.



At what price?

The bill that goes up is the patient's

The problem with overusing antibiotics of course, is quite special, due to the resistance factor. But there are other related problems as well. Price becomes a big factor in the introduction of newer

One of the ways of tackling resistance is to develop missiles that penetrate the shields that bacteria develop around them

And if the Dunkel draft agreement goes through, you can expect drug prices to go through the roof.

It is not just the price factor, however. There is also the question of side effects. While they have undoubtedly played a crucially important role in human health in the last 50 years, antibiotics have also been guilty of generating problematic side effects, most of which are commonly known, but some of which can even be deadly. For instance, the known side effects of the relatively new antibiotic, gentamicin, (available only as an injectable) are nephrotoxicity (which can lead to kidney damage) and ototoxicity, (which can cause deafness).

The rapid obsolescence of old drugs and the corresponding manufacture of new drugs also brings a sort of consumer culture into the drug industry. It only increases the misuse of medicine. Dr S. P. Tekur, an active member of the Drug Action Forum and of the Bangalore-based Community Health Cell, who himself runs a child health clinic, is very disturbed about the widespread irrational use of drugs.

There are so many antibiotics in the market today, with so many variations in side effects, half life and site-effectiveness that it is understandable that doctors themselves are confused. But sometimes, this leads to the dangerous abuse of drugs on an unsuspecting, ill-informed and apathetic public. Doctor Tekur cites the instance of Norfloxacin and Ciprofloxacin, which belong to the family of the recently introduced quinolones. "The recommended dosage per day is 400 mgs twice a day," he says. "They are not meant for children."

Quinolones are contra-indicated for children under 14 because they have been reported to cause damage to the joints of immature animals. "And yet," says Dr Tekur, "this antibiotic is available in 100 mg tablets, which tempt pediatricians to try them on children."

Shocking instances of antibiotic abuse like this expose the complete lack of coordination and implementation of the government's drug policy. But consumer awareness is the only really effective means to stop the misuse of drugs, and especially antibiotics. Because the vested interests of the manufacturer, the prescriber and the dispenser combine to perpetuate this misuse. And it is left to each individual to say, IT'S MY BODY, AFTER ALL. •

Rohini Nilekani/Bangalore

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 rural 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.....

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.

(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

W h a t w e c a n d o ?

-- Support them

-- Join them

-- Keep them informed about what you are doing

.....

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.

DRUG PUSHERS OR HEALERS?

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

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

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

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

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

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

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

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

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

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

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

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

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

....2.

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

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

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

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

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

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

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

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

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

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

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

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

a) cosmetic embellishment

b) Elegant packing

c) Irrational combination

d) Imitative drugs

e) Inadequate evidence of greater value?

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

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

....3.

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

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

Can we stop this 'tonic' practice?

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

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

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

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

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

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

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

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

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

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

.....4.

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

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

- ravi narayan

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

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Could we accept Generic prescribing? i.e., By Aspirin not Plusprin, Disprin, etc.

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

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

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

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

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

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

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

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

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

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

a) cosmetic embellishment

b) Elegant packing

c) Irrational combination

d) Imitative drugs

e) Inadequate evidence of greater value?

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

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

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

Can we stop this 'tonic' practice?

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

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

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

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

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

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

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

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

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

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

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

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

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

DRUG PUSHERS OR HEALERS?

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

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

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

Readers of this bulletin are requested to think over the following facts, observations, conclusions taken from WHO, ICMR, ICSSR, Earthscan, VHAI, Govt. of India and other sources of information. Can we collectively accept as many of these 60-points as possible?

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

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

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

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

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

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RD-14

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

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ANALGIN - A STUDY FOR DRUG ACTION FORUM-KARNATAKA

1. The Drug

A class of chemicals called PYRAZOLONES have been used as medicines for over ninety years. Pyrazolones include drugs like Anti Pyrine, Aminopyrine, Phenyl Butazone, 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 (Aspirin) 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

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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, Anaphylactic 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.

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 painkilling and fever. By 1930s it's 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 - D.T.C. sale in U.S.A was prohibited

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Between 1955-59 - The American Medical Association Registry on Adverse Reactions recorded only 10 reports of leucopenia (fall in W.B.C count) and none in children

1960-64 - 18 cases reported (7 in children)
An increase in the import into U.S.A 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.

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 - U.S.A revoked Dipyrone licence

1977 - Japan banned free O.T.C sale

1978 - Ireland and Singapore revoked licence of Dipyrone

1979 - Denmark revoked licence of Dipyrone

1980-84 - 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 G.D.I banned the manufacture and sale of Amidopyrine.

1986 - Malaysia banned dipyrone

1986 - F.R.G banned O.T.C sale

In Netherlands, Dipyrone use is only allowed for uncontrollable fever.

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following reports of anaphylactic shock, Italy, Egypt and Saudi Arabia have prohibited manufacture of injectible preparations

The F.D.A of U.S.A regards that "true risk associated with this drug far outweigh any benefit derived from its use, including use in Hodgkins and similar malignant diseases".

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 main without Dipyrone by using equally effective and safe analgesics.

ii. The 'Boston Study' generated a lot of controversy, since Hoechst used the results even before publication for a misleading advertisement campaign showing the occurence 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. The study does not look into other side effects of Dipyrone, like shock, fall in B.P., Urticaria etc.

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c. The data presented in the intermediate and final reports are inconsistent.

d. Whereas 400 cases of agranulocytosis were registered to assess risk properly, only 221 cases were analysed in the final report, and

e. There is extreme variability in data between different countries and even within the same country.

f. Some data were seen to be clearly unreliable.

Sii. 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.

iv. Since 1965, 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. <u>In India</u>

1. In 1983, the G.O.I 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.
2. The Government is the largest manufacturer of Dipyrone in this country.

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3. 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 injectables, and drops for newborns and infants for colic.

4. Analgin is available as O.T.C inspite 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 O.P prescriptions and O.T.C sales of Analgesics. One more of these drugs were given to over 50% of patients requesting an analgesic.

5. Drug action groups have initiated a campaign on Analgin especially at ACASH, Bombay, DAF West Bengal and AIDAN, New Delhi.

6. Analgin induced agranulocytosis does occur in India, especially if one looks for it systematically as a Bombay haematologist S.C.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.

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

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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 J.J 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.

— SP · Tekur

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HARRIS L. COULTER 'Homoeopathic Medicine' 1972. American Foundation of Homeopathy, 910 17th St., N.W., Washington DC 20006 (Library of Congress Catalogue card No. 74-190020)

Several comments may be made on the homoeopathic dilutions. In the first place, their value has been proven by much clinical experience. Thousands of homoeopaths have used them and are using them today. These dilutions have been found highly effective when used according to the correct indications. In the second place, a series of biological, chemical, and physical experiments have uniformly demonstrated the existence of some physico-chemical, or other, force in the ultra-molecular dilutions. In 1928, H. Junker added various substances, in dilutions up to 10^{-27}, to bacterial cultures and found that they affected the growth of the bacteria. J. Patterson and W. Boyd in Scotland found that the Schick test for diptheria was changed from positive to negative by oral administration of alum-precipitated toxoid in a dilution of 10^{-60} or of *Diphtherinum* (a homoeopathic preparation of throat swabs from diphtheria patients) in a dilution of 10^{-402}. W. Persson in Leningrad investigated the effects of dilutions up to 10^{-120} on the rate of fermentation of starch by ptyalin and on the lysis of fibrin by pepsin and trypsin; in 1954 W. Boyd announced positive results from a retest of Persson's findings with respect to the effect of dilutions of mercuric chloride up to 10^{-61} on the rate of hydrolysis of starch by diastase.[23] These findings appear to be strong evidence against any suggestion that the homoeopathic infinitesimal doses are mere placebos.[24]

Furthermore, it is worth noting that orthodox medicine has never made an effort to test this aspect of homoeopathy under controlled conditions. Criticism of the ultra-

[23]See James Stephenson, M.D., "A Review of Investigations into the Action of Substances in Dilutions Greater than 1×10^{-24} (Microdilutions)," *Journal of the American Institute of Homoeopathy* XLVIII (1955), 327-355.

[24]Some results of research on the physical basis of the action of microdilutions are reported in James Stephenson, M.D. and G. P. Barnard, "Fresh Evidence for a Biophysical Field," *Journal of the American Institute of Homoeopathy* LXII (1969), 73-85.

molecular dose has been strictly *a priori*—with vague references to common sense which is a notoriously unreliable guide in medical matters.

Use of the ultra-molecular dose, in any case, is not an essential principle of homoeopathy. Hahnemann insisted on the "minimum dose", which is an ambiguous concept in view of the associated doctrine that increased dilution of the substance actually enhances its power. Homoeopathic physicians, like Hahnemann himself, make use of the whole range of dilutions, from the lowest to the highest.

3.) *The Single Remedy.* Hahnemann's third rule requires the physician to administer one remedy at a time. Here again his rule contrasts with orthodox practice which permits the use of several drugs at once or in combination.

The homoeopathic principle is not arbitrary but stems logically from the other elements of the homoeopathic system. The physician may give only one drug at a time because the provings are only of a single substance. The physician may not give two remedies at once (i.e., on the ground that their combined symptoms match all of the symptoms of the patient) because, when two remedies are administered at the same time, they yield additional symptoms which are neither those of substance A nor of substance B, but of A and B combined. Administration of two remedies at the same time introduces an unknown into the picture, and the purpose of Hahnemann's new method was to eliminate just such speculative and unreliable procedures from medicine.

Homoeopathy is in no way averse to the use of chemical compounds *provided they have been proved as such.* Thus, *Ferrum metallicum* yields one set of symptoms, and *Phosphorus* yields another set. Phosphate of iron (*Ferrum phosphoricum*) yields symptoms of both *Ferrum metallicum* and *Phosphorus*, but, in addition, has a

ALTERNATIVE HEALTH CARE SYSTEMS
ANOTHER POINT OF VIEW

Dr. Shirdi Prasad Tekur

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The western system of medicine, also called 'Allopathy' or 'Cosmopolitan Medicine,' dominates the medical and health care systems of our country. The Bhore Committee, charged with laying down the blueprint for health care systems in India, based its 1946 recommendations on the allopathic system. This dominance continues today, with a few cosmetic changes to keep up with the times and rhetorical references to the Indian systems of medicine. The reason could be that the allopathic system has kept pace with other frontiers of scientific research. The backing required for such efforts can only come from the developed, Western countries, which look primarily for solutions to their own problems.

Allopathy came to our country with the British, as a system of medical care for themselves. It flourished with the patronage of the ruling and elite classes of India and evolved into a system sponsored by the state for all people. The Indian systems lost the patronage of the rulers and were thus unable to interact dynamically with larger issues of public health -- both of which were needed for their further development. They remained static in some areas while decaying in others and were left behind as 'native medicine.' The national movement for Independence saw a resurgence of interest in Indian systems and attempts at reviving them marginally improved their status.

Interest in Alternatives

Thus, the terms 'alternative systems' or 'traditional medicine' usually refer to a group of systems other than the 'allopathic.' Traditional medicine does not define a unified, homogeneous practice. Formalised medical systems exist, along with informal folk practices. The Government of India officially recognises formalised systems like ayurveda, siddha, unani, yoga, naturopathy and homoeopathy in addition to allopathy. Tibetan medicine (the amchi system) is gaining popularity in areas contiguous with Tibet and in and around the Tibetan refugee settlements in our country. Acupuncture and acupressure (Chinese systems) are increasingly accepted in urban India and are also prevalent in the rural areas of north-eastern India. Other non-formalised systems, such as tribal medical practices, are being documented and studied in tribal areas.

The resurgence of interest in alternatives and traditions is a worldwide phenomenon, probably linked to growing awareness of the limitations of present-day science in explaining nature. Increasing consciousness about the environment, pollution and attempts towards evolving a holistic approach to problem-solving seem to be contributory factors. Other, more immediate reasons could be because traditional systems are :-

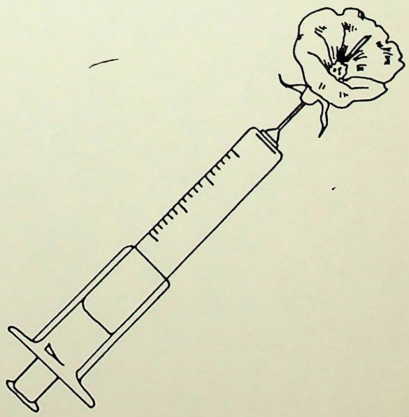
a) A valuable resource

The World Health Organisation (WHO) refers to traditional medicine as "the sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance, relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing."

It calls for the promotion of traditional medicine because of its intrinsic utility, unique and holistic approach and operational feasibility in the drive to achieve health for all by 2000 A.D.

The National Health Policy statement of 1989 clearly states : "The country has a large stock of health manpower comprising private practitioners in various systems -- for example, ayurveda, unani, siddha, homoeopathy, yoga, naturopathy etc. This resource has not so far been adequately utilized."

The table on page 27 provides an idea of health resources in our country :



	Ayurveda	Unani	Siddha	Yoga	Naturo-pathy	Allopathy
1 No. of institutionally qualified practitioners	1,08,085	7,912	1,183	-	43	3,30,755
2 Total no. of registered practitioners	2,72,800	28,711	11,581	-	108	3,30,755
3 No. of hospitals	1,469	101	106	6	10	9,831
4 Total beds provided	15,913	1,267	885	40	190	5,85,889
5 No. of dispensaries	12,109	871	316	4	43	1,18,806
6. No. of colleges / institutions	100	18	2	34	3	125

Source : Health Information India - 1988

b) Accessible to people

The WHO document, "The World Drug Situation," classifies India among countries where less than 30 per cent of the population has access to allopathic drugs. This lack of access is applicable in different degrees, to health facilities, whether government-run or private, because of costs, distances and non-functional health structures. Scarce health resources meant to be used for preventive and health promotive measures for the [illegible]ny are gobbled up by the costly diagnostic and curative services accessible to the few.

Traditional medicine is used by a significant number of people as the only health resource available, or as a substitute for or complement to allopathic services.

c) Holistic in approach

The traditional practitioner often depends more on his or her ability to mobilise the patients' hopes, restore their morale, and gain re-acceptance by their group, than on pharmacoepia.

Traditional medical practices are concerned with the totality of human functions in society and represent a more holistic approach. Illness is seen not only in terms of biochemical and supernatural disharmony, but also as a breakdown in the interaction of the patient with others in his or her social environment. The psycho logical /psychosomatic value of traditional medicine is widely recognised.

d) A fad among the elite

An awareness of allopathic medicine's limitations, the economic ability to shop around, and a fad for everything 'natural,' 'ethnic,' 'non-synthetic,' and 'non-chemical' promotes traditional medicine among affluent groups. A cause for concern is that rationality is a casualty in this keeping up with Joneses, and that patronage by the elite results in the hiking up of costs which takes traditional medicine, too, out of the reach of those who need, but now can't afford these services. The focus on curative medicine, rare and exotic, true and imaginary illnesses and the lure of lucre diverts valuable health resources needed by the majority. At the same time, it is a fact that this patronage does help promote traditional medicine.

e) Of interest to pharmaceutical producers

The drug manufacturing industry has very good reasons to promote traditional medicine if one considers the potential for profits. With the avowed aim of looking for safer, cheaper and better drugs,, big companies have entered this unorganized market of small producers. Government restrictions on manufacture and sale are less stringent, while the clientele need no selling of these products! With hardly any standards laid down, or measures for quality control, it is a market open to the unscrupulous, small or big. To the common man, it means that he pays for a bottled remedy instead of learning to use the herb in his backyard.

f) The field of community health activists

In their efforts to preserve tradition and culture, and make communities self-sufficient in tackling health needs, health activists revive and promote useful tradi-

Safety status of commonly used drugs in pregnancy

Doctors are many times confused about or even ignorant of the precise relative risk of using different types of drugs in pregnancy.There is no readymade, detailed source of information available on this aspect. The following table would help practitioners to choose appropriate drugs for use in pregnancy. It has been prepared from the booklet "Medicines in pregnancy"by the "Australian Drug Evaluation Committee" (1989). Let us quote from the `introduction' of this booklet.

The Australian catagorisation of risk associated with the use of pharmaceutical drugs in pregnancy was developed from systems used in Sweden and the USA.

The catagorisation has taken into account all known harmful effects of the drugs on the developing baby regardless of mechanisms, including the potential to cause the birth defects, the potential to cause unwanted pharmacological effects around the time of birth (effects which may or may not be reversible) and the potential to cause the cancer in later life. The catagorisation applies only to reccomended therapeutic doses in women in the reproductive age group.

The Australian catagorisation consists of five separate catagories.

Catagory A : Drug which have been taken by large number of pregnant women and women of child bearing age without an increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Catagory B : Drugs which have been taken by only a limited number of pregnent women and women of child bearing age withoput an increase in the freqency of the malformation or other direct or indirect harmful effects on the human fetus having been observed.

As experience of effects of drugs in this catagory in humuns is limited, results of toxicological studies to date (including reproduction studies in animals) are indicated by allocation to one of three subgroups.

Group B1 : Studies in animals * have not shown evidence of an increased occurence of fetal damage.

Group B2 : Studies in animals * are inadequete and may be lacking but available data show no evidence of an increased occurence of fetal damage.

Group B3 : Studies in animals * have shown evidence of an increased occurance of fetal damage, the significance of which is considered uncertain in humans.

Catagory C : Drugs which owing to their pharmacologicl effects have caused or may be suspected of causing harmful effects in the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying text should be consulted for further details.

Catagory D : Drugs which have caused an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Accompanying text should be consulted for furthe details.

Catagory X : Drugs that have such a high risk of causing permanent damage to the fetus that they should not be used in pregnency or when there is a posobility of pregnency.

SAFETY STATUS OF COMMONLY USED DRUGS IN PREGNANCY

No	Name of drug	Possible adverse effects on pregnancy/foetus/neonate	Safety status and recommendations	Category
1	OPIOD ANALGESICS Morphine, Pethidine Pentazocine, Dextropropoxyphene	Respiratory depression in newborn when given 2-3 hours before delivary	use with specific precautions	C
2	Codeine	----	can be safely used	A
3	NSAID Aspirin,Ibuprofen, Phenylbutazone Indomethacin Diclofenac Piroxicam	closure of foetal ductus arteriosus.Given at term may prolong labour and delay parturition	Not to be used in late pregnancy	C
	Paracetamol	----------	can be safely used	A
4	ANTICONVULSANT Phenobarbitone Phenytoin-Na Ethosuccimide	craniofacial abnormality mental and growth deficiancies, oral clefts,cardiac abnormalities	Use if must Overall risky teratogenicity is far outweighed by the dangers to mother and foetus of uncontrolled convulsions	D
	carbamazepine	malformations in rats	Use when necessary	B3
5	ANTIEMETICS Phenothiazines Others Meclozine,Cyclozine	High doses in late pregnancy cause prolonged extrapyramidal disturbances in the new born	Not to be used in late pregnancy	C
	Metclopramide	----------	can be used safely	A
6	ANTIHISTAMINICS Clorpheniramine Diphenhydramine	----------	can be safely used	A
7	AMINOGLYCOSIDES Gentamycin Neomycin,Kanamycin	Nephrotoxic and ototoxic to the foetus	Strictly avoided	D
8	CEPHALOSPORINS	----------	can be safely used	A
9	PENICILLINS Penicillins,Ampi Amoxy,Cloxa.	----------	can be safely used	A

No	Name of drug	Possible adverse effects	Safety status and	Category
10	Nalidixic acid	----------	can be safely used	A
11	SULFAS	When given in last trimaster may cause kernicterus in babies	not to be used in last trimester	C
12	SULPHONES Dapsone	No adverse action on human foetus so far	use if necessary	B2
13	TETRACYCLINE	When given in '2nd,'3rd trimaster,hypoplasia of enamel and discolouration of teeth of the newborn may occur	strictly avoided	C
14	ANTIMALARIALS Chloroquins etc.	Neurogenic interferance with hearing balance;but risk of malaria far outweighs this risk	use when diagnosis is certain	D
15	ANTI_T.B. INH, Ethambutol	----------	can be safely used	A
	Rifampicin	Bleeding due to hypoprothrombinaemia in neonates and mothers	Vit. K to be given in late pregnancy and to newborn infants	C
16	OTHER ANTIBIOTICS Cloramphenicol	Grey-baby syndrome in the newborn	avoided at term	C
	Clinda,Linco, Erythromycin	----------	can be safely used	A
	Metronidazale Trimethoprim	No malformations in humans High doses give rise to birth defects typical of folic acid antagonism	use when necessary if used folic acid supplementation be used	B2 B3
17	ANTI-ASTHAMATICS Theophylline derivatives Adrenaline Salbutamol	----------	can be safely used	A
18	ANTI-CHOLINERGIC Atropine,Belladona Hyoscine	----------	can be used safely	A
19	Digoxine and other cardiac glycosides	----------	can be used safely	A
	BETA-BLOCKERS Inderal,Ciplar etc	May cause bradicardia in foetus and newborn	to be given when is must in late pregnancy and delivery	C

No	Name of drug	Possible adverse effects	Safety status and	Category
20	Ca-CHANNEL BLOCKERS Nifedipine Verapamil	Foetal hypoxia with maternal hypotention	should be avoided unless a must	C
21	DIURETICS Thiazides and others	May cause electrolyte disturbances in foetus, neonatal thrombocytopenia	only be given on sound indication and at lowest effective dose	C
22	ANTACIDS	----------	can be used safely	A
23	H2-Blockers Ranitidine	No adverse effect on human foetus	may be used when necessary	B
24	ANTIHYPERTENSIVES Guanithidine Methyl dopa Reserpine	---------- ---------- Nasal discharge, lethargy poor feeding in neonate	can be used safely can be used safely use when a must	A A C
25	LAXATIVES Bisacodyl dioctyl-Na Sulphosuccinate	----------	can be used safely	A
26	ANTI-HELMENTIC	No adverse effect on human foetus		B3
27	HAEMOPOIETICS Iron Folic Acid	----------	can be used safely	A
28	CORTICOSTEROIDS	Malformations in animals, Possibility of adrenal cortex supression in fetus after long term treatment	short term treatment may be given when indicated	C
29	PROGESTAGENS	High doses can cause mascu--linization of female fetus	should not be used	D
30	ORAL-ANTI DIABETICS Chlorpropamide, Tolbutamide, Glibenclamide, etc. Metphormin Phenphormin, etc.	Sulfonyl ureas may cause hypo-glycaemia in fetus Birth defects in animal studies Metphormin may cause fetal lactic acidosis	be avoided, insulin be used instead	C

No	Name of drug	Possible adverse effects	Safety status and	Category
31	HYPNOTICS Barbiturates	Prolonged use can result in hypotension, depressed respiration, hypothermia in new born	continuous use be avoided	C
	Benzodiazepins Diazepam and analogues	as above	continuous use be avoided	C
32	ANTIPSYCHOTICS Phenothiazines Chlorpromazines Promazine Trifluoperazine	High doses in late pregnancy may cause prolonged extrapyramidal symptoms in new borns	use when essential	C
	Tricyclic anti-depressants Imipramine and analogues	may cause birth defects	Use only on sound indication	C
33	VACCINES Typhoid,Cholera BCG,Hepatitis B	----------	Use when necessary	B2
	Tetanus toxoid	----------	Can be safely used	A

The table is prepared from from the booklet" Medicines in Pregnancy"prepared by Australian Drug Evaluation Committee 1989.

EIGHTH EDITION

Handbook on Injectable Drugs

by Lawrence A. Trissel

Too expensive for CHC-

(814)

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CONTENTS

PREFACE

The *Handbook on Injectable Drugs* has evolved considerably from its initial conception in 1975. Over the years, numerous changes, additions, restructurings, and format enhancements, as well as a vastly increased volume of information, have led to an eighth edition that is more thorough and complete than ever. Nearly 1200 pages of information are presented on 272 commercially available drugs plus investigational drugs and infusion solutions. Eighteen new monographs on commercially available drugs are presented:

Aldesleukin
Bupivacaine HCl
Calcitriol
Diltiazem HCl
Filgrastim
Gallium nitrate
Indomethacin sodium trihydrate
Iohexol
Iopamidol
Ketorolac tromethamine
Melphalan HCl
Milrinone lactate
Ofloxacin
Paclitaxel
Piperacillin sodium–tazobactam sodium
Rifampin
Streptozocin
Teniposide

In addition, a section on parenteral drugs available commercially outside the United States has been updated and expanded. Seven new drugs, each having considerable published information on its stability and/or compatibility, are included:

Aclarubicin HCl
Amsacrine
Cefsulodin sodium
Clonazepam
Cyclizine lactate
Diethanolamine fusidate
Vindesine sulfate

All previously existing information has been completely updated. An additional 188 references were utilized to prepare the eighth edition, bringing the total to 1709.

The *Handbook on Injectable Drugs* has roots back in the innovations of the 1950s and 1960s with the landmark work of Bogash,[1] Kirkland et al.,[2] and Williams and Morovec.[3] Yet it remains a work of contemporary interest. This eighth edition incorporates almost 200 pages of new information. Even with all of the changes, the intent is unchanged from the first edition many years ago: to organize and summarize in a concise, standardized format the results of the primary research in parenteral drug stability and compatibility.

Note of Appreciation

I want to express my gratitude to Ms. Karen Hale, Mr. Daniel Haas, and Dr. Michael Allwood. Again for this edition, these friends as well as colleagues ably assisted me in completing this difficult and extraordinarily time-consuming project. Their continued interest and extensive help in making the *Handbook* a better reference are greatly appreciated.

Similarly, the editorial talents of Ms. Carmen Huddleston, Ms. Linda Sekino, and Ms. Kathy Brock of First DataBank greatly facilitated the revision process. Their invaluable assistance contributed significantly to improving the *Handbook*, and I am indebted to them for their efforts.

Of course, the extensive contributions of Ms. Shelly Elliott, Ms. Johnna Hershey, and Mr. Michael Soares of the Special Projects staff of the American Society of Hospital Pharmacists are especially appreciated. I want to extend to them my deep thanks for making the revision process both possible and pleasant.

My continuing thanks go to those users of the *Handbook* who make valuable suggestions for its improvement and to the numerous drug companies that supply information on their products.

Finally, my deepest thanks must go, once again, to my family who continues to endure and endeavors to understand my devotion to the *Handbook*. My love and gratitude go to them for their support and forbearance, which make it possible for me to undertake the demanding challenge the *Handbook* represents.

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1. Bogash RC: Compatibilities and incompatibilities of some parenteral medication, *Bull Am Soc Hosp Pharm 12*:445–448 (July–Aug) 1955.
2. Kirkland WD, Jones RW, Ellis JR, et al.: Compatibility studies of parenteral admixtures, *Am J Hosp Pharm 18*:694–699 (Dec) 1961.
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LAT
April 1994

HOW TO USE THE HANDBOOK

Organization of the Handbook

The *Handbook on Injectable Drugs* has been organized as a collection of monographs on each of 272 commercially available drugs. In addition, information on 42 investigational drugs and 16 drugs available outside the United States has been included. A section on the composition and characteristics of commercially available intravenous infusion solutions is presented at the end of the book. The monographs on the commercial drugs are arranged alphabetically by nonproprietary name. The names of the drugs follow the style of *USAN and the USP Dictionary of Drug Names*, 1993 edition. Also included are some of the trade names and manufacturers of the drug products; this listing is not necessarily comprehensive and should not be considered an endorsement of any product or manufacturer.

All of the information included in the *Handbook* is referenced so that those who wish to study the original sources may find them. In addition, the *American Hospital Formulary Service* Classification System numbers have been included to facilitate the location of therapeutic information on the drugs.

The monographs have been divided into the subheadings described below:

Products—lists many of the sizes, strengths, volumes, and forms in which the drug is supplied, along with other components of the formulation. Instructions for constitution (when applicable) are included in this section.

The products cited do not necessarily constitute a comprehensive list of all available products. Rather, some common representative products are described. Furthermore, dosage forms, sizes, and container configurations of parenteral products may undergo significant changes during the lifespan of this edition of the *Handbook*.

Following the product descriptions, the pH of the drug products, the osmotic value(s) of the drug and/or dilutions (when available), and other miscellaneous product information such as the sodium content and definition of units are presented.

Dosage—provides administration information first, followed by dosage information. The administration information includes route(s), rates of infusion (when applicable), and other related administration details. The recommended adult and then pediatric doses of the drug are presented. Finally, a notation is included when dosage reduction for renal and/or hepatic impairment is needed.

The dosage and administration information is derived primarily from the product's official labeling and the *American Hospital Formulary Service*. This information is, of necessity, a condensation of the available information from these sources. The intention is to provide the reader with a convenient and readily available resource for quickly verifying proper and appropriate doses and dosage ranges of injectable drugs. This information is insufficient for prescribing. For that purpose, the reader should refer to the official labeling and more therapeutically comprehensive references such as the *American Hospital Formulary Service*.

Stability—describes the drug's stability and storage requirements, if any. In addition, pH effects, the effects of freezing and exposure to light, and the sorption and filtration characteristics of the drug are presented.

Compatibility Information—tabulates the results of published reports from primary reference sources of compatibility testing of the subject drug with infusion solutions and the other drugs. The various citations are listed alphabetically by solution or drug name; the information is completely cross-referenced among the monographs.

Four types of tables are utilized to present the available information, depending on the kind of test being reported. The first type is for information on the compatibility of a drug in various infusion solutions and is depicted in Table 1. The second type of table presents information on two or more drugs in intravenous solutions and is shown in Table 2. The third type of table is used for tests of two or more drugs in syringes and is shown in Table 3. The fourth table format is used for reports of simulated or actual injection into Y-sites of administration sets and is shown in Table 4.

Many published articles, especially older ones, do not include all of the information necessary to complete the tables. However, the tables have been completed as fully as possible from the original articles.

Additional Compatibility Information—provides additional information and discussions of compatibility presented in narrative form.

Other Information—contains any relevant auxiliary information concerning the drug which does not fall into the previous categories.

The Listing of Concentration

The concentrations of all admixtures in intravenous solutions in the tables have been indicated in terms of concentration per liter to facilitate comparison of the various studies. In some cases, this may result in amounts of the drug that are greater or lesser than those normally administered (as when the recommended dose is tested in 100 ml of vehicle), but the listings do accurately reflect the actual concentrations tested, expressed in standardized terms.

For studies involving syringes, the amounts actually used are indicated. The volumes are also listed if indicated in the original article.

For studies of actual or simulated Y-site injection of drugs, the concentrations used are cited. Note that this table is designed with the assumption of a 1:1 mixture of the subject drug and infusion solution or admixture. For citations reporting other than a 1:1 mixture, the actual amounts tested are specifically noted.

Designating Compatibility or Incompatibility

Each citation in the Compatibility Information tables has been

Table 1.

Solution Compatibility

Monograph drug name

Solution	*Mfr*	*Mfr*	*Conc/L*	*Remarks*	*Ref*	*C/I*
(1)	(2)	(3)	(4)	(5)	(6)	(7)

1. Solution in which the test was conducted.
2. Manufacturer of the solution.
3. Manufacturer of the drug about which the monograph is written.
4. Concentration of the drug about which the monograph is written.
5. Description of the results of the test.
6. Reference to the original source of the information.
7. Designation of the compatibility (C) or incompatibility (I) of the test result according to conventional guidelines.

Table 2.

Additive Compatibility

Monograph drug name

Drug	*Mfr*	*Conc/L*	*Mfr*	*Conc/L*	*Test Soln*	*Remarks*	*Ref*	*C/I*
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

1. Test drug.
2. Manufacturer of the test drug.
3. Concentration of the test drug.
4. Manufacturer of the drug about which the monograph is written.
5. Concentration of the drug about which the monograph is written.
6. Infusion solution in which the test was conducted.
7. Description of the results of the test.
8. Reference to the original source of the information.
9. Designation of the compatibility (C) or incompatibility (I) of the test result according to conventional guidelines.

Table 3.

Drugs in Syringe Compatibility

Monograph drug name

Drug (in syringe)	*Mfr*	*Amt*	*Mfr*	*Amt*	*Remarks*	*Ref*	*C/I*
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

1. Test drug.
2. Manufacturer of the test drug.
3. Actual amount of the test drug.
4. Manufacturer of the drug about which the monograph is written.
5. Actual amount of the drug about which the monograph is written.
6. Description of the results of the test.
7. Reference to the original source of the information.
8. Designation of the compatibility (C) or incompatibility (I) of the test result according to conventional guidelines.

Table 4.

Y-Site Injection Compatibility (1:1 Mixture)

Monograph drug name

Drug	*Mfr*	*Conc*	*Mfr*	*Conc*	*Remarks*	*Ref*	*C/I*
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)

1. Test drug.
2. Manufacturer of the test drug.
3. Concentration of the test drug.
4. Manufacturer of the drug about which the monograph is written.
5. Concentration of the drug about which the monograph is written.
6. Description of the results of the test.
7. Reference to the original source of the information.
8. Designation of the compatibility (C) or incompatibility (I) of the test result according to conventional guidelines.

designated as being a determination of compatibility (C) or incompatibility (I) according to specific guidelines. The citation is designated compatible when the results of the original article indicated one or more of the following criteria:

1. Physical compatibility (no visible sign of incompatibility).
2. Stability of the components for at least 24 hours in an admixture under the specified conditions (decomposition of 10% or less).
3. Stability of the components for the entire test period, although in some cases it was less than 24 hours (time periods less than 24 hours have been noted).

The citation is designated as incompatible when the results of the original article indicated one or more of the following criteria:

1. Physical incompatibility (haze, precipitate, color change, etc.).
2. Greater than 10% decomposition of one or more components in an admixture in 24 hours or less under the specified conditions (time periods less than 24 hours have been noted).

Although these criteria have become the conventional definitions of compatibility and incompatibility, the reader should recognize that the criteria may need to be tempered with professional judgment. Inflexible adherence to the compatibility designations should be avoided. Instead, they should be used as aids in the exercising of professional judgment.

Therapeutic incompatibilities or other drug interactions are not within the scope of the *Handbook* and have not been included.

To gather the bulk of the published compatibility and stability information, a literature search is performed on the *International Pharmaceutical Abstracts* database. By using key terms (e.g., stability), a listing of candidate articles for inclusion in the *Handbook* is generated. From this list, truly relevant articles are selected and summarized. As a supplement to this automated literature searching, the references of each article selected for inclusion are also reviewed, and any publications not included previously are obtained. Although this labor-intensive approach yields a very high percentage of the relevant articles published in the world's literature, it is not 100% inclusive. Occasionally, users of the *Handbook* call my attention to articles that were overlooked. I am grateful to these readers and encourage anyone who finds such an article to contact me.

Limitations of the Literature

The literature on drug–drug and drug–vehicle compatibility has many contradictions. With the exception of a study indicating physical compatibility and another indicating chemical decomposition of the same admixture, such conflicting information has been included. The conflicting information will be readily apparent to the reader because of the content of the Remarks as well as the C and I designations following each citation. Many factors influence the compatibility and stability of drugs, and absolute statements are often difficult or impossible to make. Differences in buffering systems, preservatives, vehicles, temperatures, concentrations, and order of mixing may all play a role. By reviewing a variety of reports, the practitioner is better able to exercise professional judgment with regard to the compatibility of the admixture. If only one reference is used, valuable alternatives may be overlooked or marginal compatibility conditions may not be recognized.

Further, it should be noted that many of the citations designated incompatible are not absolute. While a particular admixture may incur more than 10% decomposition within 24 hours, the combination may be useful for a shorter time period. The concept of "utility time" or the time to 10% decomposition may be useful in these cases. Unfortunately, such information is often not available. Included in the Remarks columns of the tables are the amount of decomposition, the time period involved, and the temperature at which the study was conducted when this information is available.

Another limitation is that much of the work done has evaluated only "physical" compatibility. While a finding of precipitation, haze, or other visually observable effect may be a definite incompatibility, the lack of such changes does not rule out chemical deterioration. In many cases, drugs originally listed as compatible because of their lack of a visual change were later shown to undergo chemical decomposition. (As previously noted, such physical compatibility citations have not been included in the *Handbook*.) The reader must always bear this possibility in mind when physical compatibility is the only information available. Similarly, the determination of chemical stability does not rule out the presence of unacceptable levels of subvisual physical phenomena such as particles and turbidity.

And, finally, contemporary practitioners have come to expect that the analytical methods used in reports on the chemical stability of drugs will be validated stability-indicating methods. However, many early studies used methods that were not demonstrated to be stability indicating.

Solution Abbreviations

AA	Amino acids (percentage specified)
D	Dextrose solution (percentage unspecified)
D5LR	Dextrose 5% in Ringer's injection, lactated
D5R	Dextrose 5% in Ringer's injection
D–S	Dextrose–saline combinations
D2.5¼S	Dextrose 2.5% in sodium chloride 0.45%
D2.5S	Dextrose 2.5% in sodium chloride 0.9%
D5¼S	Dextrose 5% in sodium chloride 0.225%
D5½S	Dextrose 5% in sodium chloride 0.45%
D5S	Dextrose 5% in sodium chloride 0.9%
D10S	Dextrose 10% in sodium chloride 0.9%
D5W	Dextrose 5% in water
D10W	Dextrose 10% in water
DXN–S	Dextran 6% in sodium chloride 0.9%
IDCM	Ionosol DCM
IG	Ionosol G

IM	Isolyte M
IP	Isolyte P
IS	Invert sugar
LR	Ringer's injection, lactated
NM	Normosol M
NR	Normosol R
NS	Sodium chloride 0.9%
PH	Protein hydrolysate
R	Ringer's injection
S	Saline solution (percentage unspecified)
SL	Sodium lactate $^1/_6$ M
TPN	Total parenteral nutrition solution
W	Sterile water for injection

Manufacturer and Compendium Abbreviations

AB	Abbott
ACC	American Critical Care
AD	Adria
AH	Allen & Hanburys
AHP	Ascot Hospital Pharmaceuticals
AMG	Amgen
AMR	American Regent
ANT	Antigen
AP	Asta-Pharma
AQ	American Quinine
AR	Armour
ARC	American Red Cross
AS	Arnar-Stone
ASC	Ascot
AST	Astra
AT	Alpha Therapeutic
AW	Asta Werke
AY	Ayerst
BA	Baxter
BAY	Bayer
BC	Bencard
BE	Beecham
BEL	R. Bellon
BI	Boehringer Ingelheim
BK	Berck
BN	Breon
BP	British Pharmacopoeia*
BPC	British Pharmaceutical Codex*
BR	Bristol
BRN	Braun
BT	Boots
BV	Ben Venue
BW	Burroughs Wellcome
BX	Berlex
BY	Bayer
CA	Calmic
CE	Carlo Erba
CET	Cetus
CH	Lab. Choay Societe Anonyme
CI	Ciba
CL	Clintec
CN	Connaught
CO	Cole
CR	Critikon
CU	Cutter
DB	David Bull Laboratories
DCC	Dupont Critical Care
DI	Dista
DIA	Diamant
DM	Dome
DU	DuPont
EA	Eaton
EN	Endo
ES	Elkins-Sinn
EV	Evans
EX	Essex
FA	Farmitalia
FC	Frosst & Cie
FI	Fisons
FRE	Fresenius
FUJ	Fujisawa
GEM	Geneva-Marsam
GEN	Genentech
GG	Geigy
GL	Glaxo
HC	Hillcross
HO	Hoechst-Roussel
HR	Horner
HY	Hyland
ICI	ICI Pharmaceuticals
IMM	Immunex
IMS	IMS Ltd.
IN	Intra
IV	Ives
IX	Invenex
JN	Janssen
KA	Kabi
KN	Knoll
KP	Kabi Pharmacia
KV	Kabi-Vitrum
KY	Kyowa
LA	Lagap
LE	Lederle
LEM	Lemmon
LEO	Leo Laboratories
LI	Lilly
LY	Lyphomed
LZ	Labaz Laboratories
MA	Mallinckrodt
MB	May & Baker
ME	Merck
MG	McGaw
MI	Miles
MJ	Mead Johnson
MN	McNeil
MMD	Marion Merrell Dow
MRD	Merrill-Dow
MRN	Merrill-National
MSD	Merck Sharp & Dohme
MY	Maney
NA	National
NCI	National Cancer Institute
NE	Norwich-Eaton
NF	National Formulary*
NO	Nordic
NOV	Novo
ON	Orion
OR	Organon
ORT	Ortho
PD	Parke-Davis
PE	Pentagone
PF	Pfizer
PFM	Pfrimmer
PH	Pharmacia
PHX	Phoenix
PO	Poulenc
PR	Pasadena Research
PX	Pharmax
QU	Quad
RB	Robins
RC	Roche
RI	Riker
RKC	Reckitt-Colman
ROR	Rorer
RP	Rhone-Poulenc
RR	Roerig
RS	Roussel
RU	Rugby
SC	Schering
SCN	Schein
SE	Searle
SKB	SmithKline Beecham
SKF	Smith Kline & French
SM	Smith
SN	Smith + Nephew
SO	SoloPak
SQ	Squibb
ST	Sterilab
STR	Sterling
STS	Steris
STU	Stuart
SV	Savage
SX	Sabex
SY	Syntex
SZ	Sandoz
TE	Teva
TL	Tillotts
TO	Torigian
TR	Travenol
UP	Upjohn
USP	United States Pharmacopeia*
USV	USV Pharmaceuticals
VI	Vitarine
VT	Vitrum
WB	Winthrop-Breon
WC	Warner-Chilcott
WED	Weddel
WI	Winthrop
WL	Warner Lambert
WY	Wyeth

**While reference to a compendium does not indicate the specific manufacturer of a product, it does help to indicate the formulation that was used in the test.*

FLUDARABINE PHOSPHATE
AHFS 10:00

Fludara **Berlex**

Products— Fludarabine phosphate (Berlex) is supplied as a lyophilized product in 6-ml vials containing 50 mg of drug with mannitol 50 mg and sodium hydroxide for pH adjustment. Constitute with 2 ml of sterile water for injection to yield a 25-mg/ml concentration (2).

pH— From 7.2 to 8.2 (2).

Osmolality— Fludarabine phosphate 25 mg/ml in sterile water for injection has an osmolality of 352 mOsm/kg (1689).

Dosage— Fludarabine phosphate is administered by intravenous infusion over 30 minutes in 100 or 125 ml of dextrose 5% in water or sodium chloride 0.9% (2; 4). The drug also has been administered by rapid intravenous injection and continuous infusion (4).

The usual adult dose is 25 mg/m^2 daily for five consecutive days every 28 days. Safety and efficacy of fludarabine phosphate in children have not been established (2; 4).

The dosage may need to be reduced in geriatric patients and patients with impaired renal or bone marrow function (2; 4).

Stability— Intact vials should be stored under refrigeration (2). The manufacturer recommends use of the constituted solution within eight hours because it does not contain an antibacterial preservative. Nevertheless, the drug is chemically stable in solution, exhibiting less than 2% decomposition in 16 days when stored at room temperature and exposed to normal laboratory light (234).

pH Effects— Fludarabine phosphate is chemically stable in aqueous solution at pH 4.5 to 8. The pH of optimum stability is approximately 7.6 (234).

Sorption— Fludarabine phosphate 0.04 mg/ml in dextrose 5% in water or sodium chloride 0.9% was equally stable in either glass or PVC containers, exhibiting no loss due to sorption during 48 hours at room temperature or under refrigeration (234).

Compatibility Information

Y-Site Injection Compatibility (1:1 Mixture)

Fludarabine phosphate

Drug	*Mfr*	*Conc*	*Mfr*	*Conc*	*Remarks*	*Ref*	*CII*
Acyclovir sodium	BW	7 mg/ml[a]	BX	1 mg/ml[a]	Darker color visible with high intensity light within 4 hr	1439	I
Allopurinol sodium	BW	3 mg/ml[b]	BX	1 mg/ml[b]	Physically compatible with no change in measured turbidity or increase in particle content in 4 hr at 22 °C under fluorescent light	1686	C
Amikacin sulfate	BR	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Aminophylline	ES	2.5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Amphotericin B	SQ	0.6 mg/ml[a]	BX	1 mg/ml[a]	Small amount of particulate matter develops in 4 hr at room temperature	1439	I
Ampicillin sodium	BR	20 mg/ml[b]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ampicillin sodium-sulbactam sodium	RR	20 + 10 mg/ml[b]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Amsacrine	NCI	1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Aztreonam	SQ	40 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Bleomycin sulfate	BR	1 unit/ml[b]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Butorphanol tartrate	BR	0.04 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Carboplatin	BR	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Carmustine	BR	1.5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

Fludarabine phosphate

Drug	Mfr	Conc	Mfr	Conc	Remarks	Ref	CII
Cefazolin sodium	LEM	20 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cefepime HCl	BR	20 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible with no change in measured turbidity or increase in particle content in 4 hr at 22 °C under fluorescent light	1689	C
Cefoperazone sodium	RR	40 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cefotaxime sodium	HO	20 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cefotetan disodium	STU	20 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ceftazidime (sodium carbonate)	GL	40 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ceftizoxime sodium	SKF	20 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ceftriaxone sodium	RC	20 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cefuroxime sodium	GL	30 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Chlorpromazine HCl	ES	2 mg/ml[a]	BX	1 mg/ml[a]	Initial light haze intensifies within 30 min	1439	I
Cimetidine HCl	SKF	12 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cisplatin	BR	1 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Clindamycin phosphate	LY	10 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cyclophosphamide	MJ	10 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Cytarabine	UP	50 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Dacarbazine	MI	4 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Dactinomycin	MSD	0.01 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Daunorubicin HCl	WY	2 mg/ml[a]	BX	1 mg/ml[a]	Slight haze, visible with high intensity light, forms within 4 hr at room temperature	1439	I
Dexamethasone sodium phosphate	MSD	1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Diphenhydramine HCl	WY	2 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Doxorubicin HCl	CET	2 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

	Fludarabine phosphate						
Drug	*Mfr*	*Conc*	*Mfr*	*Conc*	*Remarks*	*Ref*	*CII*
Doxycycline hyclate	ES	1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Droperidol	JA	0.4 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Etoposide	BR	0.4 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Famotidine	MSD	2 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Filgrastim	AMG	30 μg/ml[a]	BX	1 mg/ml[a]	Physically compatible with no change in measured turbidity or increase in particle content in 4 hr at 22 °C under fluorescent light	1687	C
Floxuridine	RC	3 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Fluconazole	RR	2 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Fluorouracil	LY	16 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Furosemide	AB	3 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ganciclovir sodium	SY	20 mg/ml[a]	BX	1 mg/ml[a]	Darker color forms within 4 hr	1439	I
Gentamicin sulfate	ES	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Haloperidol lactate	MN	0.2 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Heparin sodium	SO, WY	40, 100, 1000 units/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Hydrocortisone sodium phosphate	MSD	1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Hydrocortisone sodium succinate	UP	1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Hydromorphone HCl	KN	0.5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Hydroxyzine HCl	WI	4 mg/ml[a]	BX	1 mg/ml[a]	Slight haze, visible with high intensity light, forms immediately	1439	I
Ifosfamide	MJ	25 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Imipenem–cilastatin sodium	MSD	5 mg/ml[b]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Lorazepam	WY	0.1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Magnesium sulfate	SO	100 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Mannitol	BA	150 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

Fludarabine phosphate

Drug	*Mfr*	*Conc*	*Mfr*	*Conc*	*Remarks*	*Ref*	*CII*
Mechlorethamine HCl	MSD	1 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Melphalan HCl	BW	0.1 mg/ml[b]	BX	1 mg/ml[b]	Physically compatible with no change in measured turbidity or increase in particle content in 3 hr at 22 °C under fluorescent light	1557	C
Meperidine HCl	WI	4 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Mesna	BR	10 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Methotrexate sodium	CET	15 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Methylprednisolone sodium succinate	UP	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Metoclopramide HCl	DU	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Mezlocillin sodium	MI	40 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Miconazole	JA	3.5 mg/ml[a]	BX	1 mg/ml[a]	Light haze, greater than for miconazole alone, forms immediately	1439	I
Minocycline HCl	LE	0.2 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Mitoxantrone HCl	LE	0.5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Morphine sulfate	WI	1 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Multivitamins	ROR	0.01 ml/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Nalbuphine HCl	DU	10 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Netilmicin sulfate	SC	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ondansetron HCl	GL	0.5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Pentostatin	NCI	0.4 mg/ml[b]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Piperacillin sodium	LE	40 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Piperacillin sodium-tazobactam sodium	LE	40 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible with no change in measured turbidity or increase in particle content in 4 hr at 22 °C under fluorescent light	1688	C
Potassium chloride	AB	0.1 mEq/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Prochlorperazine edisylate	WY	0.5 mg/ml[a]	BX	1 mg/ml[a]	Slight haze forms within 30 min	1439	I

Y-Site Injection Compatibility (1:1 Mixture) (Cont.)

Fludarabine phosphate

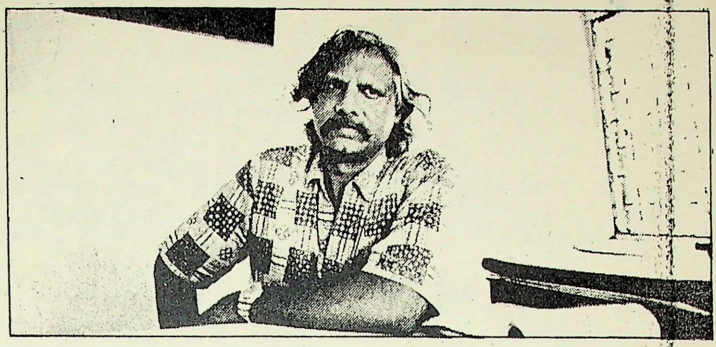
Drug	*Mfr*	*Conc*	*Mfr*	*Conc*	*Remarks*	*Ref*	*CII*
Promethazine HCl	WY	2 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ranitidine HCl	GL	2 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Sodium bicarbonate	AB	1 mEq/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Tetracycline HCl	LE	2.5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ticarcillin disodium	BE	30 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Ticarcillin disodium–clavulanate potassium	BE	31 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Tobramycin sulfate	LI	5 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Trimethoprim–sulfamethoxazole	ES	0.8 + 4 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Vancomycin HCl	LI	10 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Vinblastine sulfate	LY	0.12 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Vincristine sulfate	LY	1 mg/ml	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C
Vinorelbine tartrate	BW	1 mg/ml[b]	BX	1 mg/ml[b]	Physically compatible with no change in measured turbidity or increase in particle content in 4 hr at 22 °C under fluorescent light	1558	C
Zidovudine	BW	4 mg/ml[a]	BX	1 mg/ml[a]	Physically compatible for 4 hr at room temperature under fluorescent light	1439	C

[a]Tested in dextrose 5% in water.
[b]Tested in sodium chloride 0.9%.

Additional Compatibility Information

The manufacturer recommends diluting the dose in 100 to 125 ml of dextrose 5% in water or sodium chloride 0.9% (2). At a concentration of 1 mg/ml in these solutions, less than 3% decomposition occurred in 16 days at room temperature with exposure to normal laboratory light. At a concentration of 0.04 mg/ml in dextrose 5% in water or sodium chloride 0.9%, little or no loss occurred in 48 hours at room temperature or under refrigeration (234).

Dr Zafrullah Chowdhury, who has earned world renown for giving Bangladesh a people-oriented drug policy, talks to Bharati Sadashivam



The man with the right prescription

"Keep drug formulations restricted to essential drugs, control prices and start consumer education and awareness," is Dr Zafrullah Chowdhury's message to Indian drug policy-makers.

As the man whose pioneering efforts in people-oriented health programmes have made Bangladesh a uniquely successful example of rational drug policies, Dr Chowdhury is eminently qualified to give this piece of advice. What's more, he has, almost single-handedly, helped his poor and tiny country achieve what its giant neighbour has failed to do: by implementing in spirit India's Hathi committee recommendations of 1974 to regulate the drug market.

Bangladesh's National Drug Policy of 1982, formulated by Dr Chowdhury, has ended the monopoly cartel of multi-national pharmaceutical corporations, forced them to put health before profits, transferred production to local companies, brought down prices while increasing the volume of business and improved the quality of medicines.

His efforts earned him the Magsaysay Award in 1984 and the Alternative Nobel last year, much admiration and encouragement from scientists the world over – and opposition and opprobrium from the drug and doctor lobbies at home.

"Over the last ten years, the price of every commodity in Bangladesh has gone up, except drugs. Drug prices have remained low despite the taka dropping from 18 to the dollar to 40 and drugs being taxed now, unlike in 1982," says Dr Chowdhury, who was in Bombay recently to interview doctors in an effort to start an intra-SAARC exchange programme.

Just one figure points to the telling contrast between the drug situations in India and Bangladesh. India has over 60,000 drug formulations, ranging from unnecessary to useless, of which more than two-thirds are irrational multi-ingredient combinations. Bangladesh's total is 250 (the WHO lists a total of 270 drugs as being enough to treat all the world's ailments), most of which are generic drugs.

"The Hathi committee had the right prescription for India. It is a pity that your government threw it away because of pressure from the drug lobby," says Dr Chowdhury. It is especially unfortunate, he adds, that India is one of the world's worst examples of irrational drug policies despite the Indian Patent Act of 1970 which has helped the indigenous drug industry grow from Rs 10 crore in 1974 to Rs 4,300 crore today.

The Indian Patent Act, which protects process and not product patents, was an inspiring factor for both Bangladesh and Sri Lanka in the '70s. But, under US pressure, Sri Lanka abandoned its unique drug policy based on price control and competition between MNCs which saw prices fall over seven years.

Determined to avoid the pitfalls in India and Sri Lanka which led to the failure of people-oriented policies, Dr Chowdhury made tight regulation of the eight MNCs operating in Bangladesh a key element of his strategy. He had the strong support of the then president, Gen. H.M. Ershad who, unlike his neighbourhood counterparts, withstood pressure from the highest quarters in the US urging him to allow the MNCs a free hand and remove price controls.

"Most Third World countries draw up a list of essential drugs for the public sector, allowing the rest to be imported. We said that what cannot be produced locally cannot be produced by the MNCs and that no drug outside the list of 250 can be produced or imported."

The Bangladesh drug policy barred the MNCs from producing high-priced drugs, like antacids, vitamins and syrups, to enable local companies enter this market segment. It made them compete with one another, which helped slash prices and improve quality. And it put an end to the cost-cutting methods they employed to maximise profits with minimum investment – such as using local small-scale factories to manufacture drugs, or producing injection drugs and getting a local company to supply the water.

All this predictably raised a howl of protest from the MNCs, many of which threatened to leave. "But none have left. In fact, two more have come in," says Dr Chowdhury.

Most developing countries hesitate to criticise the functioning of MNCs, he says, because they are thought to bring in valuable foreign investment. "But these claims must be examined. In 1989, the MNCs' total investment in Bangladesh was 381.86 million takas, while their profits were 972.88 million takas. In 1981, Pfizer invested 11.4 million takas and took out 200 million takas."

An important reason for quality control of drugs in Bangladesh is that most of them are single-ingredient or generic products – a Hathi committee recommendation – which enables faster testing, he says. Only 8 per cent of the drugs in the market today are sub-standard, as against 35 per cent in 1981.

Along with the 'demythification' of MNCs, Dr Chowdhury's singular success lies in his demystification of health and medical procedures. The Gonoshasthaya Kendra, a charitable trust devoted to public health set up by him just outside Dhaka, covers ten areas of Bangladesh. It has made it a point to educate and involve women, whose role in development is crucial in a Muslim and agricultural society, says Dr Chowdhury.

Women have been taught to take blood pressure, give injections, even perform tubectomies. The results have been dramatic: the infant mortality rate in areas covered by the Kendra is 65 / 1,000 (Bangladesh national average 120-140), maternal mortality rate 1-2 (6.9), birth rate 1.5 (2.4).

The Gonoshasthaya Kendra has also made consumer education a priority. One of its effective methods is to place ads in newspapers, as conspicuously as those by pharmaceutical companies, questioning or clarifying their claims. "A drug is like any other commodity. But while you make your own decision when you buy clothes or food, your doctor decides what drugs you buy, and he is most often tutored not by medical textbooks but by drug companies. That's why consumers have to be informed."

There are still a few failures dogging Bangladesh's enormous success in rational medicine – like bad prescriptions by doctors. There is also the problem of banned drugs being smuggled in from India. "You complain about Bangladeshis living illegally in your cities. But they contribute to your GDP, while your illegal drugs affect our health!"

Medicines for the poor

Impediments to a WHO programme

brand name. It points out that "a simple name linked to the active ingredient is easily recognisable; it also makes for greater safety in prescribing, dispensing and administering. Most of the essential drugs are no longer under patent and can be manufactured freely under their generic names?"

Various consumer groups and non-governmental organisations have also stressed the need to reduce the number of inessential drugs and regulate the pharmaceutical industry in developing countries. Panos, a London-based group, has described the pharmaceutical market in the developing world as a "strange combination of too many and too few drugs"? It adds that "the wrong drugs proliferate — those that have little or no efficacy, poor safety records, are expensive and divert attention from useful therapies. At the same time, drugs that can meet public health needs effectively, safely and at an affordable price are often hard to find."

Consumer and public interest groups are also sceptical about the value of many of the new drugs that are coming into the market. According to Health Action International, a network of public interest groups, as many as seven out of every 10 new products offered "little or no therapeutic gain over existing products." It also reported that more than four in five cough and cold products contained ineffective ingredients, and more than two out of five vitamin preparations contained non-essential or ineffective ingredients."

Various reports and resolutions of the WHO have urged poorer countries to adopt national drug policies geared to the production and marketing of a basket of essential drugs. This has aroused stiff opposition from the pharmaceutical industry, which argues that promotion of generic names and restriction of drug use will affect their ability to develop new drugs. Panos, in a briefing paper, stated that the pharmaceutical industry has consistently opposed the implementation of the policy. Officially, the industry has not opposed the essential drugs programme provided it is limited to the public sector in developing countries. But, given the retreat of the state and the growing importance given to the private sector in health care even in developing countries, this would seriously weaken the concept of an essential drugs programme.

> Consumer and public interest groups are sceptical about the value of many of the new drugs coming into the market.

The WHO, in a report to its recently-concluded annual meeting in Geneva, has expressed itself strongly in favour of firm state intervention. "Government regulation of the pharmaceutical market is essential for appropriate drug use," the report stated. It stated that it was "essential that the state defines the objectives of rational use and develops a policy for the benefit of public health and the patient rather than relying totally on free choice and the exchange between consumers and providers, which fails to ensure universal coverage or equal access to even the most essential drugs or their rational use."

But the majority of governments are unwilling to take the strong regulatory steps necessary to implement an essential drugs programme. Every two years, the World Health Assembly, the annual meeting of WHO member-countries, discusses the programme and passes a resolution calling for its strengthening. This year was no exception. The resolution urged the members to "commit themselves to the development and implementation of national drug policies to improve equitable access to essential drugs of good quality at affordable cost and to intensify efforts to promote the rational use of drugs."

But only a few countries follow an essential drugs policy. Bangladesh, in 1982, was one of the first countries to develop such a policy. Panos estimates that in 10 years, Bangladesh had saved $600 million in health care, and the proportion of substandard drugs had fallen from 36 to 9 per cent, while local production increased from 35 to more than 60 per cent. However, with changes in the government and greater liberalisation of the economy, Panos has reported that inessential drugs such as vitamin syrups have begun to appear on the market.

Nigeria also passed sweeping legislation in 1989 banning the import, sale or manufacture of any drug which was not on a list of 400 drugs, and making it compulsory for drugs to be sold under their generic names.

More than 113 countries are reported to have adopted model lists of drugs, but despite this a WHO report acknowledges that a lot remains to be done. "Access to essential drugs remains limited and inequitable in many countries, despite much effort. Structural weakness of the public drug sector continues to handicap the functioning of the health system."

Thus more than a decade after its launching, the idea of an essential drugs programme is widely acknowledged as desirable, but few countries seem to have had the administrative ability or political will to put it into operation. One of the reasons for this is the influence wielded by multinationals. The WHO refers to this, though obliquely: "There is a global imbalance in the pharmaceutical sector: a strong supply side influences consumption in the wrong way when the demand side consists of often poorly-informed prescribers and public. This is particularly true in the developing countries, where the administration often has limited resources and negotiating power. Such an imbalance contributes greatly to the difficulty of implementing rational drug policies." ■

Drug references contd

(1) There is much evidence to show that the lower levels of prices fixed for more essential items have, instead, discouraged new production in favour of relatively inessential items that are free from price controls.

pg 117 - Dev of Drug Ind in India

(2) All that regulation achieves in the longer run is to depress the growth rate of production without altering its 'undesirable' composition.

pg 117 - ibid.

(3) At present out of the 22 foreign companies (with equity participation exceeding 40%) only 2, Hoechst Pharmaceuticals & Ciba geigy, have any significant R+D organizations and they too have yet to make any significant contributions.

pg 89 ibid.

(4) "The per capita consumption of modern drugs & pharmaceuticals in India is currently estimated to be Rs 6 per year and according to some estimates, only about 20% of the population use modern drugs. On a rough estimate it would appear that the total annual expenditure on drug formulations will probably be below Rs 30 per family where the family income is Rs 4,200 per year. The pricing of drugs is thus a socially important issue not because of its effect on the family budget but for certain other considerations. High prices of drugs, for instance, would affect the ability of the public hospitals to cater to the needs of the poor; but even here, it has to be recognised that the cost of medicines constitutes a relatively small proportion around 12 to 15 percent of the total cost of the public health services. The reduction in the price of drugs, by itself, therefore, will not make much difference to the ability of the municipal or state agencies to provide medical facilities. The concern about drug prices, therefore, really arises from the fact that many of them are essential to the health & welfare of the community; & that there is no justification for the drug industry charging prices & having a production pattern which is based not upon the needs of the community but on aggressive marketing tactics & created demand. In other words the main objective of policy has to be to secure a better convergence of commercial considerations & social needs & priorities. The emphasis has to be on increasing the social utility of the industry particularly in the context of extreme poverty & the urgent need for expanding as rapidly as possible certain minimum facilities in terms of preventive & curative medicines to the large mass of people both urban & rural." (3) Hathi Committee 1975

(5) "While the operation of price control so far has certainly helped in preventing the emergence of very large or excessive profits by the drugs + pharmaceutical industry, it does not appear to have contributed materially to the emergence of a product or price pattern which is more in consonance with social needs or national objectives. For instance, in spite of the fact that the industry has been under some form of price control for over a decade, there are still fairly wide variations in the prices charged by different units for the same or similar formulations. Even more disturbing, however, is the fact that the structure of product pricing appears to have a bias in favour of greater profitability in respect of less essential formulations which are consumed by the more affluent sections"

Hathi Committee

(2)

(10) There is total neglect, in the part of pseudo expansionist colleges: profit calculations are based on a global scale, (3) of research activities aimed at developing effective therapeutics against the diseases more prevalent in the Third World. On a world-wide scale, an estimated $2 billion are spent annually on R+D in drugs of which less than $70 million, or 3.5%, is spent on tropical diseases (1) At the same time, over 1 billion poor people in the world or about 30% of the world's population are extremely vulnerable to these diseases.

Most of the research in this field was done in the early 20th century when the western countries were themselves struggling against such infectious diseases both at home + in the occupied colonies in the Third World. In the last 30 years there has been considerable neglect even in basic research on the biology of tropical disease parasites which was called "a disgrace" by Jacques Monod, the Nobel prize winning French molecular biologist (1)

pg 47, Drug Ind. in India.

(11) Many developing countries have found that only 1 to 2% of the drugs on their markets are essential for meeting the basic needs of their people. The Joint Mission Hospitals Equipment Board Ltd. (ECHO), which supplies essential drugs to christian mission hospitals around the world, found that about 25 generic drugs were adequate for most patients in some 48 hospitals all over the Third World (1)

pg 47 - Dr Ind. in India

(12) In India, at present, some 20,000 branded medicines are on the market, a large number of which are considered irrational + not commensurate with prescribed dosage requirements. The basic bulk drugs used for their formulations number only 400. The Hathi committee considered just 117 generic drugs (0.6% of the number of drugs currently marketed) sufficient for satisfying the basic requirements of the country (4)

pg 47 - Drug Ind in India.

(13) As far as sub-standard drugs are concerned, there is a urgent need to tighten up the drug control machinery of the States. This will require first + foremost, deeper resources in the form of trained personnel + fully equipped testing laboratories being made available to the States by the Centre. But again, this had nothing to do with the brand names controversy. Brands or no brands, the food + drug administration of the States needs to be made more effective. It is well-known that sub-standard + spurious drugs originate largely in those States where the drug control administration is ineffective.

(14) Production increased rapidly from an insignificant Rs 10 crores in 1947-48 to Rs 150 crores in 1965-66. To an estimated Rs 1200 crores in 1980-81. The 1960's also marked the beginning of rapidly growing exports. In the 14 year period ending 1973-74 exports increased about 10 times.

(15) Formulation activity represents the high pay-off sector of the pharmaceutical industry & bulk drugs manufacture gives comparatively low profits" Hathi Committee.

(16) The multinationals impeded the rapid local manufacture of galenicals & such simple drugs by means of their monopolistic control of the raw materials under the international patent system. Their primary interest was, & remains till today, to import the basic drug ingredients, from their parent companies, often at monopoly prices that had no relation to the ruling international prices. They fabricate them into fast selling, finished products sold under popular brand names: Thus, even the formulations sector that got established in the country continues to remain under the domination of the foreign companies whether a foreign majority or minority equity ownership.

(17) According to some estimates, upto 80% of the present output of many foreign drug companies comprises of simple household remedies & inessential formulations. Essential drugs like insulin, anti-leprosy drugs, anti-TB drugs, cholera vaccine account for only 30% of the value of formulations sold by many large firms. (5)

pp 59 · Drug Ind in India

(18) There are several instances where it would be cheaper to import the drug itself rather than to import its late intermediates & then locally manufacture the final drug.

pp 60 Dr. Ind in India

(19) Summarised failures of public sector on pg 86

Widening Horizons : on drug issues

copy

Periodicals

(1) Pune Journal of continuing Health Education

Presents scientific information & opinion on drugs and health issues to stimulate thought & further investigation

Annual subscription Rs 10/- or a five year subscription for Rs 45/-

from: Arogya Dakshata Mandal, 1913, 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 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.

(4) HAI News : A very informative bimonthly of the Health Action International (HAI), covering world-wide news of special relevance for the Third World.

~~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 and development oriented associations and professionals concerned with health & pharmaceutical issues, particularly those that adversely affect the poor.

~~A very informative newsletter covering world drug news of special relevance for the third world.~~

Annual subscription : US $10 from

HAI Clearinghouse, Regional office for Asia & the Pacific, International organization of consumer unions (IOCU) PO Box 1045, Penang, Malaysia.

A number of journals have brought out special issues on drugs. These may be available 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, N 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" pp

(2) Health for the Millions from, Publications Deptt., Voluntary Health Association of India, C-14, Community Centre, Safdarjung Development Area, New Delhi – 110016.
a) Medicines as if people mattered – April-June 1981
b) special issues on diarrhoea & TB.

(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 & fraud.

(4) World Health : The magazine of the World Health Organization, Avenue Appia, 1211 Geneva 27, Switzerland.
July 1984 : Essential drugs for the World.

Widening Horizons - on drug issues

copy

Books

1. Hathi Committee: Report of the Committee on drugs & pharmaceutical industry.
Ministry of Petroleum & Chemicals, Govt. of India. April 1975
Rs 17.00.

2. Health for all - an alternative strategy
ICSSR + ICMR 1981 Rs 18.
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 care system. Has a very comprehensive chapter on drugs & pharmaceuticals.

The essential drug list suggested here could provide the foundation for a demand for a Rational National Drug Policy.

3. Aspects of the Drug Industry in India
Mukarram Bhagat Feb 1982 Rs 191-
from: Centre for Education & Documentation (CED),
3 Suleman Chambers, Battery street, Bombay.

4. Insult or Injury.
Charles Medawar 1980 Rs 15/- 139 pp.
Social Audit England
Available from: Indian Social Institute, Lodi Road, N. Delhi 110003.
Highlights marketing & sales of British drugs & food products.
Illustrated easy reading.

5. Health care - which way to go
Medico friend circle anthology II 1982 Rs 10.00.
from: medico friend circle office, 326, 5th Main, Ist 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 & the drug industry to people's health".

6. Under the Lens: Health & medicine.
IInd anthology of medico friend circle is due shortly & will be available from VHAI & mfc office (above)

P.T.O

(7) Kuji Holy Family Hospital: Formulary and Therapeutic Guide
January 1983 Rs 121-
available from UHAI
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 78% of hospital admissions — it also gives the generic name, dosage, indications, contra-indications & 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 P0 DR
A very comprehensive overview of the drug situation in the Third World & the problems & causes.

(9) Prescription for change
Health Action International's guide to national health projects
Virginia Beardshaw Nov 1983 85 pp US $10.00
from: Health Action International Clearinghouse
PO Box 1045, Penang, Malaysia.
For suggests more than 40 ideas for action research projects on drugs
- a summary of the main elements of the national health issue and suggestions about how to 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

(10) Pill-peering the poor: Drugs & the Third World.
an information/action pack on drugs & the Third World
from: Interfaith center on Corporate Responsibility,
International Health programme, 475 Riverside Drive,
Room 566, New York, NY 10115.
US $4.00 + 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 & 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 & suggestions for action on how you can get more involved in helping to stop abuses.

(10) Widening horizons - on drugs - Books contd

(11) Therapeutic guidelines : A manual to assist in the rational purchase & prescription of drugs

Upunda, Yudkin et al 1981 PP 166 Rs 25/-
African Medical & Research Foundation
Available from VHAI

An excellent guideline for rational therapeutics, giving special emphasis on drug cost as criteria for choice of drug. Diagramatical format.

(12) Management schedules for dispensaries : A manual for rural health workers

Peter Patil 1983 Rs 35/-
African Medical & Research Foundation.
Available from VHAI.

(13) 44 problem drugs : a consumer action & resources kit on pharmaceuticals

IOCU May 1981
Available from HAI clearinghouse (see 9)
gives information about 44 problem drugs. also with articles by some of the leading drug campaigners.

(14) A number of interesting papers to keep you up to date about the drug issue is available from Low Cost Drugs & Therapeutics Cell, (write to them for a list)
VHAI, C-14. Community Centre,
Saplaying Enclave, N. Delhi. - 110016
~~write to them~~

PRINCIPLES OF IRRATIONAL DRUG THERAPY

Michael A. Vance
William R. Millington

Drugs are extensively used in medicine when they are unlikely to produce a benefit to the patient. In most instances this does no apparent harm to the patient but sometimes (for example, the extensive use of thorotrast) the results are tragic. Even when the patient is not injured, overuse of medicines is an undesirable and money-wasting behavioral pattern. Several factors relating to the social process of drug use which encourage overprescribing are discussed and the Principles of Irrational Drug Therapy are derived. These principles are presented as negative role models for the use of medicines in developing countries.

A drug is irrationally used if it is employed when there is little likelihood that it will have a beneficial effect or when the anticipated benefit is not worth the potential harm or cost of the drug. The basic contention of this article is that drugs are routinely overused in the practice of medicine (1, 2). Contributing to excessive drug use are subtle pressures to use medicines which are independent of any specific therapeutic action of the drug. This paper outlines several of these non-pharmacologic factors, which generally operate on a subconscious level.

NON-PHARMACOLOGIC FACTORS THAT ENCOURAGE DRUG USE

Drugs are Seductive

Drugs appear more effective than they really are. A drug is likely to be given credit for a cure in which it played no part if the patient improves as a result of the natural course of the disease. Both the patient and especially the physician ("Oh, thank you Doctor") receive incentive to use the drug repeatedly as long as the drug appears occasionally effective and does no apparent harm.

There is also the placebo effect in which case the act of taking medicine causes improvement in the patient regardless of any curative agent the medicine may contain. An apparent example of the placebo effect is the marketing success of a propoxyphene (Darvon). Numerous double-blind studies have documented that propoxyphene is at best a weak analgesic (3). Yet as little as 11 years ago a propoxyphene-containing preparation was the largest selling prescription drug in the United States and many

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propoxyphene-containing drugs continue to be big sellers today (4). The explanation for the widespread use of these essentially inactive compounds is that pain responds well to placebo. These drugs would therefore be almost as effective if they contained milk sugar instead of propoxyphene. Unfortunately propoxyphene is not as innocuous as sugar, it has been implicated in 1,000-2,000 overdose deaths per year (5).

There are many additional examples of popular drugs of questionable utility (6). Sleeping medications are used by millions of people on a regular or semiregular basis although they are effective as sleep aids only when used for brief periods and despite the fact that regular users have an unexplained increase in mortality (7). A possible cause of drug overuse involves cimetidine, a staggeringly popular and expensive medication used to accelerate the healing of ulcers. Moerman has demonstrated that the published studies, which often are cited to document the efficacy of the drug, indicate that when properly administered to ulcer patients a placebo is at least as effective as cimetidine and is certainly less toxic (8).

It is unfortunate that the placebo effect is frequently under-valued. To many, a favorable response to a placebo is suggestive of mental instability. However, virtually everyone responds to placebos. This is reason to be grateful—not ashamed—because it indicates that the human body is capable of readjusting itself without depending upon exogenous chemicals.

Drugs Are An Easy Way Out

If a person becomes ill because of poor living or working conditions it is much easier to administer a drug than to address the underlying issues of social injustice. In some cases this may be a valid short-term approach. Thus, for example, the use of an anti-infective drug may be appropriate if limited resources preclude improvement of public sanitation. However, this practice is less justifiable when drugs are used to control behavior such as when physicians load patients with haloperidol to keep them from disrupting ward routine or give housewives diazepam to coerce them into adapting to an unwanted life situation.

Drug Toxicity is Often Underestimated

By nature, many toxic effects of drugs are hidden. If a drug-induced disease is common in the population receiving the drug, the relationship between the drug and the disease will be obscured. For instance, the use of estrogens by post-menopausal women may be associated with an increased risk of breast cancer (9). Yet, despite millions of patient years experience, there is no clear consensus as to whether these drugs cause breast cancer because the background rate of this disease is high.

In some cases serious toxic reactions to drugs do not develop until after drug therapy has been discontinued. This also hampers identification of the drug-related nature of the disease. Examples of delayed toxicity include aplastic anemia associated with chloramphenicol, retinal damage associated with chloroquine, and liver damage associated with halothane.

Lastly, toxicities may occur in the offspring of patients such as was the case with thalidomide-induced phocomelia and diethylstilbesterol (DES)-induced vaginal cancer.

The dangers of thalidomide and DES were discovered only because the drug-induced diseases were very severe and very rare in the unexposed population. In light of the high level of drug use by pregnant women (10), it is probable that some portion of commonly occurring birth defects are the result of preventable exposure to medicines. Recent knowledge about DES further highlights the threat of delayed toxicities. It appears that mothers who were given DES are now, 20 or more years later, at an increased risk of developing breast cancer (11, 12). This is especially regretable because the drug was useless for its intended purpose in the first place (13).

As a generalization it is reasonable to conclude that drug toxicity is underrated. However, it is important to realize that in some instances side effects are improperly attributed to drugs (14, 15).

Drug Toxicity Information May be Intentionally Suppressed

When Seligweiss announced that unhygienic practices of physicians led to deadly childbirth fever he was persecuted by the medical profession. Such pressure to protect physicians and the medical establishment are still operant today (16).

In 1980 the diuretic drug tricrynafen (Selacryn) was withdrawn from the U.S. market because it causes liver and kidney damage (17). One physician was interviewed after a patient for whom he prescribed the drug died of liver toxicity (18). He expressed surprise that the manufacturer had continued to promote tricrynafen after it had learned of drug-related deaths. There was no reason to be surprised. Withholding information on life-threatening side effects has occurred repeatedly over the years and continues today (19, 20). The only reasonable conclusion is that it is a standard operating procedure for drug manufacturers to suppress reports on the toxicity of their products as long as they can get away with it.

Advertising Promotes Irrational Drug Use

It is estimated that selling costs represent about 25 percent of the total expenditures of the large drug companies (21, 22). This is a huge sum and, as with all advertising, drug advertising is designed to create an image of the product that will maximize its consumption. That a significant amount of advertising is aimed at encouraging irrational drug use has been suggested (22) and is indeed obvious when one peruses the advertising pages of almost any medical journal. It appears that such advertising does succeed in producing inappropriate drug therapy (23) although this is disputed (24). There is no way of knowing how many people have been needlessly killed by aplastic anemia caused by misuse of the antibiotic chloramphenicol (Chloromycetin)—but the number is undoubtedly in the thousands. In the United States the surges in popularity of the drug—and in the inevitable deaths associated with its use—are directly related to increased promotion of the drug by its manufacturer, Parke Davis (25, 26).

While doctors are aware that printed propaganda and visits by company-paid drug promoters are advertising, they may not believe that industry support of medical education and the physicians' privileged lifestyle are just that too. One physician, who

was in a position to know, was Dale Console, a former Medical Director of Squibb Pharmaceuticals who said (27):

> It seems impossible to convince my medical brethren that drug company executives and detail men are either shrewd salesmen or shrewd businessmen, never philanthropists. They make investments, not gifts.

Physicians Are Often Unaware of the High Cost of Drugs, or Worse Yet, May Not Even Care (28)

The cost of some drugs, especially antineoplastics and new antibiotics, is astronomical. For example, a week of therapy for one patient with 12 grams a day of cephamandole could cost the pharmacy 500 dollars for the drug alone (29). Moreover, the growth of third-party coverage for drug purchases has led to a decrease in incentive for health care providers and consumers to behave responsibly in regard to excessive drug expenditures. When external controls are brought to bear on drug prescribers, such as restricting the indications for which expensive antibiotics may be used, considerable monetary savings can be achieved without loss of therapeutic benefit (30).

Education is Very Pro-drug

Pharmacology courses in pharmacy, nursing, and medical schools are taught by persons whose vocation is the study of drugs. Their identity exists, in part, due to the fact that they are drug experts and their livelihood depends upon the continued use of drugs in medicine. It is to be expected, therefore, that they would approach almost every problem in medicine with the question, "What drug should be used?"

The Social Side Effects of Drugs Are Not Fully Appreciated

A product of our highly industrialized society is alienation. Ritualistic drug ingestion to escape the pain of alienation legitimizes the pain, diminishes our ability to deal with life's problems and denies the healing power of our body. The phenomenon of social iatrogenesis is developed in the work of Illich (31).

The Suffering Caused by Drug Reactions Is Not Fully Appreciated

Expectedly patients, who are usually ignorant of the toxic potential of the drugs they are given, do not appreciate the misery caused by serious reactions until they experience them. Physicians who time and again see people who have been devastated by drug toxicity ("the acute leukemia secondary to chemotherapy in room 1" or the "exfoliative dermatitis after antibiotics in room 2") are often unaware or unwilling to be aware that these persons are suffering because to do so would bring into focus some painful questions about indiscriminate drug use.

Patients Share With Physicians the Same Unhealthy Attitudes Towards Drugs

Physicians are aware that many or most of their patients arrive with the expectation that they are going to receive a prescription and would be dissatisfied if they were instead told that they didn't need to take medicine. As Oliver Wendell Holmes said 100 years ago, "Another part of the blame (apart from that which falls upon the physician) rests upon the public itself, which insists upon being poisoned" (32). How much more fitting this statement must be today in a population brought up on television commercials which insist that such phenomena as everyday headaches and irregularity constitute normality and that the solution to the problem of eating and drinking too much—as well as virtually every discomfort—is to take a pill.

There Is Overt As Well As Subtle Pressure To Take Medicines

Consider the occasional patient who escapes the early socialization toward liberal drug use. He or she presents themself to the medical profession as someone reluctant to take drugs; in other words as a compliance problem. The second line of socialization springs into action when physicians, nurses, and pharmacists employ various strategies to coerce the patient into adopting the correct attitude toward drug treatment—that is, the attitude of physicians, nurses, and pharmacists. So sensitive is the medical community to deviation on this matter that a leading journal published an article entitled "Diagnosis and management of patient noncompliance" which suggested that patient reluctance to follow doctors' orders be viewed as if it were a disease (33). This attitude is curious, to say the least, given the long list of crippling and killing drugs which have been pushed upon unprotesting victims. This ever-growing list includes, but is not limited to, thorium dioxide (34, 35), chloramphenicol (36), DES (13), MER-29 (19), and thalidomide (37). An intravenous preparation of vitamin E, which is apparently responsible for numerous neonatal deaths, is one of the newest additions (38).

Table 1

Principles of irrational drug therapy

1. No discomfort is so trivial that it does not warrant drug treatment.
2. Double-blind studies are informative but not as useful as your own clinical experience.
3. Stay on the cutting edge of medicine; always choose new and exciting drug treatments in preference to mundane, extensively used therapies.
4. The best source of information on the side effects of drugs is your professional sales representative.
5. If you have never encountered a toxicity it probably doesn't exist. (Examples: Aplastic anemia and chloramphenicol and cancer and thorotrast).
6. Choose what drug to use on the basis of which manufacturer gives you the best gifts.
7. People who do not comply with prescribed drug treatment regimens are contemptible wierdos.

CONCLUSIONS

These are not just hypothetical constructs of problems that might happen. Tragedies have already occurred because these factors have not been recognized in the past. American physicians persisted in the use of thorium dioxide for many years in spite of warnings that the drug was radioactive and in spite of the fact that it was banned in other countries (33, 34). DES was used in spite of a well controlled study demonstrating its inefficacy (13). Its supporters, ignoring the fact that many women with high-risk pregnancies have safe deliveries and healthy babies without medication, believed that DES was effective because they had observed ("in my clinical experience") that some women did well while taking the drug. And in the case of chloramphenicol some prescribers apparently believed that the drug did not cause aplastic anemia simply because the drug company told them so. It is clear that the Principles of Irrational Drug Therapy (Table 1) have been widely adhered to in the past.

We recognized that many experts do not agree that drugs are overused in medicine (39, 40) but we find their arguments unconvincing. We also realize that the present overview dealt primarily with North American experiences. However, excessive drug usage is likely a universal phenomenon. It is of particular importance to developing countries where multinational drug companies display greater irresponsibility promoting drugs (41-44) and a larger proportion of inadequate health care monies is spent on drugs (42). In addition to knowingly exporting dangerous drugs, multinational pharmaceutical companies have collected excessive payments on drugs sold to developing countries (44, 45). Developing countries should be aware that along with the importation of medical technology they receive indoctrination with prevailing medical attitudes, one of which is an unhealthy reliance upon ritualistic drug ingestion. Rational drug use can be achieved only when it is widely appreciated that the use of drugs in medicine is a social process that is under the control of a number of forces, only one of which is the desire to better health care by reasoned pharmacologic intervention.

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DR-1.

2-3

Table 1. Diagnostics.

1. A 32 year old woman, a childless divorcee attended the hospital asking for treatment for 'mitral valve prolapse' (MVP) which was causing her severe chest pain. On clinical examination, she was found to be normal. She then showed a newspaper article on MVP in which, she had underlined all the symptoms that tallied with that of hers. She wanted tests including echo scan as advised in the article. They were done and turned out to be normal. Then she said "You doctors do not know how to diagnose the disease, I know I have MVP". She showed a newsletter on a new cardiologist in town and asked "he seems good - shall I consult him?" [Copy of the newsletter is enclosed]. (For discussion: Psychological problems manifesting as diseases, power of printed messages, can doctors and hospitals advertise?)

2. A 70 year old man, a rich farm land owner had pain of upper abdomen for 12 hours. "Heart problem" had been predicted by an astro-palmist one year ago. So he consulted a heart specialist for opinion. On clinical examination, he was normal. However, ECG showed minor changes and he was advised further consultation at a corporate hospital in Madras. There he was put on 24 hour ECG recording, in addition to other tests like X-rays, echo scan, blood tests etc. A computerised exercise ECG was done. All these were normal. He was sent back home but his pain worsened despite medicines for heart. On the fourth day, he became moribund and was taken to a teaching hospital. General surgeons diagnosed perforated peptic ulcer with shock. He died one hour later. (For discussion: Danger of lateral entry into health care system, blind belief in predictions by astrologers etc.)

3. A 48 year old university professor has severe head ache in the evenings for one week - apparently related to a stressful situation. Past history of similar episodes present for many years since student days. His friend had died of brain cancer six weeks ago. So he wants to rule out brain cancer and asks for a C.T. scan. (For discussion: How do lay people get the idea that C.T. scan rules out brain cancer? Is such faith justified?)

4. A 47 year old statistician had a proven peptic ulcer and was on repeated courses of medicine over four years. The pain shifted to right side after recent treatment. Some friends suggested liver disease. He got a physician's advice. After an ultrasound scan and blood test, "fatty liver" was diagnosed. The patient was obese and was advised weight reduction. He got two more scans repeated at two other centers. One reported "four gall stones likely", and the other reported "irregular gall bladder wall - cancer cannot be excluded". On this, he became depressed, anxious, miserable and did not know what to do. He was not willing for any surgical option but wanted cancer to be ruled out. He consulted at least ten different doctors in three

weeks' time before returning to the personal physician. (For discussion: burden of diagnostic uncertainty - can it be passed on to a patient in the name of consumer empowerment? Problem of doctor shopping, is there a need for a personal physician?)

5. Shocked by the news of some innocent brides contracting HIV (virus causing AIDS) from their husbands after marriage, a suggestion was made by a group of senior citizens to enforce compulsory HIV testing of all prospective grooms before marriage. Assuming HIV positivity of 1:25000 of general population in South India, what are the consequences and the feasibility of taking such a step? (Hints: ELISA test does not miss a HIV positive specimen, but gives false positivity of about 4%. Cost per test is Rs.60. Western Blot, the confirmatory test costs about Rs.200).

d 3 - Table 1

(COPY OF NEWSLETTER - NAMES CHANGED TO PRESERVE CONFIDENTIALITY)

Dear Colleagues/Investors/Friend,

CUREALL CARDIAC CENTRE (CCC) with its unrelenting enthusiasm to extend health care facilities, now proudly introduces the Department of Cardiology, headed by Dr. Irudayanathan, a unique, invasive and non-invasive consultant Cardiologist of special calibre.

Dr. Irudayanathan, a qualified DM Cardiologist, knows much more than what his stethoscope can do for him, can read ECG beyond the trace, can interpret the stress system and the Holter with accuracy and can extract more details from the Colour Doppler beyond its potential. As you can see, even his name shows that he is born to care for the heart and to master all Cardiological problems.

Dr. Irudayanathan, the first recipient of the Fellowship award from the Department of Cardiology, Edward George Medical College, Bangalore, after having worked in different centres in India for nearly a decade, has gained enormous experience and acquired vast knowledge by travelling across the world. His visits to Massachusettes - United States, Edinburgh - United Kingdom, Melbourne - Australia, Paris etc. have helped him to master his techniques in Balloon Valvuloplasty, Atrial Septostomy, Pacemaker implantation, Coronary angiography and PTCA (PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY). He had hands-on training in invasive Cardiology at THIRUVALLUVAR INSTITUTE OF CARDIOLOGY, MADRAS, TAMILNADU.

Being son of the soil, his care to the patients of Tamilnadu is extraordinary. His personal attention is such that he practically lives with every single patient in the hospital which makes the recovery faster. Such a person is, needless to say, will be an asset to every heart patient and of course to CCC hospitals too. With the rich experience of Dr. Irudayanathan, coupled with most modern high tech cardiac equipments, we should be able to provide the best possible service.

State-of-the-art equipments, affordable costs, comfortable stay, excellent nursing service, competent and popular experts, proper administration and symbiotic growth are a few characteristics of CCC hospitals.

Please visit and appreciate
THE DIFFERENCE OF CCC HOSPITALS
for unmatched health care.

MANAGING DIRECTOR

5. (a) A 15 year old girl with one day fever of 102 degrees and body ache, vomited twice. On consultation, the physician diagnosed viral fever and ordered tests to rule out malaria and typhoid. Parents wants their only child to be cured without wasting time. She was given Ciprofloxacin and anti-vomiting drugs with vitamins and drugs for fever. The problem persisted and on the third day, they consulted gastroenterologist. He did an endoscopy (Cost: Rs.1000) and ruled out any serious problems in the stomach. He gave two drugs for vomiting and brain tonic for her nervous weakness. The child recovered on the seventh day.

(b) A domestic servant took her 15 year old son to a primary health centre with similar complaints as (a). Viral fever was diagnosed and paracetamol was given to control fever and body ache. The mother demanded an i.v. drip or atleast an injection to cure her only surviving son. She was scolded and sent out for creating disturbance. On the way back, she entered a retail pharmacy and asked the small boy on night duty to give some strong medicine for fever. The boy sold her a `fever set' which contained two tablets each of antibiotic, anti-allergic drug, steroid and paracetamol. (For discussion: Socio-cultural factors and communication gaps that cause irrational therapy. Unregulated drug sale in retail shops)

Table.2 Macro level drug issues

1. All bad drugs are to be removed by regulatory bodies and good usage of drugs to be promoted by education (Ivan Dharamsjah). Do you agree with this?

2. Please go through the statistics of drug sale at retail level in South India highlighting sale by means other than through doctors' prescriptions. What is your comment on this?

3. About 70,000 formulations are on sale in India at a time when free market economy is being embraced by the country. What is the likely effect of unbridled market forces on the drug scene? What should be done to curb any adverse influences?

4. "Our attitudes towards medicine are shaped by the society in which we live - with all its irrationality. To strive for rationality may be a grand long term goal". This was stated by Mark Nichter in the Australian Workshop on wise use of medicine. Can you promote prudent use of medicine in a society like India? If so, how?

5. "The hand that prescribes is nothing but an extension of the marketing arm of the drug industry". Crores of rupees spent on medical promotion seems to justify this statement. It is a fact that the only continuing education received by practising doctors especially in rural areas is through detailmen striving to promote their products. Suggest ways and means by which unbiased information, communication, education can be disseminated to professionals who need them most.

Table.3 Micro level issues on therapy

1. A few small blood banks in Germany were found to cut corners in testing blood and blood products for HIV contamination. This serious offence is being investigated in Germany. The media played up this scandal during October-November 1993 meriting a cover story on news magazines like Time. On 14th November, a young German got injured in a road traffic accident and was bleeding severely due to abdominal injuries. In spite of repeated pleas to accept blood transfusion as a life saving procedure, the young man totally refused to accept "AIDS blood". He died next day of continued bleeding. (For discussion: Media hype and scare mongering. Information for education or for nihilism?)

2. A 55 year old man with diabetes, high BP and anginal chest pain was taking the following drugs: 3 types of anti-diabetic tablets, six types of medicines for BP and heart and two medicines for preventing blood clot, vitamins and sleeping pills plus pain killer for headache! When asked how so many drugs were prescribed, he showed prescriptions from three different doctors. (For discussion: Family doctor concept. Why is it fading?)

3. A 60 years old ex-Bharatanatyam dancer, 160 cms tall and weighing 87 kgs with osteoarthritis (degenerative joint disease) of both knees came to consult her 25th doctor in eight years. She said "I have tried all pain killers - no use. Tried Ayurvedha, Siddha, Unani, Homeopathy, Naturopathy, Acupuncture, Magnetotherapy, Pyramid therapy, Crystal therapy, Gem therapy etc. All of them work for 1-3 weeks but not longer than that. Please advise me on what to do". When advised to reduce body weight by 25 kgs over two years by strict diet and exercise, she said "I cannot even walk without pain, how can you expect me to do exercise and diet?". The next doctor (26th) suggested experimental interferon therapy which will cost Rs.25000/- per month.

Unknown to public, the area manager promoting interferon in India tells doctors: If you can make a quick study of 10 patients on interferon therapy, we can sponsor you as an Indian Delegate to a Conference in Germany early next year.

(For discussion: Consumer's inability to modify life style, relief in chronic degenerative diseases - care or cure? Indirect pressure on doctors to use experimental therapy. Who should bell the cat - the dancer in this case?)

4. A diabetic difficult to control saw the effects of magnetised water highlighted in a TV program. Thereafter, he stopped all drugs and changed over to magnetised water therapy. He was admitted in coma two weeks later with blood sugar level of 564 mg% (normal is about 100 mg%). (For discussion: Consumer's freedom to be foolish - who are responsible, how to inform and educate in a prudent manner?)

d-2

TABLE.1 - NUTRITION

Case 1.

At the time of discharge, every mother from a maternity hospital is routinely advised to give her newborn the following:

- Water between milk feeds
- Bonnisan 1/2 tsp once a day (Herbal appetiser)
- Liv 52, 5 drops twice a day (about 10 herbal ingredients)
- Vitamin C drops 5- drops once a day
- Multivitamin drops- 5 drops once a day

Case 2.

A three month old child had watery motion (4 times) and vomiting (2 times) in one day. The child was regularly getting water in a bottle in between breast feeds and was also being given gripe water. The mother was medically advised to stop breast feeds and switch over to formula feeds. In addition, child was put on streptomagma (antibiotic), pectokab (a bowel binder) and loperamide (an antimotility drug). Loperamide has been incriminated in many infant deaths in Pakistan & India due to dilatation and paralysis of the gut (a serious side effect).

Case 3.

A seven month old infant was exclusively breast fed till 6 months of age and then was put on home based cereal pulse mix alongwith continued breast feeds. He developed fever and cough for 2 days and was taken to a Paediatrician. Child was prescribed:

- Syrup Amoxycillin (antibiotic) 1 tsp 3 times/day x 4 days
- Syrup Protussa (cough syrup) - 1/2 tsp 3 times/day x 4 days
- Vit C drops - 5 twice daily
- Cerelac infant food

In spite of mother's explanation of home made cereal pulse mix, she was advised to give a formula weaning food.

Case 4.

A six year old boy, the only child, was brought to a government hospital by his mother (poor S.E. status, her husband died in an accident and she was given employment on compassionate grounds). He had loss of appetite, cough and fever for 3 days. He was malnourished weighing 15 Kg. On examination, he was found to have signs of mild chest respiratory infection (without increased respiratory rate and chest retraction). The hospital had cotrimoxazole, penicillin tablets and injections, vitamin A preparation, cough syrups. Blood tests (TLC, DLC) and chest x-ray were ordered and the mother was advised to buy the following medicines outside:

- Tab Ceptalexin - 3 daily
- Becadexamin cap 1 daily
- Cough Syrup Ped 3 1 tsp x thrice daily
- Syrup Elcarim - 1 tsp x thrice daily
- Entamezole - 1 thrice daily

Case 5.

A two year old child weighing 12 Kg. was brought for loss of appetite of two months duration. On examination, child was active and energetic and there was no abnormal finding. Child was advised

- Syrup Bonnisan - 1 tsp x tds
- Syrup Ciplactin 1 tsp x bd
- Syrup Mulmin - 1 tsp x tds (zinc multivitamin drops)

IMMUNISATION

A prestigious hospital has given repeated advertisements in dailies and periodicals about the need for vaccination against Japanese B Encephalitis, a viral induced brain fever which often affects children and adults of poor socio-economic status in specific areas of Tamilnadu, Karnataka and Andhra Pradesh. The advertisements outline the gravity of the condition and creates a sort of fright or panic in the minds of the readers who are often from middle class and rich strata of society where this condition usually does not occur. This disease is caused by a virus transmitted from pigs or herons to man by field mosquito bites. The vaccine to prevent is an imported one and two vaccines should be given to prevent the disease and they must be given much earlier to be effective. It needs to be repeated once in two or three years if the effectiveness has to be maintained.

(Discuss the relevance and ethics of such advertisements from medical, consumer and media points of view and give your comments and recommendations in the plenary session regarding similar situations which may be appropriately or inappropriately highlighted in the media)

GROUP TASK - TABLE.2 (CHECK-LIST)

A. DISCUSS AMONG YOUR GROUP THE ROLE AND RESPONSIBILITIES OF:

a. the medical professionals,
b. the industry,
c. the media, and
d. the consumer beneficiaries.

1. in the implementation and practice of rational drug therapy and in the use of essential drugs for common childhood ailments.

2. in the provision of adequate, relevant, correct and factual informations to the professionals and consumers regarding childhood diseases and drugs (health educational, communication and advertisement materials and media reports).

3. in the implementation and monitoring of ethical promotional advertisement policies and practices.

B. IDENTIFY THE EXISTING PROBLEMS.

C. SUBMIT IN THE PLENARY SESSION SOLUTIONS, RECOMMENDATIONS AND AN APPROPRIATE PLAN OF ACTION.

The common childhood problems to be covered in the discussion are:

1. diarrhoeal disorders
2. respiratory (chest infections, primary complex)
3. mental illness.

Enclosed: 3 situations (brief case reports).

I. An eight month old child of a casual labourer with two loose motions since morning was given an antibacterial agent (nalidixic acid), a stool binding agent (pectokab), antispasmodic and antimotility drugs (loperamide and diphenoxylate) and antivomiting agent (metaclopromide). Child continued to have 3 to 4 loose motions for the next two days and the mother was advised to stop breast milk and other dietary cereal food and was put on an artificial lactose free commercial formula food. Child was given this formula by bottle (lactonyl) and child became progressively drowsy and the child was also given injection gentamicin (an antibiotic with potential kidney damaging side effect). The child developed abdominal distension and was referred to this hospital where within 12 hours the child died. Before admission, the father had already spent Rs.500/- towards the medical expenses.

POINTS TO BE DISCUSSED ARE:

1. Role and need of antibacterial agents and antibiotics in diarrhoea; its harmful and undesirable effects when routinely prescribed (advised for control of loose motions).

2. The dangers of stopping breast milk.

3. The need for introduction of commercial lactose free artificial formula.

4. The use of bottle feeds and its role in causation of diarrhoeal episodes.

5. Hazards and irrelevance of use of antimotility and antispasmodic drugs sold in the market.

6. The promotional and advertisement aspects of such agents.
7. Means to be adopted to educate the public.

II. A two year old child weighing 12 kg. was brought for recurrent episodes of cold and cough, each episode lasting for 2-4 days. Each episode was treated with costly antibiotics for 5-7 days and cough and cold medicines, vitamin C drops and paracetamol (for fever). The child's father had allergic problems of the skin. There was no family history of tuberculosis. Child had received BCG immunisation immediately after birth. Child was started on isoniazid, antituberculous drug for primary complex. Even after 3 months, the child continued to get the same episodes as frequently as before. (DISCUSS WITH YOUR MEDICAL COLLEAGUES AND OFFER APPROPRIATE SOLUTIONS TO THE PROBLEM).

III. A four year old only male child not sitting and walking from birth with mental retardation and small head was given costly brain tonics for the last 3 years without any advise regarding physiotherapy and prognosis. Monthly costs worked out to about Rs.600/-. There was no apparent benefit. Then the parents (low middle class) went to a teaching hospital for advice.

Subject: Fw: Medication Recall
Date: Mon, 4 Feb 2002 17:32:08 +0530
From: "Parveen Sikand" <parveen@vwebsol.com>
To: "Aditya" <aditya@vwebsol.com>, "Dr. Ravi Narayan" <sochara@vsnl.com>, "Dr. Sylvan Rego" <sylvanrego@yahoo.com>, "Dr. Subba Rao" <nikan@vsnl.com>, "sanjiv lewin" <lewin@vsnl.com>

> > > Subject: Fw: Medication Recall
> > > Date: Sat, 26 Jan 2002 22:06:14 -0500
> > >
> > > All drugs containing PHENYLPROPANOLAMINE are being recalled.
> > > You may want to try calling the 800 number listed on most drug boxes
> > > and inquire about a REFUND.
> > >
> > > Please read this CAREFULLY, as I know that some of you may USE
> > > some of these drugs (Alka Seltzer Plus for one). Also, please pass
> > > this on to everyone you know. STOP TAKING anything containing this
> > > ingredient. It has been linked to increased hemorrhagic stroke
(bleeding
in
> > > brain) among women ages 18-49 in the three days after starting use of
> > > medication. Problems were not found in men, but the FDA recommended
> that
> > > everyone (even children) seek alternative medicine. The following
> > > medications contain Phenylpropanolamine:
> > >
> > > Acutrim Diet Gum Appetite Suppressant Plus Dietary
> > > Supplements
> > > Acutrim Maximum Strength Appetite Control
> > > Alka-Seltzer Plus Children's Cold Medicine Effervescent
> > > Alka-Seltzer Plus Cold medicine (cherry or orange)
> > > Alka-Seltzer Plus Cold Medicine Original
> > > Alka-Seltzer Plus Cold & Cough Medicine Effervescent
> > > Alka-Seltzer Plus Cold & Flu Medicine Effervescent
> > > Alka-Seltzer Plus Cold & Sinus Effervescent
> > > Alka Seltzer Plus Night-Time Cold Medicine Effervescent
> > > BC Allergy Sinus Cold Powder
> > > BC Sinus Cold Powder
> > > Comtrex Deep Chest Cold & Congestion Relief
> > > Comtrex Flu Therapy & Fever Relief
> > > Day & Night Contac 12-Hour Cold Capsules
> > > Contac 12 Hour Caplets
> > > Coricidin D Cold, Flu & Sinus
> > > Dexatrim Caffeine Free
> > > Dexatrim Extended Duration
> > > Dexatrim Gelcaps
> > > Dexatrim Vitamin C/Caffeine Free
> > > Dimetapp Cold & Allergy Chewable Tablets
> > > Dimetapp Cold & Cough Liqui-Gels
> > > Dimetapp DM Cold & Cough Elixir
> > > Dimetapp Elixir
> > > Dimetapp 4 Hour Liquid Gels
> > > Dimetapp 4 Hour Tablets
> > > Dimetapp 12 Hour Extentabs Tablets
> > > Naldecon DX Pediatric Drops
> > > Permsthene Mega-16
> > > Robitussin CF
> > > Tavist-D 12 Hour Relief of Sinus & Nasal Congestion

Lib - Rational Therapeutics file

fw

> > > Triaminic Expectorant Chest & Head Congestion
> > > Triaminic Syrup Cold & Allergy
> > > Triaminic Triaminicol Cold & Cough
> > >
> > > I just found out and called the 800# on the container for Triaminic
and
> > > they informed me that they are voluntarily recalling the following
> > medicines
> > > because of a certain ingredient that is causing strokes and seizures
in
> > > children:
> > >
> > > Orange 3D Cold & Allergy Cherry (Pink)
> > > 3D Cold & Cough Berry
> > > 3D Cough Relief
> > > Yellow 3D Expectorant
> > >
> > > They are asking you to call them at 800-548-3708 with the lot
> > > number on the box so they can send you postage for you to send it back
> to
> > > them, and they will also issue you a refund. If you know of anyone
else
> > with
> > > small children,
> > >
> > > PLEASE PASS THIS ON. THIS IS SERIOUS STUFF. DO PASS ALONG TO ALL ON
YOUR
> > > MAILING LIST so people are informed. They can then pass it along to
> their
> > > families. To confirm these findings please take time to check the
> > following
> > > URL:
> > >
> > > http://www.fda.gov/cder/drug/infopage/ppa/default.htm
> > > <http://www.fda.gov/cder/drug/infopage/ppa/default.htm>

DR - 1.

Thank you 1 set

Tel : 3379016

DRUG ACTION FORUM, KARNATAKA

CLINIC APARNA, 1st Main, 4th Cross, Yeswanthpur, Bangalore -560022.

Ref :

Date : 1.2.2001

Dr Sudarshan
Chairman
Task Force on Health & Family Welfare
Public Health Institute Building Annexe
Seshadri Road
BANGALORE 560001

Dear Sir,

S.s. EVOLVING A DRUG POLICY FOR KARNATAKA

The task force on health in its interim report (APRIL 2000) has considered the aspect of Procurement & Supply of medicines for the government health department, and has noted certain anomolies and given recommendations to improve. This is a Commendable job indeed.

To achieve good health, it is necessary to 'Control' Common disease & ailments

for 13/2/01

in this. In order to achieve this, there is a need for an effective drug policy

'Essential Drugs' play a very important role, but there are a host of other issues in the drug policy. This document enlists some of these issues. I hope this document will be of some use. I am ready to clarify any doubt regarding my draft.

We are interested in a 'People oriented Drug Policy'. Hope the task force will give due consideration to these aspects. I am sure, you as a Public Health pioneer will consider this.

Regards

Yours Sincerely

Dr Prakash C Rao

Secretary, Drug Action Forum Karnataka

EVOLVING A DRUG POLICY FOR KARNATAKA

CONTENTS

EVOLVING A DRUG POLICY
(FOR KARNATAKA)

INTRODUCTION

At the outset let me define the WHO (World Health Organisation) definition of Drug - Drug refers to the pharmaceutical preparation used for medicinal purpose. Drugs play a crucial role in the health care. The offer a simple cost effective answer to many health problems provided that they are accenible, affordable and properly used.

Quite often the availability of drugs in the rural areas is questionable. The health Centre operates without adequate supply of drugs. Drugs are prescribed to be bought outside. Socio Economic Conditions of the majority of the people do not permit them to buy medicines from outside Pharmacies. Many of them do not buy medicine as per the prescription, Prescription often leads to denial of the health Care. often the prescribed medicines are expensive unnecessary & do not offer benefit to the patient.

The pharmaceuticals have flooded the market with so many drugs that it is often confusing

which drugs are worth to use. Multinational Companies have Control over the market and this leads to erosion of Self reliance and dependance.

There is lack of adequate Supply of drugs. It is not necessary due to budgetary Constraints but its due to the apathy of the government, Prescribers, Consumers, drug industry.

The prescribing patterns of doctors vary and one can make out that doctors are influenced by pharmaceutical industry

The literacy level of the people is quite low and people are unable to recognise the need for quality drugs.

Though the WHO has recognised Some drugs as Essential drugs. this Concept is not known even to many doctors.

The Cost of the drugs vary greatly, and there is no rationale. As a result, Patients tend to pay more unnecessarily for Some drugs

There is no people oriented drug policy in the

introduce the Concept of Essential Drugs in Some States and that is not enough.

India can boast of good network of pharmaceutical & we have the technology to produce all the drugs.

It is the responsibility of the Civil Society to maintain the health of its citizens. One Cost effective way is to provide drugs which are easily available, accessible, affordable & properly used.

2 WHY A DRUG POLICY

Drugs have become an essential component of our life. Despite the increase in the production and consumptions of the pharmaceuticals, there is a serious problem of the availability of the drug for the majority of the population. The reasons for this are complex. They derive not only from the financial & budgetary constraints but also the characterisation of the market & the attitude & behaviour of the government, prescribers, dispensers consumers & the drug industry.

Economic reforms & the structural Adjustment programmes towards liberalisation have further complicated the situation & made the objective of the social equity still more remote.

The problems of drug demand is also changing in many countries as new diseases such as AIDS, emergence of resistance to drugs Antibiotics, Antimalarials) increases.

The advances in biotechnology is offering new medicines & in a wold where few countries obtain patents, rest of te wold Suffer, not becaue of not having patents but becaue of te exploitation of tie patents.

The prescribing patterns are varying & in a countr where thee is illeteracy & poverty, drug policy is a must to bring Social justice.

To overcome these problems, it is widely accepted that each Country should make Positive efforts to achieve optimal availability & use of drugs for patients. The State Shall adopt a drug policy that ensures drugs of good quality, Safety, Efficacy, affordable to all those who need them., where & when they need them & they are rationally used. The drug policy Shoud be part of health policy, that ensures effective primary, Secondary & tertiary health care (at the most Procurement Policy)

Since thee is no drug policy of te Karnataka, it is necesary to have a drug policy.

DRUG POLICY FOR KARNATAKA

A Drug policy is both a Commitment to a goal and guide for action.

The ministry of health Should be the principal agency and driving force in the formulation and implementation in the Context of health policy. other ministries in the field Such as planning, finance, industry, Commerce, education, human resource development Should also be involved. The drug policy Calls for partnership between government which acts in the interest of the public, and those who prescribe, dispense, market, distribute, Sell medicines. Partnership Should include Universities specialised institutes for research and training, insitutes involved in training of medical, dental, nursing & pharmacy personnel. The partnership also Should include persons from profesional anociation, Consumer groups & the people from the industry

The aim of formulatory a policy should be A to enlist essential drugs for

i) Primary / Secondary / tertiary Care

ii Primary Health Care / Secondary & tertiary Centres

iii) dispensing by the health workers

iv) Emergency Care (Floods/Earthquake & other natural disasters)

B to prepare a formulary

C to prepare treatment guidelines for day to day conditions in primary Care

C to prepare antibiotic guidelines for Primary Care, outpatient and inpatient Care.

D to promote Essential drugs at all levels for Rational drug therapy

to Ban all inessential irrational drugs after thorough review at the market.

E to prepare guidelines for procurement Supply, distribution, storage, Regulation at drug at the government level, to

F To promote Rational Drug use by Consumers and people at large.

G To rationalise the use of herbal Preparations

H To legislate issues in drugs

Essential Drugs

Essential drugs are basic to any drug policy in today's Context, because it enables Priorities to be Set. The principle of the Concept is that a limited number of drugs are more than enough to Control and relieve majority of the health problems of any Society in the world. The Essential drug list is a carefully chosen list of drugs by experts from all over the world, the drugs useful in Primary Secondary & Tertiary health Care. Essential drug list leads to better Supply, more rational prescibin and lower Costs, quality assurance, Procurement Storage, distribution & dispensing all easier

Training & drug information becomes more focused, and prescribers gain more experience

with fewer drugs and recognise adverse drug reactions better.

Essential Drug List announced by WHO has been adopted by both developed & developing Countries & thee is substantial evidence that this has contributed to a considerable savings on drug costs. Essential drug is adopted by both public & private Sector in Some developing Countries

Selection of the Essential drugs

A Committee should be appointed to give technical advise on Selection of Essential drug for different Situations. It Should include competent individuals in the field of medicine, nursing, Pharmacology, Pharmacy Public health, Consumers.

The drug Selection should be based on EDL of the WHO.

Drug should be in International Non proprietary Name (INN - Generic names only)

The drug selected should meet the adequate

Quality Control Standards including stability to & when necessary bioequivalence. The Suppliers Should provide documentation of to drugs Compliance with The requested Specification

Formulation should be a Single ingradient medicine except Some of the approved with Combinations;

- New drugs should be introduced into the EDL only if they offer distinct advantage Over drugs Selected previously, and the old drug removed from the list

When two or more drugs are similar, preference Should be given to drug products on

- The basis of established local experience in Therapeutic use.

Knowledge of prevailing drug Sensitivity pattern is Vital for proper Selection

EDL Should Serve as the primary or exclusive basis for Public Sector drug Procurement & distribution

EDL & formulary should serve as the basis for all formal education & in service training of health profession & for health education of the public about drug use.

Supply & procurement: The basic requisite should be cheaper drugs, effective drugs. Substantial public savings can accrue from effective procurement. In the public sector, the system should be based on a systematic tendering procedure with prequalification of suppliers. Procurement should include a quality assurance system covering registration, quality control, effective drug inspection & whenever necessary application of WHO certification scheme.

The drug procurement should consider the following factors also

- Supplier's performance including reliability
- Public & private facilities for storage, packing, repackaging, transport, quality control

The Process Prepare estimates of the types & qualities of pharmaceutical product annual / biannual / quarterly

Estimate the financial resources available

Inventory Control & utilization survey of Past drug use.

Negotiate the Price

Tenders to be called

Verification of Expiry drugs

Quality of the drugs to be ensured

In Distribution & Storage; Cold chain to be maintained

A qualified pharmacist should be incharge of all these procedures

Throughout the procedure Good Manufacture Practices Good Pharmacy Practice, Good Laboratory Practices, Good Clinical research pratices Should be practiced

Regulation: by the Drug Control. The issues should be discussed with the Drug Control authorities. The System of regulation (drug Control) must Prevent the procurement, marketing & the use of Substandard, Counterfeit false, & Spurious drugs.

Preferably drugs only from the EDL Should be procured.

Rational use of drugs (RUD)

Rational use of drugs by health workers, medical people & Consumers will contribute to the health of the people. Government, industry, media should support rational use of drugs. Government can take the leadership role by adopting a clear policy on (RUD) that involves & encourages key groups to develop complementary policies & practices Eg: Standard treatment guidelines,

Objective drug infamation: A medicinal product must be accompanied by appropriate infamation. The quality of infamation accompanying the drug is an important as the quality of the active substance.

Infamation should be based on agreed Standards, easily available, accesible & understandable to users, independent, unbiased, Pilot tested for usefulness & acceptibility. This job can be done by Drug Infamation Centres

There Should be a News Letter to give this infamation to doctors and it Should be available free or reasonably charged.

Drug information should be given through Lectures & Symposias sponsored by dept of health & not the industry as is the practice now.

Drug Information for Consumers Should be available freely in Drug information Centres and patients Should be given patient information Sheets. Patient information Sheets Should be prepared for common drugs & government institution Should start giving it as a model & encourage private institutions also.

Doctors Should be given training on Rational use of drugs & these training Courses Should be encouraged to all doctors in the Primary Secondary & Tertiary Care, There may be resistance to Such training in the beginning by saying "we have learnt & Passed pharmacology", but this can still Continue

other health professionals like Nurses pharmacists also Should receive training in Rational Drug use.

Private personnel also. Special modules should be prepared for the training & where assistance can be obtained

Rational Drug Use is not generally taught in medical Schools. It helps the students to learn techniques of problem solving and making rational choices between drug treatment alternatives which includes the skill to evaluate new drugs critically. Hence it should be taught at undergraduate & postgraduate levels.

Public Education on drugs should be based on

- Use of medicine
- When to Self medicate / when to see the doctor
- Correct use of medicine
- Benefits of medicine
- Limitations of medicine

Radio and Television can be used to give this information.

Drug Companies also need to follow certain standards in making people use drugs properly

Labels on drugs should be legible accurate, understandable by lay person

Information should be reliable, accurate truthful informative, balanced, updated, capable

of Substantiation.

Should not Contain misleading statements & disguise facts.

Drug regulatory authorities should develop methods to monitor promotion

In view of the changes in the patent regimen the situation in the Country is going to be affected. A responsible government should make sure that

- ~~They~~ All Essential drugs are available
- Drugs are of good quality, & safe, and cheaper

Public Pharmacy Establishment & public pharmacy in order to ~~make drugs available the Essential & Cheaper~~ Sell all Essential drugs at the reasonable rate all the times of the day & night is a basic requisite. The public pharmacy may be available in govt hospital premises

Generic drugs often are cheaper & of good quality. The WHO Essential drugs list includes only generic drugs Hence it is desirable to have generic prescribing, generic dispensing & generic substitution. It may be

necessary to legislate this. The private multinational drug industry have been pushing only brand drugs & have created the myth that branded drugs are better. As a result the drug prices are higher, side effects more, and ~~Confusion~~ treatment gets mystified. The drug bulletins should give comparative costs of drugs & that supports generic prescription

Drug Prices The survey of to drug prices reveals that it is on the increase. The drug price control mechanisms have failed utterly. Price fluctuations should not affect at least drugs.

The drug should be fixed based on the real cost of the drug. At least the drugs that are bought for the government supply should be based on this. The generic drugs offer lower prices, hence all the Govt Supplies should be generic by principle.

The Govt should draft the policy
It should be circulated & revised
It should be formally endosed in the Cabinet

Drafting a drug policy needs the political will. Let there be an open debate with qualified people, opinion leaders, Media & to public. The policy should be periodically monitored and evaluated.

Legislation is the most important part of a drug policy. Must address the rights & responsibilities of different parties concerned with drugs & pharmaceutical products. Legislation must ensure products are of acceptable quality, safety, efficacy. It must regulate their availability & distribution.

The legislation must also specify the sanctions that will apply in the event of failure to confirm with any provisions of an act. Sanctions must be enforced if the policy is not adhered to.

Annexure 1

Drug Information Model

(WHO)

International Non Proprietary Name (INN)

Generic name

Pharmacological data

Clinical information

Indications

Dosage regime — Adult Children Elderly
Dosage interval
Average duration of the treatment
Specific Conditions
Renal Hepatic Cardiac
Nutritional deficiencies

Contra indications

Precautions / Warning
(in Pregnancy / Lactation etc)

Adverse effects

Drug interaction

Over dosage & treatment

Pharmacological information on drug Labels

The INN
Dosage form — Name & address of the manufacturer
Batch identification
Package size
Strength of dosage form
Excipients
Storage Condition & Shelf life (Expiry)

THE INFORMATION SHOULD BE IN KANNADA

Annexure 2

Short Course on Rational Drug use

Historical aspects
WHO Concept of Essential Drugs
Rational Drug use / Therapy
WHO Ethical Criteria for drug promotion
Antibiotic guidelines
Health Economics
Non pharmacological therapies
Banned & Bannable drugs
Drugs & Patents

Annexure 3

SUMMARY & ACTION CHART

A Committee to be Set up to go into the details of different activities.
(Members of to Govt, Medical Fraternity, Industry Consumers etc.)

↓

Study the disease pattern, Asses the need for medicines

↓

WHO Essential drug to be submitted to a group of Experts from medicine & a Essential Drug List to be adopted

↓

Implement to EDL for PHC, Secondary & Tertiary Hospitals

EDL to be adopted for Health workers PHC Doctors & Various Specialties

EDL for Emergency Care (Floods / Earthquake)

Drug Donation guidelines to be worked

Formulary for Govt of Karnataka

Treatment guidelines for Primary Care Hospital
Antibiotic guidelines for Primary & Secondary Care.

↓

Drug Procurement for hospitals

Asses the need for medicines based on Previous requirements

Asen the Financial Situation

Call Tenders

Asen te Supplyers

↓

Indent

Drug Shield accompany objective drug information

Ban/Restrict the use of drugs which are inemential, harmful.

Training for PHC doctors/nurses/Pharmacist on Rational Drug Therapy

↓

Certificate course on Rational Drug Therapy for private practitioners

↓

Orientation for Secondary Care & Tertiary Care doctors on Rational DrugTherapy

↓

Call to all to Establishments for EDL, Formulary call to profesional organisation

Undergraduate & patgraduate training on Rational Drug use

↓

Public pharmacies to be established.

(Newsletter) Bulletin on Essential Drugs & Therapeutics

Drug Information Centre to be Established

↓

Research on Essential Drugs of

↓

Legislation - Generic prescribing etc

Discuss with legal Profession

Annexure 4

References

1) Guidelines for developing national drug Policies WHO, Geneva 1988.

2) Report of the WHO expert Committee on National Drug Policies Geneva 19-23 June 1995

3) WHO Technical Report Series No 615 1977

4) WHO Essential Drug List December 1999

Annexure 5 Good Manufacturing Practice

It includes general guidelines covering the following areas

Personnel
Premises
Equipment
Sanitation
Starting Material
Manufacturing Operations
Labelling & packaging
The quality Control System
Self inspection
Distribution records
Complaints & reports of adverse reactions

Other issues with Consideration is

Self Medication, Over the Counter medication
Monitoring of adverse drug reactions
Post marketing Surveillance of the new drugs
Distribution & Storage of drugs
Traditional drugs

(2) 4

DR-1

Tackling Drugs to Build a Better Britain

The Government's Ten-Year Strategy for Tackling Drugs Misuse

Presented to Parliament by the President of the Council by Command of Her Majesty, April 1998

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(1)

A Personal Statement from the Prime Minister

10 DOWNING STREET
LONDON SW1A 2AA

The Prime Minister

This government was elected on a promise of change. A promise to create a new and modern Britain for the 21st century. That is what we pledged to do. And we are delivering.

Step by step that change is happening and Britain is becoming a better place to live in. But it could be so much better if we could break once and for all the vicious cycle of drugs and crime which wrecks lives and threatens communities.

The fight against drugs should be part of a wider range of policies to renew our communities and ensure decent opportunities are available to all.

We are tackling inequalities through the largest ever programme to get people off benefit and into work and a series of reforms in the welfare state, education, health, criminal justice and the economy.

But that is not enough. I am determined to tackle the drugs problem. That is why I appointed Keith Hellawell as the first ever UK Anti-Drugs Coordinator to put together a comprehensive strategy, coming at the problem afresh.

This strategy is an important step forward in developing a cooperative approach. But the fight is not just for the Government. It is for teachers, parents, community groups, those working in the field and everyone who cares about the future of our society. We owe it to our children to come up with a truly imaginative solution and create the better Britain they deserve.

Tony Blair

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The Government's Ten-Year Strategy for Tackling Drugs

Ann Taylor **John Prescott** **Gordon Brown**

Robin Cook **Jack Straw** **David Blunkett**

Donald Dewar **Frank Dobson** **Mo Mowlam**

Ron Davies

The Problem

Drugs are a very serious problem in the UK. No one has any illusions about that. Illegal drugs are now more widely available than ever before and children are increasingly exposed to them. Drugs are a threat to health, a threat on the streets and a serious threat to communities because of drug-related crime.

Some progress has been made. The last Government's strategy for England "Tackling Drugs Together" was an important step in the right direction. It has been implemented with some success. For the first time, Drug Action Teams set up partnerships to tackle the problem. We will build on that valuable work. But a fresh long-term approach is now needed.

Vision

There are no easy answers. To really make a difference in tackling drugs, goals must be long term. Our new vision is to create a healthy and confident society, increasingly free from the harm caused by the misuse of drugs. Our approach combines firm enforcement with prevention.

Drug problems do not occur in isolation. They are often tied in with other social problems. The Government is tackling inequalities through the largest ever programme to get people off benefit and into work and a series of reforms in the welfare state, education, health, criminal justice and the economy. And a new Social Exclusion Unit is looking at many of the problems often associated with drug taking.

The Government will promote action against drugs that makes substantial progress over the long term. Action will be concentrated in areas of greatest need and risk. All drugs are harmful and enforcement against all illegal substances will continue. And we will focus on those that cause the greatest damage, including heroin and cocaine.

Partnership is the key to the new approach, building on the good work that has already been done. This strategy is based on an extensive review by the UK Anti-Drugs Coordinator, Keith Hellawell and his Deputy, Mike Trace. They analysed all the available evidence and together consulted over 2,000 people and organisations.

The strategy has four elements:

Young People - to help young people resist drug misuse in order to achieve their full

potential in society;

Communities - to protect our communities from drug-related anti-social and criminal behaviour;

Treatment - to enable people with drug problems to overcome them and live healthy and crime-free lives;

Availability - to stifle the availability of illegal drugs on our streets.

This is a framework for designing and implementing policies to tackle drugs. It is just the beginning of a long-term strategy.

In the first year of the strategy, clear, consistent and rigorous targets will be set to help achieve our aims. The performance of the Government and its agencies therefore will be readily measurable against these targets. And the UK Anti-Drugs Coordinator will publish an annual report to check progress.

Partnership

Because of the complexity of the problem, partnership really is essential at every level. At government level, the work will be led by the Cabinet Sub-Committee on Drug Misuse chaired by Ann Taylor and by other groups chaired by Keith Hellawell and his Deputy Mike Trace.

These will bring together key players in the field from the statutory, voluntary and private sectors and others with an interest. They will work closely with the local partnerships set up by Drug Action Teams. The Drug Action Teams are the critical link in the chain, ensuring that this strategy is translated into concrete action. To assist in that, detailed guidance notes are being issued to those working in the field putting this strategy into practice.

Resources

In central and local government alone, well over £1 billion a year is spent on tackling the drugs problem. And yet the number of addicts is going up and availability and drug-related crime are on the increase. We need to improve the efficiency and coordination of anti-drugs work. And eventually, we hope to achieve better results. If we invest wisely now, there is a real chance of breaking the cycle of drugs and crime which wrecks lives and threatens communities. Along with the obvious benefits of creating a healthier society, there could also be significant savings through big reductions in crime and health risks.

To achieve that, all government departments have committed themselves to the principles guiding the allocation of resources described in Keith Hellawell's report. There will be a progressive shift away from reactive expenditure, dealing with the consequences of drug misuse, to positive investment in helping prevent them ever arising. The Coordinator's report takes into account work currently being done on the comprehensive spending review of drugs-related spending which will be completed later this year. And for the first time, a proportion of assets seized from drug barons will be channelled back into anti-drug programmes to help those who have suffered at their hands and on whose misfortune they have prospered. The Government is considering how this can best be achieved. More details of these considerations will be issued later this year.

The Way Ahead

The strategy is a challenging work programme to which all relevant agencies will need to respond. Work must be properly coordinated. The Government will make clear what it expects from its key agencies with an interest - police forces and authorities, probation committees, prison establishments, health authorities, local authorities (including Directors of Education and Social Services), HM Customs and Excise, the National Crime Squad and the National Criminal Intelligence Service. Similarly, with Drug Action Teams.

Although the strategy focuses mainly on England, it is relevant to Scotland, Wales and Northern Ireland and it highlights our international responsibilities. We will make sure it gets the widest circulation. And our international effort remains vitally important, working with our European and other partners, to stem the flow of illegal drugs into the UK.

The legal framework provided by the Misuse of Drugs Act 1971 and other legislation provides some of the tools needed to crack down on the availability of drugs and reduce the misery they cause. But enforcement alone will never be enough. We need to ensure that young people have all the information they need to make informed decisions about drugs; that we follow up tough words with decisive action; and that there really is proper partnership to tackle the problem. If we can make our vision a reality, we have the chance to make Britain a better place. This new strategy presents a real opportunity to do that.

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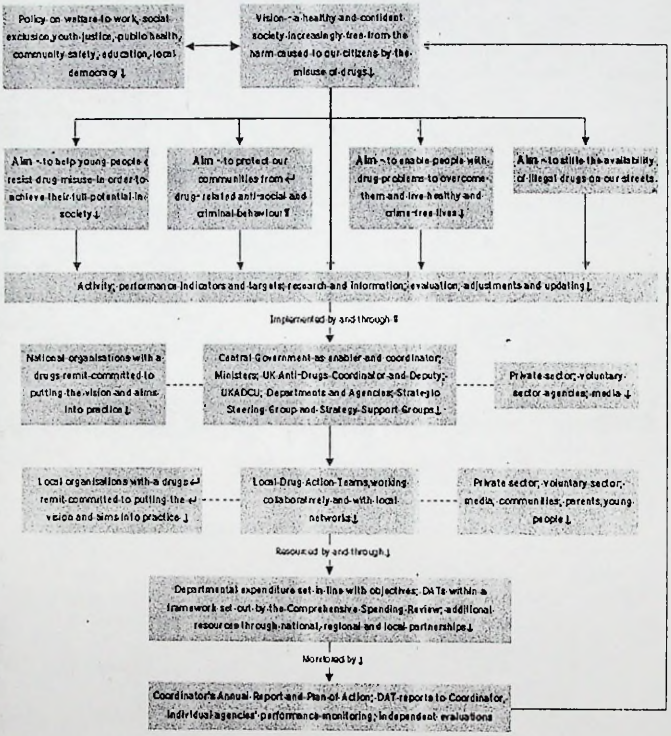
 Prepared 27 April 1998

(5)

The Government's Anti-Drugs Strategy: Outline



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We welcome your comments on this site. *Prepared 27 April 1998*

Report of The UK Anti-Drugs Coordinator

Introduction

I share the Government's vision for the future - a healthy and confident society increasingly free from the harm caused by the misuse of drugs.

To achieve this we must all combine to:

- address the social issues which contribute to young people, in particular, becoming attracted to drug taking;
- bolster and support those who wish to help and guide them;
- provide sufficient services to treat those who have drugs problems;
- concentrate our international and law enforcement effort on those who produce, process, distribute and sell them;
- develop a criminal justice system which deals effectively both with those who appear before it for greed and for need.

The focus of this document is on illegal drugs as determined by the Misuse of Drugs Act 1971. However it is clear to me that legally obtainable substances such as alcohol, tobacco, solvents and prescribed drugs used without medical control have close links with illegal drugs problems and should therefore be addressed, as appropriate, within the strategy.

Drug misuse in the late 1990s poses many problems for our society. Research suggests that there are all kinds of reasons for misuse; that key factors include unemployment, low self esteem, educational failure, boredom and physical, psychological or family problems. Even where the cause relates more to experimentation or enjoyment, or to a shift from alcohol or tobacco, the fact is that overtly mind-altering substances have greater pull than other activities. And many people misuse drugs because they don't have the opportunity to lead fulfilling lives.

The consequences of drug activity include serious and organised crime; wide-spread acquisitive crime for drug addicts funding their habit; violence generated by drug intoxication and dealers; and hidden social problems - in homes and schools, on the roads and in the workplace.

The social, economic, psychological, crime and health-related costs are formidable. The latest Government-funded research suggests that annual costs arising from the most serious drug misusers alone are **well over £4 billion**.

Significant health risks are associated with drugs - the more evidence that becomes available about the risks of, for example, cannabis and ecstasy, the more discredited the notion that any of the substances currently controlled under the 1971 Act are harmless.

But there are many misconceptions. All young people do **not** take drugs; all drug takers are **not** addicts; all drugs do **not** kill; all drug takers do **not** commit crime; illegal drugs are **not** the unique preserve of people from particular social or ethnic backgrounds.

The majority of people in this country **do not nor have ever** taken an illegal substance; and the majority of those who have are experimenters or casual users. A majority of illegal drug users do so for so-called "recreational purposes". By far the minority of illegal drug users - between 100,000 and 200,000 people - become addicts. It is this group which causes the greatest problem for society and themselves. They are responsible for a substantial amount of crime; many are victims of abuse from drug dealers and pimps; they are often disruptive and make disproportionate demands on law enforcement, medical, counselling and social services. The response to this group has so far been patchy. Although individuals and agencies are working very hard within their own area, they are trying to achieve progress against inconsistencies within the operation of the criminal justice system; inadequate treatment and prescribing facilities; haphazard funding arrangements which have a bias towards reacting rather than preventing; and a paucity of timely and consistent information. It is crucial that we learn from the past and adopt a consistent approach in the future.

I believe that the four aims of helping young people, protecting communities, enabling those with problems to overcome them and stifling availability of drugs will allow us all to channel our efforts towards significant improvements over time. I believe that over the next ten years we should be looking to achieve significant reductions in young people's drug use and drug-related offending; an increase in the participation of problem drug misusers in treatment programmes;and reductions in the availability of drugs. In our progress towards these aims it is essential that we monitor the effectiveness of our individual and collective activities in an objective way. We need also to set about achieving our corporate and single agency targets on an annual basis and monitoring our progress in reaching them. Much work will need to be done within the next twelve months to develop these targets in relation to the activities outlined in each section of this report.

The focus of this first report is on England, but I would expect all other parts of the UK to reflect on the implications of this strategy for them and report back on relevant developments by February 1999.

By March 1999:

- all agencies should realign their priorities, resources and operational focus in line with this White Paper and produce their forward plan;
- all agencies should develop corporate and individual performance targets and measures;
- national, local, private and voluntary sector funding should be realigned in support of the plan;
- I will publish my first Annual Report and Plan of Action Against Drugs.

This process will be repeated every year. It will be influenced by experience, research, evaluation, changes in patterns of drug misuse, successes and failures at national, corporate and individual level. Every three years, we need to have a systematic and comprehensive appraisal of the strategy's impact based on independent evaluations, and adjust the way forward accordingly. The importance of rigorous evaluation cannot be overstated.

In tackling the drugs problem, we must now shift our emphasis from reacting to the consequences of drug misuse to tackling its root causes. This should be reflected in Government financial programmes. The challenge is to protect the young and vulnerable, offer alternatives to the disaffected, stop those who flout the rules, and arrest and imprison those who profit from the drugs trade.

There are a great many talented and committed people working in the field. I want to see them really working together. I want them to be free from obstacles which stop them doing that effectively now. Action against drugs should be at the heart of government policy. Working together we can make an impact in schools, colleges, universities, on the streets, in the workplace and in our homes. There is now a unique opportunity to invest in the future. We must not squander it.

Keith Hellawell

The Drugs Problem: Where We Are Now

"Tackling Drugs Together", published in May 1995, was the first genuinely strategic response in England to the complexities of the drugs problem. It had cross-Party support and has been successful in sustaining a coordinated approach to a difficult issue. The fact that all 88 of the tasks required in that White Paper have been completed indicates good progress. It remains one of the best and most influential strategies for effective action against drugs. But in building on its success, we need to recognise its weaknesses:

- it focused on structures rather than results, with the general public insufficiently engaged as a consequence;
- it treated drug misuse largely in isolation from other social and environmental factors;
- it advocated partnership without making sufficient structural and fiscal changes to support it;
- it was too short-term and did not bring together common research, information and performance bases.

Alongside "Tackling Drugs Together", there have been other important developments:

- A strategic review of **international drugs activity** - with a clear overall commitment of all the law enforcement, intelligence and diplomatic agencies to reduce the flow of illicit drugs to the UK.
- **Strengthened links** between a wide range of national agencies, working together to achieve collaborative goals on drug prevention/education and enforcement - an approach which has been confirmed by recent reports from the statutory Inspectorates on the Police, Probation, Prisons, Education and Social Services.
- Increased **collaboration on resources** between the statutory, private and voluntary sectors - for example, the £2 million drugs Challenge Fund in 1996/7 and 1997/8 respectively has generated a total of over £2.5 million resources from those sectors.
- The creation and development of **Drug Action Teams** and their Reference Groups which has been very encouraging, with substantially greater cohesion of effort and sharing of resources amongst health and local authorities, criminal justice agencies and other key players, agreed action plans and better prioritisation of local needs.
- Community initiatives which have generated a diverse range of projects, clearly highlighting that local people are best placed to tackle local drugs problems. Evidence of this has been disseminated, in particular by the Home Office **Drugs Prevention Initiative**.

Significant progress too has been made in Scotland, Wales and Northern Ireland:

- in **Scotland**, the 1994 strategy "Drugs in Scotland: meeting the challenge" has

been implemented, along with the development of the Scotland Against Drugs campaign and a Scottish drugs Challenge Fund. The emphasis has been on an integrated approach to service provision, the development of a national information base and strong partnership links with the private and voluntary sectors;

- in **Wales**, a drug and alcohol strategy "Forward Together" was launched in 1996. The Welsh Drug and Alcohol Unit oversees the strategy, and is committed to developing a national prevention campaign, action on treatment and rehabilitation, and guidance for those involved in combatting drug and alcohol misuse;
- in **Northern Ireland**, the Central Coordinating Group for Action Against Drugs was established in 1995 to oversee coherent efforts against drug misuse within a clearly defined policy statement. The key action areas are education and prevention, treatment and rehabilitation, law enforcement, information and research - including a major publicity campaign - and monitoring and evaluation.

The scale of the problem

Despite this progress, the drugs problem remains formidable. For example:

- record levels of drug seizures reveal the increasing threat of a widening range of trafficking routes to the UK, against a background of expanding global production;
- offenders dealt with under the Misuse of Drug Act 1971 are up from 86,000 in 1994 to 95,000 in 1996;
- 48% of 16-24 year olds questioned in 1996 had ever used illegal drugs compared with 45% in 1994 (and 18% had used in the last month, compared with 17% in 1994);
- the number of drug misusers attending services was 24,879 in the six month period ending September 1996, 48% higher than the equivalent period three years earlier;
- the number of deaths in the UK attributable to the misuse of drugs has risen from 1,399 in 1993 to 1,805 in 1995.

In addition, more localised trends - particularly the increasing availability and use of cheap, smokeable heroin - suggest growing exposure and consumption by increasingly younger people.

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The Underlying Principles of The Strategy

Integration. Drug problems do not occur in isolation. They are often tied in with other social problems. The Government is tackling inequalities through the largest-ever programme to get people off benefit and into work and a series of reforms in the welfare state, education, health, criminal justice and the economy. And a new Social Exclusion Unit is looking at many of the problems often associated with drug taking such as school exclusions, truancy, rough sleeping and poor housing. It is important to remember these connections, and that key results in other areas of activity, such as general take-up rates for further and higher education and employment, relate clearly to the development of this strategy.

Evidence. Drug misuse can be a highly-charged subject. Learning about an illicit activity can be difficult but our strategy must be based on accurate, independent research, approached in a level-headed, analytical fashion.

Joint Action. Partnership is not an end in itself, and can be an excuse for blurring responsibilities and inactivity. But the evidence is that joint action - if managed effectively - has a far greater impact on the complex drugs problem than disparate activities.

Consistency of Action. While activities must relate to local circumstances and priorities, drugs misuse is a national problem requiring fairness and consistency in our response.

Effective Communication. We need to be clear and consistent in the messages we send to young people and to society Ð in particular, the importance of reinforcing at every opportunity that drug-taking can be harmful.

Accountability. Through the Coordinator's Annual Report and Plan of Action Against Drugs, we can dispassionately and objectively track progress. The structures, resources and performance mechanisms set out in this report exist solely for that purpose, so that we can be sure our achievements are real. A special focus will be given to the four key objectives identified below - one for each aim.

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Aim (i): Young People - To Help Young People Resist Drug Misuse in Order to Achieve Their Full Potential in Society

Young people, and those responsible for them, need to be prepared both to resist drugs and, as necessary, to handle drug-related problems. Information, skills and support need to be provided in ways which are sensitive to age and circumstances, and particular efforts need to be made to reach and help those groups at high risk of developing very serious problems. Prevention should start early, with broad life-skills approaches at primary school, and built on over time with appropriate programmes for young people as they grow older via youth work, peer approaches, training and wider community support. The aim is for approaches to be better integrated nationally and locally.

Key objective

Reduce proportion of people under 25 reporting use of illegal drugs in the last month and previous year.

Drugs and young people: the facts

We now know a great deal about the relationship between drugs and young people. Many never take drugs at all, many who do experiment grow out of it quickly, but a small hardcore develop very serious problems. In particular:

- drugs misuse is most common amongst people in their teens and early twenties, but the average age of first drug use is becoming younger;2
- almost half of young people are likely to take drugs at some time in their lives, but only about one-fifth will become regular misusers, (ie at least once a month), with a tiny minority of that group taking drugs on a daily basis; 2
- most young people who take drugs do so out of curiosity, boredom, or peer pressure - and continue misusing drugs through a combination of factors ranging from enjoyment to physical and psychological dependency;
- cannabis is easily the most commonly-used drug amongst the young, followed by amphetamines, poppers, LSD and ecstasy2 - while there are some identifiable groups such as cannabis users , dance drug users and addicts, the trend is towards more indiscriminate use, based on price and availability;
- there is a very strong correlation between the use of illegal drugs and the use of volatile substances, tobacco and alcohol amongst young people;
- there is increasingly strong evidence that the earlier a young person starts taking drugs, the greater the chance that he or she will develop serious drugs problems over time;
- for early to mid-teenagers, there are strong links between drugs problems, exclusion or truancy from school, break-up of the family, and initiation into criminal activity;

- for older teenagers and people in their twenties, there are strong links between drugs problems and unemployment, homelessness, prostitution and other features of social exclusion;
- whatever other influences affect young people, the role of parents throughout this process is crucial.

Programme of action

All activity supported by this stategy will:

- inform young people, parents, and those who advise/work with them about the risks and consequences of drug misuse, linked to other substances - including alcohol, tobacco and solvents - where appropriate;
- teach young people from the age of five upwards - both in and out of formal education settings - the skills needed to resist pressure to misuse drugs, including a more integrated approach to Personal Social and Health Education in schools, and with particular reference to the forthcoming 1998 DfEE guidance;
- help make the misuse of drugs less culturally acceptable to young people, including the use of effective and targeted national and local publicity and information;
- promote healthy lifestyles and positive activities not involving drugs and other substance misuse;
- ensure that the groups of young people most at risk of developing serious drugs problems receive appropriate and specific interventions;
- ensure that young people from all backgrounds, whatever their culture, gender or race, have access to appropriate programmes:
- build on and disseminate good practice in identifying what works best in prevention and education activity.

Assessment

Performance indicators for each of these activities will be introduced to monitor achievement and specific targets set for agencies against the following objectives:

- reduce proportion of people under 25 reporting use of illegal drugs in the last month and previous year - **Key Objective**;
- increase levels of knowledge of 5-16 year olds about risks and consequences of drug misuse;
- delay age of first use of illegal drugs;
- reduce exclusions from schools arising from drug-related incidents;
- reduce the number of people under 25 using heroin;
- increase access to information and services for vulnerable groups - including school excludees, truants, looked after children, young offenders, young homeless and children of drug-misusing parents.

Research and Information

To support these objectives we will make use of the best available sources of information and plan as a priority to commission additional research as follows:

- comprehensive surveys of young people (age 5 upwards) and drugs misuse;
- qualitative studies of patterns of misuse of regular young users;
- long-term evaluations of effectiveness of prevention and education programmes;
- qualitative and long-term assessment of impact on drug misuse of wider social factors;
- operational summary of effective prevention and education.

[2]Drug Misuse Declared in 1996: Key Results from the British Crime Survey" - Ramsy H an Spiller J. Home Office Research Findings 56 (1997)

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Aim (ii): Communities - To protect our Communities from Drug-Related Anti-Social and Criminal Behaviour

Helping drug-misusing offenders to tackle their drug problems and become better integrated into society has a significant impact on levels of crime. Local partnerships can work successfully to tackle local drug problems, and to improve the quality of life for communities.

Key objective

Reduce levels of repeat offending amongst drug misusing offenders.

Drugs and the communities: the facts

Drugs and crime are of concern to all communities, particularly drug possession, manufacture and trafficking, the involvement of criminal syndicates in the drugs trade, the acquisitive crime committed by drug misusing offenders to feed their habits, and the anti-social behaviour and feeling of menace that the drug culture generates within neighbourhoods. It is very clear that effective enforcement under the 1971 Act remains vital to minimising the availability of drugs and the threats to the community that the drug culture carries in its wake. The criminal justice system operates with considerable discretion within this framework but we must guard against this resulting in inconsistencies. The growing clarity of the relationship between drugs and crime has highlighted that:

- many police forces estimate that around half of all recorded crime has some drug related element to it, whether in terms of individual consumption or supply of drugs, or the consequent impact of it on criminal behaviour;
- a small number of people are responsible for huge numbers of crimes - 664 addicts surveyed committed 70,000 offences over a three month period;[3]
- latest indications from a random sample of suspected offenders arrested by the police suggest that over 600/0 of arrestees have traces of illegal drugs in their urine;[4]
- emerging evidence suggests that effective and targeted treatment for drug misusing offenders can have a major impact on reducing subsequent offending;[3]
- the general costs to the criminal justice system of drug-related crime are, at a very conservative estimate, at least £1 billion every year;[5]
- community safety partnerships - which target specific drugs problems in the community - such as disrupting visible markets, drugs in pubs and clubs, drugs in the workplace and drugs and driving - have great potential where the approach taken is locally based, properly resourced, consistently delivered and long-term.

Programme of Action

All activity supported by this strategy will:

- develop sustained and collaborative treatment for those committing drug-related crime - including support for the piloting of Drug Treatment and Testing Orders, promotion of Caution Plus schemes (according to Home Office and ACPO guidelines) and associated projects within existing legislation, ensuring that their lessons are spread and implemented as widely as possible;
- target police resources on the detection of drug-related crime and refer offenders where appropriate;
- provide visible deterrence and public reassurance through the consistent punishment of drug dealers and suppliers, and the disruption of their markets;
- ensure community support in achieving a consistent application of the drugs laws, including compatibility in dealing with low level possession offences amongst different prosecution agencies;
- energise and involve local communities through collaborative responses to local drug problems - with imaginative use of existing and planned community safety/estate action/drug network partnerships - so that positive outcomes, focused on the drugs and the people that cause most damage and danger, are achieved;
- increase take-up rate of further education and employment by former addicted criminals through welfare to work, New Deal and other means;
- tackle drugs in clubs in line with recent Home Office guidance;
- implement drugs in the workplace initiatives in line with Health and Safety Executive guidance for employers;
- enhance detection and underline the social unacceptability of driving while influenced by drugs.

Assessment

Performance indicators for each of these activities will be introduced to monitor achievement and specific targets set for agencies against the following objectives:

- reduce levels of repeat offending amongst drug misusing offenders - **Key Objective**;
- increase the number of offenders referred to and entering treatment programmes as a result of arrest referral schemes, the court process and post-sentencing provision;
- reduce levels of crime committed to pay for drug misuse;
- reduce drugs market places that are of particular concern to local communities;
- reduce levels of drug-related absenteeism/dismissals from work;
- reduce numbers of road deaths and injuries where drugs are a contributory factor.

Research and Information

To support these objectives we will make use of the best available sources of information and plan as a priority to commission additional research as follows:

- long-term evaluations of community safety programmes within high risk communities;
- further assessment of cost-effective treatment in the criminal justice system;
- practices that have led to sustained reductions in drug-related crime and community fear; and

studies into the links between drug misuse and absenteeism, and between drugs and road deaths.

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[3]"National Treatment Outcom Research Study. Summary of the Project, the clients and preliminary findings" - Gossop M. NTORS (1996)
[4]"Drug Testing Arrestees, Home Office Research Finding", No 70 - Bennett T. (1998)
[5]Preliminary Results from Drugs Comprehensive Spending Review.

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Aim (iii): Treatment - To Enable People With Drug Problems to Overcome them and Live Healthy and Crime-free Lives

Many of those with the most serious drugs problems have a range of other problems, including lack of housing or employment. We will ensure that specific, appropriate and timely help is provided to those with drug problems and that their needs are recognised and addressed by wider Government programmes.

Key objective

Increase participation of problem drug misusers, including prisoners, in drug treatment programmes which have a positive impact on health and crime.

Drug treatment: the facts

There is growing evidence that treatment works. In particular, harm reduction work over the last 15 years has had a major impact on the rate of HIV and other drug-related infections. And rehabilitation programmes have shown real gains in crime reduction. The rate of demand for treatment services amongst seriously dependent drug misusers shows no sign of abating, and the supply of effective treatment services is failing to match that demand. In particular:

- the number of addicts has risen steadily - there were 38,000 people notified in England as drug addicts in 1996, compared with 22,000 in 1992;[6]
- the total number of seriously problematic drug misusers in this country is estimated to be between 100,000 and 200,000, many of whom do not seek or cannot get access to effective services;[7]
- the scope, accessibility and effectiveness of available treatments are inconsistent between localities and generally insufficient. There is considerable insecurity about funding and disparity in provision. Consequently, there is rarely immediate access for a drug misuser to a treatment programme - given the urgency of the needs of most drug misusers, this is unacceptable. The Department of Health report "The Task Force to Review Services for Drug Misusers" (1996) points a clear way forward for developing effective treatment provision in this country - as does the Health Advisory Service report on "Children and Young People - Substance Misuse Services" (1996) with respect to services to adolescents. The challenge is to put the recommendations of these two reports firmly into practice;
- the most significant health risks for this group beyond drug dependency are HIV, hepatitis B and C, and a wide range of psychiatric and psychological problems. Drug related deaths - proportionately rare but probably under-reported - are increasing. Injecting, however, appears to be continuing its fall, with only 2 in 5 addicts now admitting ever injecting;[8]
- there is increasing evidence of the links between health problems of individual drug misusers and public health concerns - notably mental health problems,

alcohol abuse and tobacco use, and social exclusion.

Programme of Action

All activity supported by this strategy will:

- ensure all problem drug misusers - irrespective of age, gender, race and drug with which they have a problem - have proper access to support from appropriate services - including primary care - when needed, providing specific support services for young people, ethnic minorities, women and their babies;
- provide problem drug misusers with accurate information, advice and practical help to avoid infections and other health problems related to their misuse;
- support problem drug misusers in reviewing and changing their behaviour towards more positive lifestyles - linking up where appropriate with accommodation, education and employment services;
- provide an integrated, effective and efficient response to people with drugs and mental health problems;
- ensure that prescription of substitute medications (eg methadone) in particular and dispensing of clinical services in general (including prescribed legal drugs) are in line with forthcoming Department of Health clinical guidelines;
- improve the range and quality of treatment services provision specifically for the under 25s, in line with Standing Conference on Drug Abuse guidance;
- ensure that throughcare and aftercare arrangements for drug misusing prisoners are coherent, focused and linked to community provision;
- develop collaborative, coherent, accessible and cost-effective service provision through Drug Action Teams.

Assessment

Performance indicators for each of these activities will be introduced to monitor achievement and specific targets set for agencies against the following objectives:

- increase participation of problem drug misusers. including prisoners, in drug treatment programmes which have a positive impact on health and crime - Key Objective;
- increase the proportion of problem drug misusers in contact with drugs services;
- reduce the proportion of drug misusers who inject. and the proportion of those sharing injecting equipment over previous three months;
- reduce numbers of drug-related deaths;
- reduce numbers of drug misusers being denied immediate access to appropriate treatment.

Research and Information

To support these objectives we will make use of the best available sources of information and plan as a priority to commission additional research as follows:

- the clinical and social care of people with drugs and mental health problems;
- the cost-effectiveness of current treatment and care options;
- the effectiveness of treatment interventions for young people;
- the lessons from the Advisory Council on the Misuse of Drugs study of drug-related deaths;
- the links between recreational drug misuse (including cannabis) and later health problems;
- the treatment of stimulant drug dependency.

6Statistics of Drug Addicts Notified to the Home Office, United Kingdom, 1996 - Corkery JM (1997)
7"Arrest Referral - Emerging lessons from research" - Edmunds M et al(1998)
8Drug Misuse Statistics for six months ending September 1996 - Department of Health (1998)

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Aim (iv): Availability - To stifle the Availability of Illegal Drugs on our Streets

Constant vigilance is needed to tackle availability where it matters most, close to home. It is crucial to gain a better understanding of which activities have the most impact on local availability and to pursue them, improving partnership between agencies along the way.

Key objective

Reduce access to drugs amongst 5-16 year olds.

The drugs trade: the facts

The drugs trade is an international multi-billion pound industry. A 1997 report by the UN Drug Control Programme estimates that the industry's turnover amounts to about 8% of total international trade, approximately the same as textiles, oil, gas or world tourism. The threat is ever present and growing. And, however impressive the enforcement activity in general, there have been no signs of street level availability reducing over recent years. The facts are:

- the routes into the UK for heroin and cocaine have become increasingly complex, but remain primarily, for heroin, the Golden Crescent through Turkey and the Balkan route and, for cocaine, South America and the Caribbean - over half of all seizures arrive in the UK via other EU countries;
- the routes for synthetic drugs have been characterised by heavy ecstasy production in the Netherlands and increasing flows of manufactured drugs from Eastern Europe;
- the UK is primarily an importer of drugs. Domestic production, although limited, is increasing.
- proven cases of internal corruption within enforcement agencies are few, but the threat is real and requires constant vigilance;
- the impact on street level availability of activity against supplies is difficult to assess and the price of drugs within the UK has generally shown a stable or downward trend. However, there is a marked difference between the price of drugs here and in source and transit countries - for example, heroin is sold at £850 per kg in Pakistan, £7,000 in Turkey, £15,300 in the Netherlands and £24,000 in the UK, which then translates into £72,000 on our streets. There is therefore evidence to suggest that effective enforcement is a factor in pushing up those prices;
- the direct impact of enforcement on short term availability is difficult to establish. There is, however, Home Office research evidence which suggests that focused and coordinated activity on local drug markets can make a significant and sustained impact on availability, reducing supplies, pushing prices up and reducing the threat of exposure of young people to drugs;
- the drugs trade also includes significant quantities of drugs which have been

legally manufactured and then "leaked" on to the illicit market, primarily via the prescription system.

Programme of Action

All activity supported by this strategy will:

- reduce the acreage of drug crops produced and the amounts processed; control the illicit supply of chemicals and materials used in production and manufacture of drugs; and control the movement of drugs from producer to processing countries;
- raise the commitment and effectiveness of interdiction efforts in countries which pose a threat of drug supplies to the UK;
- reduce the amount of drugs coming to and crossing the UK borders through seizures and by dismantling or disrupting trafficking organisations;
- reduce the growth, manufacture and distribution of drugs within the UK, preventing them from reaching local dealers through seizures and by dismantling or disrupting internal networks;
- target money launderers and increase the amount of assets confiscated and recovered from drug activities;
- reduce levels of street dealing and the availability of drugs in communities;
- reduce the availability of drugs within prisons;
- ensure full cooperation and collaboration, at every level, amongst the enforcement and intelligence agencies, with the focus clearly on tackling activity which causes the most damage to local communities

The respective roles and responsibilities of the police and HM Customs and Excise are well defined. Within that framework, the creation of the National Crime Squad as of 1st April 1998 will enhance the effectiveness of the police service. During 1998/99 we shall look at how the objectives of the various agencies engaged in stifling availability can be further coordinated to secure increased effectiveness.

Assessment

Performance indicators for each of these activities will be introduced to monitor achievement and specific targets set for agencies against the following objectives:

- reduce access to drugs amongst 5-16 year olds - **Key Objective**;
- increase the effectiveness of the overseas diplomatic and operational effort;
- increase the value of illegal drugs seized and/or prevented from entering or distributed within the UK;
- increase the number of trafficking groups disrupted or dismantled;
- increase the numbers of offenders dealt with for supply offences;
- increase the amount of assets identified, and the proportion confiscated and recovered from drug trafficking and money laundering;
- reduce prisoner access to drugs.

Research and Information

To support these objectives we will make use of the best available sources of information and plan as a priority to commission additional research as follows:

- harness all the information gathering agencies, both within our control and those with whom we have influence, to produce a common data model which has strategic as well as operational benefits;
- establish the quantity, quality and type of drugs reaching our streets; its place of origin, distribution network and means of transport; and the most effective methods of intervention at each stage of the process;
- establish the quantity and type of precursor chemical manufactured, its place of origin, its destination and its route of passage;
- establish an objective base for the level of assets and money associated with the drug industry mapping the agencies and individual concerned;
- establish the relationship between street level prices, availability and demand.

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Resourcing and Managing the Work

For the strategy to be effective, clarity about the delivery mechanisms - the structures, resources, responsibilities, accountability and basis for audit and evaluation - is essential.

UK Coordination

Genuine collaboration across Government is the driving force behind this strategy. The role of individual departments, agencies and the voluntary and private sectors is to contribute to the overall vision and aims, in addition to their own specific tasks. The Cabinet sub-Committee on Drug Misuse - known as HS(D) - will be the Ministerial body responsible for ensuring that this occurs.

The UK Anti-Drugs Coordinator and his Deputy report to HS(D). Their role on behalf of Ministers is to provide the day-to-day leadership and focus on implementing and developing the Government's strategy. The Coordinator will, in particular, scrutinise rigorously the performance of departments and agencies - individually and collectively - against the actions, objectives and performance indicators set out in this report; and produce a National Anti-Drugs Plan for implementation in each succeeding year. Departments will continue to be responsible for their own policies and resources, and accountable to their Ministers accordingly. But the Coordinator's responsibility to the Government for the production of his Annual Report and Plan, means that progress across the board will be coordinated and open to scrutiny.

To aid his role, the Coordinator will chair a new body named the UK Anti-Drugs Strategic Steering Group, which will meet regularly to help the Coordinator assess overall progress in implementing the strategy, including its resources; consider relevant developments in the rest of the UK and internationally; and plan to account for progress and the way forward via the Coordinator's Annual Report and Plan.

Representation on the Strategic Steering Group will include senior officials from within Government, and individuals from independent bodies, professional drug agencies, local government, business and Drug Action Teams.

The Deputy UK Anti-Drugs Coordinator will, in turn, take forward the key elements of this White Paper through four newly formed Strategy Support Groups - one group for each aim of the strategy, each group meeting regularly. The key tasks of these groups will be to monitor progress against each aim; assess the need for further support in its implementation; consider emerging training, research and information needs; and monitor resource implications. These groups will report back to the Steering Group.

The Coordinator's and Deputy's roles can only be effective through collaboration and involvement of a wide range of supportive groups and individuals. To this end they will have support from the UK Anti-Drugs Coordination Unit (previously known as the Central Drugs Coordination Unit), a Unit in the Privy Council Office, reporting to the President of the Council, whose funding arrangements will be put on a long-term basis. The UKADCU's role will be to support the monitoring and effective implementation of this strategy. To fulfil this role, the UKADCU will work very closely with Departments, Drug Action Teams and individual agencies to develop a comprehensive network of resources and support mechanisms geared towards the

strategy's implementation.

Resources

Government expenditure in tackling drug misuse is considerable but poorly coordinated. As a result of the work on drug-related spending carried out for the Comprehensive Spending Review, we know that total Government expenditure for 1997/98 was in the region of £1.4 billion. This big increase in estimated expenditure - compared to £500 million in 1993/94 - relates primarily to a more realistic assessment of the drugs related proportion of generic police/prison/probation/education/health activity. We estimate that 62% of this total is currently spent on enforcement related work, much of it reactive and not drugs-specific (eg police, court, probation and prisions) and therefore, not straightforwardly transferable to preventative programmes; 13% on treatment; 12% on prevention and education; and 13% on international supply reduction. No more than a third of that total expenditure is currently spent on preventing drug misuse (as opposed to coping with the consequences of the problem). Minimum estimated costs of the social problems generated by severely dependent drug misusers alone are in the region of £3-4 billion annually.

Existing resource provision is ad hoc rather than strategic; allocation mechanisms are largely historically driven; the pattern of the delivery of resources to local anti-drugs projects is complicated and random; efforts to realise substantial confiscated assets from drug-related activity have not previously been successful; and there has been a lack of clear coordination between objectives, resources and outcomes. In moving forward, it is clear that the Government's resources must be linked to this strategy.

An announcement on funding from 1999/2000 will be made later in the year, following the outcome of the Government's Comprehensive Spending Review. Reforms will be guided by the following principles:

- drug-related expenditure should over time shift away from reacting to the consequences of the drugs problem and towards positive investment in preventing and targeting it;
- the bulk of targeted resources should be spent on collaborative projects which tackle high priority groups - in particular vulnerable young people, drug-related offenders and problem drug misusers;
- resources for drug-specific activities should receive priority within health authorities budgets. and on the basis of partnership work wherever appropriate. **Health authorities** should be required to deliver this strategy through the NHS Priorities and Planning Guidance. The development of the new NHS and Public Health White Papers should be used to ensure that health authorities give adequate provision to meeting the aims of the strategy through central guidance. Health authorities will be expected to include anti-drugs measures in their Health Improvement Programme;
- an element should be identified within health authorities' drug allocation for developing specific young people's services. This should enable health authorities to develop services in line with Department of Health guidance;
- funding for the purchase of community care services for drug misusers should be given adequate priority by **local authorities**. The Department of Health should take steps to ensure that this money is used for drug-specific partnership work, with mechanisms put in place to ensure that current expenditure on drug misusers from local authority community care funding is protected;

- **police forces** should aim to direct resources from within their budgets to drugs-specific partnership work, with explicit priority given to this work in Police Authority Annual Policing plans and the national key policing objectives, set by the Home Secretary and performance indicators and targets aligned explicitly to the new strategy;
- the **Prison Service** should aim to direct resources from within their budget to drugs-specific partnership work, including treatment provision, with explicit priority given to this work in the Prison Service business plan, and performance indicators and targets aligned explicitly to the new strategy;
- **probation services** should aim to direct resources from within their budgets to drugs-specific partnership work, with explicit priority given to this work in local plans and the national key probation objectives, and performance indicators and targets aligned explicitly to the new strategy;
- **local education authorities** should include clear policy statements on drugs education, and any performance indicators and targets aligned to the new strategy, within their behaviour support plans. An LEA's anti-drugs strategy will also be reflected in its education development plan where this emerges as a priority;
- **HM Customs and Excise** should maintain their commitment to funding drug-related activity - and ensure that partnership work is reaffirmed strongly in their management plans, with performance indicators and targets aligned explicitly to the new strategy;
- the **National Criminal Intelligence Service** should ensure that partnership work is reaffirmed strongly in their service plan, and to consider in consultation with the Coordinator the development of objectives with performance indicators and targets aligned explicitly to the new strategy;
- the **National Crime Squad** should ensure that partnership work is reaffirmed strongly in their service plan, and to consider in consultation with the Coordinator the development of objectives with performance indicators aligned explicitly to the new strategy;
- **Drug Action Teams** should be the principal mechanism by which agencies will develop the resource partnerships outlined above, and will assess regularly whether the spending plans and projected outcomes of all agencies represented on them are aligned explicitly to the new strategy;
- the value for money of Government and other anti-drugs expenditure against outcomes should be monitored at national level via the UK Strategic Steering Group and Strategy Support Groups and locally via the Drug Action Teams; and
- securing partnership funding should be given high priority at every level, led by the national partnership between Government and Business in the Community;

For the first time, a proportion of assets seized from drug barons will be channelled back into anti-drugs programmes to help those who have suffered at their hands and on whose misfortune they have prospered. The Government is considering how this can best be achieved. More details of these considerations will be issued later this year.

The efficient and effective delivery of the strategy's objectives will, of course, determine the specific resources required over time, and resource provision will accordingly be regularly reviewed in the Coordinator's Annual Report and Plan of

Action Against Drug Misuse.

Regional Coordination and Delivery of Strategy

Drug Action Teams, supported by their Reference Groups, have worked well in most parts of the country in forging partnerships against drugs amongst the key local agencies. The time is right to step up a gear in relation to this partnership activity, so that a sharper focus is brought to bear on implementing this strategy. This should link up where necessary with other local partnership initiatives on welfare-to-work, health, education, housing, community safety, youth justice, local democracy and social exclusion. Links with these other partnerships will develop over time, but will not diminish the importance of the work against drugs at local and regional level, via Drug Action Teams. The strategic requirements set out below reinforce both the need for a continuing focus on local drugs problems and ensuring that other social partnerships contribute to that work.

All Drug Action Teams in England are to agree corporate plans annually with the UK Anti-Drugs Coordinator by the end of each calendar year. Templates will be provided by UKADCU. These plans will feed into the Annual Report and Plan and include:

- an assessment of current progress against the new strategy;
- an analysis of existing local resources upon which each DAT has influence both within its own organisations and jointly targeted;
- proposals for allocating those resources to match the priority aims and actions set out in this strategy;
- specific outcome measures against all relevant areas under the aims set out in this strategy - including services for vulnerable young people, criminal justice/treatment; rehabilitation of problem drug misusers and disruption of local drug markets;
- proposals for short, medium and longer-term targets against those measures in line with the national targets to be developed;
- agreement with all other Drug Action Teams within their metropolitan or shire county area on the basis of a corporate and strategic overview to the plans individual DATs have drawn up. This is to ensure strategic coherence to the plans across each county, a genuinely senior level of strategic input from the key players, and consonance with the development of other relevant shire and metropolitan county partnerships. Where appropriate, DATs will wish to liaise with relevant regional tiers of government. **This overview will be the most important part of the plan in enabling the Coordinator to take stock of progress.** Those DATs which currently do not operate on a shire or metropolitan county level will have a more complex process to go through than the 26 DATs currently operating on those lines. The focus of our support will therefore be on the remaining 80 DATs.

These plans will deliver greater consistency and provide the basis for attracting additional resources - including some drugs-specific funding from central Government, Lottery funding and partnership money from the private and voluntary sectors - and will be assessed on that basis. The Government and the Coordinators will be engaging directly with Drug Action Teams across England to ensure that the planning process is as clear and unbureaucratic as possible.

Drug Action Teams must develop as the mechanism for ensuring local resource collaboration in line with this strategy. Their corporate plans will provide the benchmark for distributing resources from 1999/2000 onwards - further guidance to

DATs will be provided later this year taking forward this challenging remit. This will include more information about the future of centrally provided development funding.

This funding has helped DATs in providing essential local coordination. Most DATs have demonstrated best value in using this resource through an identifiable coordinator, working closely to the DAT Chair, and with a clear role and set of requirements. This coordination role must include coherent representation to the DAT of the views and expertise available from local communities. The Chair of each Drug Action Team will continue to have overall responsibility for the formulation and implementation of corporate plans. Clearly that responsibility, which also entails some accountability to the Coordinator, can only be discharged by individuals with considerable authority and influence within their DAT area. The personal qualities of any individual Chair are far more significant than the agency from which they come.

Representation on DATs - beyond the core agencies of health authorities, education, social services, police, prisons and probation - will continue to be a local matter, with the exception that all DATs should include senior representatives from local authority housing. They should also liaise more closely with the Crown Prosecution Service, key sentencers, the Employment Service, the voluntary sector, Training and Enterprise Councils and Chambers of Commerce. DATs must also actively engage their elected members and Members of Parliament, to ensure that there is no "democratic deficit" to their activity. Developing the representation and function of Drug Reference Groups and other networks in support of the agreed plans of the Drug Action Teams will be a local matter, but will need to ensure effective community involvement, consultation networks and clarity of responsibilities for implementation.

Drug Action Teams or their equivalents in Scotland, Wales and Northern Ireland are invited to consider their own development in the light of this strategy, as part of the overall response to the Coordinator by February 1999.

Partnerships

Action against drugs problems cannot be undertaken effectively by any single agency. The performance of all statutory agencies, accountable to central Government Departments, will be scrutinised to assess their progress in forging effective, enduring and practical partnerships with other agencies. The following are being developed as a priority:

- **The FCO's Special Representative's** international coordination committee will continue under the Chairmanship of the Special Representative to ensure the strongest possible links with our European partners to give continuing effect to the leading role of the UK in the fight against drugs established during our Presidency of the EU from January to June 1998. The UK will also take a visible lead in international coordinated efforts against drugs, through the UN and other mechanisms, where that has a direct contribution to make to this strategy's vision. Our resources will be made available accordingly;
- **statutory Inspectorates** - each HM Inspectorate will continue to have direct responsibility for monitoring the impact of drugs policies for which their agencies are responsible. The importance of collaborative working across and beyond the Inspectorates is recognised by all of them. A multi-disciplinary review process - involving representatives from HM Inspectorate of Constabulary, HM Inspectorate of Prisons, HMI Probation, OFSTED and the Social Services Inspectorate - will be established by December 1998. The importance of monitoring health authorities in this context will need further examination;

- **national programme delivery** - the role of Government is to facilitate and enable this strategy's implementation through leadership and resource provision. In areas such as publicity, spreading of best practice, project programmes, information collation, and specialist guidance, there is already expertise and experience among a number of organisations, funded by Government or others. In view of its valuable contribution to date, it is planned that there should be some successor arrangements to the Home Office Drugs Prevention Initiative after its current programme ends in March 1999, which will support this strategy and promote community-based drugs prevention across England. Other bodies with a role to play include the Standing Conference on Drug Abuse, the Institute for the Study of Drug Dependence, Alcohol Concern, the Substance Misuse Advisory Service, the Local Government Drugs Forum and the Health Education Authority. To avoid unnecessary duplication of effort, any work the Government commissions in support of the vision, aims and actions set out in this strategy - contracted to one or more of these agencies - will only be provided on the basis of clear partnership agreements;

- **Advisory Council on the Misuse of Drugs** - the ACMD has the statutory responsibility to advise Government on the continuing operation of the Misuse of Drugs Act 1971, and to any changes to the law necessary in the light of emerging evidence. The Council will continue to exercise that vital function. In addition, the Council has produced many extremely valuable reports on specific issues - most recently on drugs and the environment which will be published soon. Its composition and focus of work need to be harnessed as closely as possible to the thrust of this long-term strategy and to the work of the Coordinator, and its future work priorities will evolve in that context;

- **private sector** - the private sector plays a vital role at national, regional and local level in working to combat drug misuse. Many businesses now recognise the commercial benefits and ethical imperatives of involvement in this work. Some - such as BT, Boots, Proctor and Gamble, Marks & Spencer, Royal and Sun Alliance, McDonald's, Lloyds TSB - have already contributed significant resources and commitment to this work. Business in the Community is driving forward a major strategy programme to engage the private sector as systematically as possible - especially through initiatives aimed at young people;

- **voluntary sector** - much of the energy and innovation in tackling drug misuse, as well as professional and cost-effective delivery, comes from the voluntary sector. We are determined to maximise the contributions that this sector can make set against this strategy. The UK Anti-Drugs Coordinator will convene an annual national stocktake of voluntary sector providers, in concert with the Standing Conference on Drug Abuse, to ensure that their interests and contributions to the developing strategy are fully developed and properly used, and that best practice is being implemented;

- **the media** - responsible and informed coverage of drugs stories can make an important contribution to the strategy's vision. We will engage extensively with national, regional and local media to try to ensure a good level of informed debate, analysis and coverage;

- **parents/young people/communities** - drugs impact on all of us, our lives, worries and aspirations. We will consult and engage with people in schools, clubs, at parents meetings, with users, at community events and in all locations where there is real concern and real commitment to addressing it.

Audit and Evaluation

Objective and rigorous assessment of the effectiveness of implementing this strategy will be a central feature of its development, and necessary adjustments will be made as a consequence. The key components of this process will be as follows:

- the Coordinator's Annual Report and Plan of Action Against Drug Misuse which will be published every Spring, based on the strategic framework set out here, together with data on progress and proposals for future priorities;
- annual reports from Drug Action Teams in England made to the Coordinator - these will be submitted as part of the corporate planning process at the end of each calendar year. Results and best practice will be incorporated into the Coordinator's Annual Report and Plan;
- the statutory Inspectorates - regular thematic and multi-disciplinary reviews will be published by these bodies;
- quality indicators for the core statutory agencies - these will reflect the fact that the quantitative indicators to be set out need harnessing to more qualitative assessments of progress, which will form part of the DAT reporting process at local level and of an overview from the Coordinator's Annual Report and Plan;
- research and information - this will be regularly assessed against each of the strategy's four aims by the four strategy support groups, as an integral part of the implementation process. They will consult a wide range of external bodies as necessary, and report collectively to the Strategic Steering Group;
- independent strategic evaluation - over the longer term, we will all need to be satisfied that the implementation of this strategy is achieving the most effective results possible. The National Audit Office and the Audit Commission will be engaged in discussions about what might be undertaken over the next decade to fulfil this remit;
- consultations - the continual process of "listening and learning" which the Coordinator and his Deputy have undertaken from day one, will form a more informal, but essential, part of evaluating the strategy. They will continue this consultation for the rest of their appointments, so that progress on the ground - where it really matters - can be properly assessed.

Previous Contents

DR-1-

Laws that protect

Various laws exist for the protection of public health. But a lack of knowledge or a neglect of their provisions often results in drug induced ill health. Dr S.G. KABRA describes some of the cases that suffer due to a neglect or a non implementation of the law and the efforts made to bring breaches before law courts.

There are several laws, the provisions of which are meant to regulate health care facilities for the benefit of the public. Indifference to or neglect of these legal provisions engenders a tacit nexus between offenders and the authorities. It is therefore necessary to identify these legal provisions to create awareness and to evolve a strategy to ensure that the authorities entrusted with the enforcement of these provisions do in fact do so. Enumerated below are several laws with a direct bearing on public health.

Drugs and Magic Remedies (Objectionable Advertisement) Act,1954

In statement of objects and reasons :

"In recent years there has been a great increase in the number of objectionable advertisements in newspapers or magazines or otherwise relating to alleged cures of venereal diseases, sexual stimulants and alleged cures for diseases and conditions peculiar to women. These advertisements tend to cause the ignorant and the unwary to resort to self-medication with harmful drugs and appliances or to resort to quacks who indulge in such advertisements for treatments which cause great harm. It is necessary in the public interest to put a stop to such undesirable advertisements. This bill is intended for this purpose."

Taking into account specific provisions, Section 3 of the Act states :

"Subject to the provisions of this Act, no person shall take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for:

a) promoting miscarriage in women or prevention of conception in women; or
b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or
c) the correction of menstrual disorder in women; or
d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule,* or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act.

(* The Schedule appended to the Act lists 54 diseases, disorders and conditions which cannot be advertised.)

Section 4 of the Act states :

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains matter which : a) directly or indirectly gives a false impression regarding the true character of the drug; or b) makes a false claim for the drug; or c) is otherwise false or misleading.

No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes in Section 3. Under Section 9A of this Act, an offence punishable under this Act is a cognizable one.

A test case

Offending advertisements are a very common feature in the print media in India. To invoke the provisions of this Act, we initiated a test case in a magistrate's court in Ajmer against the then Editor and Publisher of The Hindustan Times, Delhi (Khushwant Singh and Dr Hans Raj respectively) for an advertisement by Dr Sablok which appeared in the newspaper. The case was registered only after letters written to the editor, drawing attention to the provisions of the Act went unheeded, the advertisements appearing unchecked. Though the case was ultimately dismissed through default, it did succeed in ensuring that all three defendants

appear in court whenever required through the execution of a bond and surety. The case also succeeded in establishing the following :

* The offence is cognisable. Any court in whose jurisdiction a newspaper or magazine is sold or circulated has jurisdiction in the case if the offence is deemed to be committed locally and the cause of action local

* The editor and publisher along with the advertizer are all equally liable to offence.

Efforts at implementation

After my deputation to SDM Hospital, Jaipur, I wrote letters to the Director, Health Services, Inspector General of Police and Health Secretary of Rajasthan, drawing their attention to the provisions of the law and its breach. There was no response. Marudhar Mridul, a leading lawyer of Rajasthan, agreed to file a writ petition which was decided on September 1989. The Hon'ble Mr. Justice SN Bhargava issued a directive to the Inspector General of Police, Rajasthan, to establish a special cell to monitor such advertisements in the print media and initiate prompt action against the offenders. Some cases have been registered by the police. Some of the newspapers have stopped carrying such advertisements. Much still remains to be done to fully get the court's order implemented.

Drugs and Cosmetics Act

This Act provides for the control and regulation of safe production, distribution and sale of drugs and cosmetics. Powers to enforce the provisions of the Act are vested in the State Drugs Controllers whose activities are coordinated by the Drug Controller of India who in turn ensures the uniform application of its provisions throughout the country.

Despite its existence, precious little has been done to implement its provisions. A case in point is drug induced blindness. Eye drops and ointments with steroid content are widely used for allergic conjunctivitis. Due to prolonged use of eye drops, I have known several cases turn blind through drug induced glaucoma and cataract. Though every text book of medicine and pharmacology mentions that steroids should not be used for prolonged periods, no warning to this effect is written on preparations. The implications are specially ominous when one considers the fact that self medication is a very common phenomena. Even well meaning parents regularly administer eye drops to children, oblivious of the dangers. The six year old son of a compounder first put me on the trail which led me to compile over 18 cases of blindness in

one year due to prolonged use of steroid - containing eye drops. None had been warned.

Letters were written to apprise the Drug Controllers of Rajasthan and India of the cases in point. Articles were written in the lay press, giving case histories of the patients to highlight the dangers of steroids in eye medicines. One such article which appeared in Rajasthan Patrika, a Jaipur daily, attracted the attention of the local government. A committee of experts was appointed to investigate the facts and to submit their report.

The committee recommended that all steroid eye preparations should carry a warning that the medicine's prolonged use may lead to blindness due to cataract, glaucoma or fungal infection. The State government forwarded the recommendations to the State Drugs Controller, who in turn, instead of acting under the provisions of the law, forwarded it to the Drugs Controller of India. The Central Drugs Controller returned it to the State Drugs Controller, agreeing with the recommendations of the Committee. The State Drugs Controller still did not act. Even the report of the Committee was not made public.

A writ petition was then filed in the High Court on 20th January 1989. Hon'ble Mr. Justice Mahendra Bhushan Sharma and Mr. Justice I.S. Israni directed the Drugs Controller of Rajasthan to ensure printing of the necessary warning on all steroid-containing eye preparations. Their lordships quoted extensively the specific rules under which the State Drugs Controller had the power to implement the provisions so as to allay any impression to the contrary.

Though a number of steroid preparations now carry a warning, many still do not. Despite a large number of cases brought to his notice, no public warning was issued by the Drugs Controller against the prolonged use of steroid-containing eye drops. Partially implemented, the court order has not been followed in true spirit.

Banned and bannable drugs

According to a writ petition filed under the Drugs and Cosmetics Act, the decisions of the Drugs Consultative Committee and the Drugs Technical Advisory Board, the highest technical bodies under the Act, once accepted and communicated by the government, are binding on all health authorities and government doctors. A drug that has been declared harmful or irrational by the technical bodies cannot be purchased or prescribed by any government authority. This is irrespective of the fact that government orders prohibiting manufacture and sale of the drug might have been stayed by a court. Prohibiting the manufacture and sale of a drug and directing all government doctors not to prescribe a drug found to be harmful are two different consequences that flow from the decisions of the two technical bodies.

An interesting observation made by the court during the hearing was that a stay order by one High Court is not automatically binding on the other High court. Evidence of banned drugs still being purchased, prescribed and reimbursed by health authorities was produced before the court. The case is still pending before it.

Atomic Energy Act, 1962

The Atomic Energy Regulation Board constituted by the Central Government under the provisions of the Act have codified the mandatory safety provisions for diagnostic x-ray units. The safety code details the mandatory measures necessary to prevent unnecessary exposure to radiation. Yet no state government machinery exists to ensure that these safety provisions are followed. The result : no x-ray units follow them. With commercialisation of diagnostic x-rays and their rapid proliferation, there is grave danger to the population. After having written to all authorities bringing to their notice the mandatory provisions and having failed to persuade them to fulfill their responsibilities under the Act, a writ petition has been filed in the High Court with notices issued to the central and concerned State government.

The Indian Medical Council Act and the Medical Degrees Act

Provisions of these two Acts have been invoked to prevent advertisements and unethical practices, professional misconduct and the use of unrecognised or fake degrees by doctors. The State Medical Council must be made to do its duty to regulate and supervise the professional conduct of the doctors registered with it and to ensure ethical standards of medical practice.

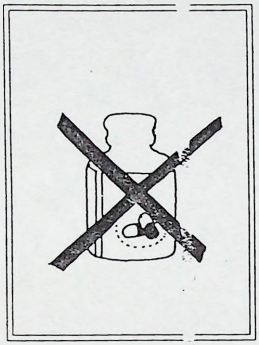
The Insecticides Act.

The provisions of this Act have been invoked to prevent the availability of the deadly pesticide, aluminium phosphide, in the open market. Numerous articles have been written to bring to light a large number of deaths that result every year from aluminium phosphide. All the concerned authorities have been warned. Questions have been raised and answered in parliament. Though there are widespread assertions on the illegality of open market sale of aluminium phosphide, nothing has been done to prevent it. A writ petition, it is felt, should now be filed to prevent thousands of deaths due to this deadly pesticide.

– Dr S.G. Kabra is a Professor of Anatomy, a trained surgeon, a medical journalist who has also done law and written extensively on medical - legal issues.

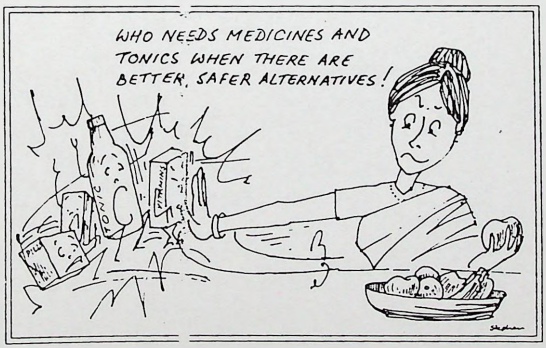
CONSUMER ACTION

WHAT YOU CAN DO



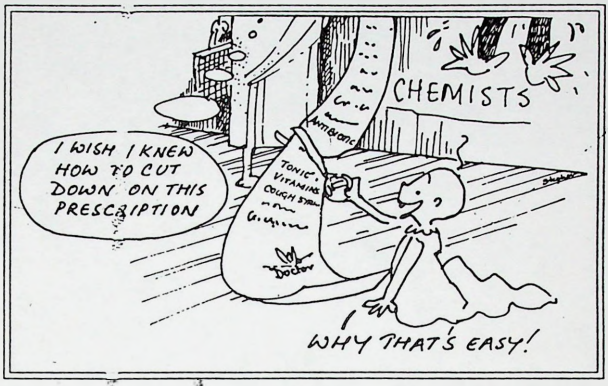
1. Stop using banned and hazardous drugs. Stop using useless and irrational drugs.

2. Whenever you are prescribed a drug, ask your doctor politely what side effects may occur, how long you should continue taking the drug and what are the expected benefits. Know your rights as a patient.

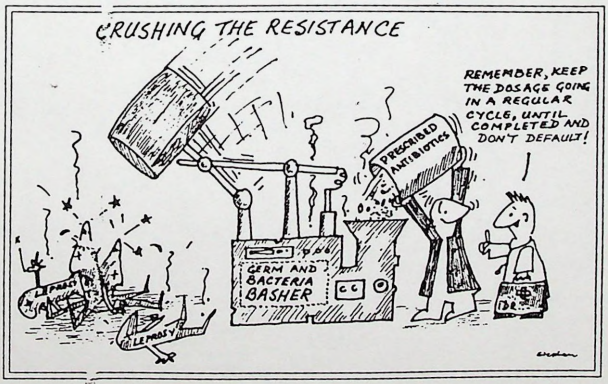


3. Encourage the use of traditional home remedies, instead of expensive and unnecessary drugs for trivial problems.

4. Refuse to take a drug if it's expiry date is over, or if it is discoloured and if there are suspended particles in it.



5. If given a very long prescription, find out which are the most essential drugs for your health problems and which can be avoided. (Studies have shown that many patients can buy only the first one or two drugs listed on long prescriptions).

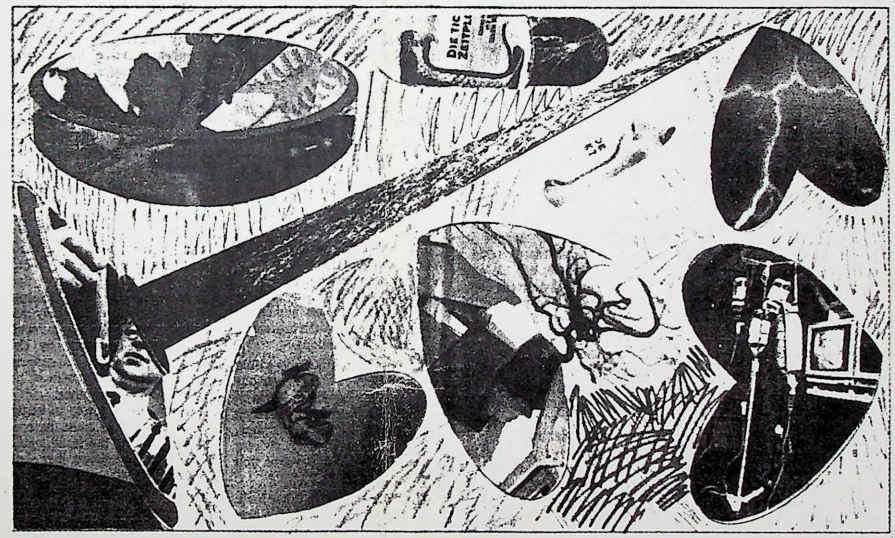


6. Ensure that anyone prescribed antibiotics or put on long term treatment, as for TB or leprosy, takes medicine regularly and for the required length of time to avoid emergence of drug resistance.

DR-7

New Drug Policy has many loopholes...

From the consumer point of view any drug policy should not only ensure good quality of medicines at reasonable prices but also eliminate irrational, useless and hazardous drugs. In addition, an ideal drug policy should provide a graded, essential and priority list of drugs in keeping with the actual health needs of the people. But the NDP does not seem to answer any of these requirements, writes Y G MURALIDHARAN



AFTER a long wait of eight years the New Drug Policy (NDP) has been announced, the objective of which is to create 'conditions of adequate availability of medicines of good quality at reasonable prices'.

While the objectives are laudable, one doubts whether these would be achieved in the light of the earlier experience and the contents of the NDP.

For, what we have as a drug policy is basically a pricing and production policy where the dominant force is the 'profit motive'. It is a policy which is heavily oriented towards the benefit of the multinationals. It attempts to address many of the problems facing the drug industry and not the availability of cheap and good quality medicare to the public.

From the consumers point of view any drug policy should not only ensure good quality of medicines at reasonable prices but also eliminate irrational, useless and hazardous drugs.

In addition, an ideal drug policy should provide a list of graded essential and priority list of drugs in keeping with the actual health needs of the people. But the NDP does not seem to answer to any of these requirements.

For the past many years, the objective of drug policies has been hovering around the same principles of price, quality and easy availability. For instance the S.L. Bhatia Committee (1963) laid emphasis on quality and recommended centralisation of drug regulatory set up in the country. The Borkar Committee did the same a few years later.

During 1974 the Jaisuklal Hathi Committee not only recommended strengthening quality control measures, but also nationalisation of multinational drug companies, establishment of a National Drug Authority, elimination of irrational drug combinations etc., While these recommendations were put to practice in the neighbouring Bangladesh, it was not implemented in India.

Even the successive Drug Policy statements of 1978, 1982 and 1986 had similar objectives. These statements aimed to ensure that drugs are available in abundance to meet the health needs of our people, to make drugs available at reasonable prices, to keep a careful watch on the quality and malpractice etc.,

But none of these objectives have been achieved. India is a signatory to the Alma Ata of bringing health to all by AD 2000. Only a miracle can bring about this in another five years.

One of the objectives of the NDP is to control prices. But how does it propose to do? By decontrolling more drugs! The NDP states that 'it has been decided to keep the drugs having an annual turnover of Rs. 400 lakh or more under price control'. In effect drugs, the turnover of which is below Rs. 4 crore will be out of price control.

As a result of this decision, the number of drugs under price control will get reduced to 73 from the present 142 and the span of control to about 50 per cent from the present 70 per cent.

Decontrolling half of the present drugs under control would definitely mean rise in prices. As such it would defeat one of the objectives of the NDP. The policy further states that the government would keep a close watch on the price movement of drugs not in the list and reclamp price control, if necessary.

But the earlier efforts in this direction have not been encouraging. Drugs came under price control for the first time in 1962. The Drugs (Display of Price) Order 1962 and the Drugs (Control of Price) Order 1963 were promulgated under the Defence of India Act, freezing prices of medicines as of April 1, 1963.

The Drugs Price Control Order (DPCO) 1970 was issued under the Essential Commodities Act 1955 to bring down prices of 17 essential bulk drugs and their combinations. The DPCO 1979 and 1987 was also issued with the same objective.

Despite price control mechanism, prices of drugs have increased steadily. And many of the drug industries have been pulled up by the courts to pay back the excess amount collected on price controlled drugs.

Following the Supreme Court verdict against over-pricing by drug companies the government is to realise Rs. 270 crore from the industry. The available figures indicate that the actual recoveries is not more than Rs.13.82 crore up to 1992.

However in reality, prices of all categories of drugs have increased by almost 50 per cent. The prices of cardiac and hypertension drugs have increased by 40 per cent. Similarly, prices of anti-TB drugs like Rifampicin have gone up by 40 per cent in the last two years. Several essential drugs are not available in the market.

Even after the DPCO of 1987 was issued prices of drugs has shown an upward trend. Though the government intends to monitor price rise, one cannot be optimistic about it. Way back in 1978, the Lovraj Committee was set up to investigate the allegation of large profits of foreign companies, suggested that the effect of DPCO (1979) on profitability of the drug industry should be assessed periodically. So far no attempt has been made to monitor prices and profits.

The NDP states that prices would be kept in check by forces of market com petition'. One need not be an economist to understand the economics of drug industry.

The Indian drug industry has all the problems associated with an oligopolistic industry dominated by a few private firms and an industry dominated by foreign companies i.e. MNC's.

As such, market is a poor mechanism for regulation of prices of drugs. Production and price control measures are very much essential to ensure drugs at low prices.

Secondly, the market for drugs is not determined by consumers but by pharmaceutical companies, detail men (medical representatives) and doctors. Unlike all other commodities in the market, in case of drugs, the consumer has no say over the choice of the commodity he purchases. He goes entirely by the doctor's prescription.

The very fact that the concept of 'turnover' has been taken as basis to determine drugs which are to be brought under price control is itself an indication that the NDP is trade oriented.

Although medicinal products constitute essential tools for health care, it is observed that drug policies are often directed towards industrial and trade development. It is precisely for this distorted objective, that the drug policy is formulated by the Ministry of Chemicals and Fertilisers and not by the Ministry of Health.

This is the first time that we have a policy which determines the list of drugs under price control on the basis of turnover. In the DPCO 1976, essentially was the basis for categorisation of drugs. The Kelkar Committee list of drugs for DPCO 1987 also used essentiality as basis. This concept of essential drugs find no mention in the NDP.

According to the Health Action International (HAI) an essential drug is one which meet real medical needs, has sufficient therapeutic value, be acceptably safe and offer satisfactory value for tial drugs are those that satisfy the health care needs of the majority of the population.

Some efforts have been made in the past to prepare a list of essential drugs with the main objective of price control. The Committee on Essential Drugs (1967) listed 17 drugs. The Hathi Committee gave 104 drugs as essential.

The Drug Policy of 1978 prepared 37 bulk drugs grouped in Category I and II which are highly essential and life saving. The Steering Committee of NDPDC shifted from the essential drug list and prepared priority list of 96 drugs.

However, simultaneously efforts were not made to ensure production of these price-controlled essential drugs and check proliferation of non-essential drugs. The NDP states that the DPCO will be issued in "three months time". This was in September 1994. The DPCO is yet to be announced. The time lag has given enough opportunity to the interest groups to step up their lobbying efforts at New Delhi, to be out of the list.

It is fortunate that the NDP has a provision for setting up an authority for price fixation. This is a welcome move. The NDP states that the government would set up an independent body of experts to be called the Pharmaceutical Pricing Authority (NPPA) to do the work of price fixation. In addition it will also oversee the enforcement of the provisions of the DPCO. The degree of autonomy of this proposed authority is to be watched.

For the past few years drug manufacturers have been trying to pressurise the government to concede its demand for decontrol of production, and pricing. The drug industry has been claiming that its turnover and profit have suffered due to controls. And the NDP has favoured the industry. But in reality, the sales and profits of drug companies have increased over the last few years. The half yearly results (up to March 1994) of drug industry shows that sales has gone up by 32 per cent and profit by 84 per cent.

Another set back to consumers is the provision in the NDP to bring companies with foreign equity up to 51 per cent on par with wholly Indian companies. The NDP states that automatic approval would be given for foreign technology agreements, as per the Industrial Policy for all products except those produced by the use of recombinant DNA technology'. Since the government aims to revise the drug policy "so as to bring it in consonance with the Industrial Policy 1991 and the present EXIM policy" allowing foreign companies is no surprise.

Allowing foreign companies (already we have in surplus) to operate without restrictions would hit the welfare of the consumers. It is well known that MNC's are interested in the financial health of the companies and not in health of consumers. Secondly, they are not interested in producing essential bulk drugs, but in multiplying unnecessary medicines, tonics and syrups. The recommendations of the Bhore Committee, Sokhey Committee, Mudaliar Committee and the Hathi Committee have warned the exploitation of the consumers in our country by the MNC's. Again these MNC's utilise developing countries including India, as dumping grounds for substandard and discarded drugs which have been banned in the country of origin.

Due to extensive price decontrol, liberal licencing and free access to multinationals, the drug market will go unregulated. This will lead to economic drain of crores of rupees on non-essential drugs. As long as the industry is free to produce what it likes, it is almost impossible for the customers to get rational drugs. Backed by vast promotional network, the MNC's are capable of distorting the genuine marketing information and pushing the people to consumer irrational drugs. Non-essentials like tonics, vitamins, health drinks, digestive enzymes, sex stimulants and cough expectorants will increase as against essential drugs to combat TB, Malaria etc.,

A welcome feature of the NDP is that it provides for setting up of a National Drug Authority (NDA) to ensure quality control and rational use of medicines. The NDA to be set up by an Act of Parliament would also prepare and publish national formulary and also the formularies relevant to various levels (like district hospitals, community centres, PHC etc.,) for the guidance of consumers as well as doctors. One hopes that drug information, which is almost absent in the country would be soon available to consumers.

The establishment of more zonal and sub-zonal offices under the Central Drug Standards Control Organisations as well as additional regional drug testing laboratories is a welcome move. If the quality of drugs is not up to the mark, it is also because of insufficient manpower, and other facilities. The NDP needs to be reviewed before implementation so that the welfare of the consumers will get priority and not the industry as it is now.

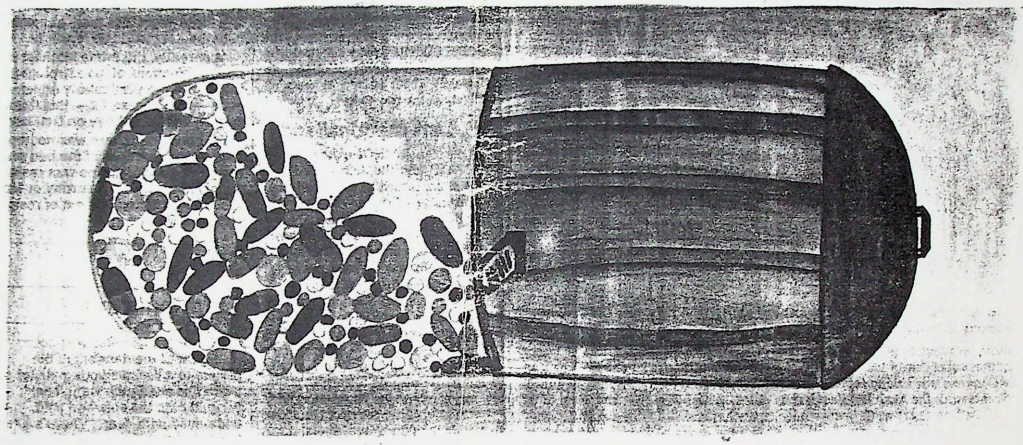
THE DELCAN HERALD

DR-1

FORUM

The big question on drugs — healers or killers?

Sub-standard drugs, contaminated intravenous (IV) fluids and infected blood have been taking their toll of innocent lives quite regularly. It is strange that medicines and drugs which are meant to cure patients are killing them, says Y G MURALIDHARAN



DESPITE differences of opinion with regard to the quantum of sub-standard and spurious drugs, the fact remains that the country's drug market is not all that clean and safe. Though sub-standard drugs have been in the market for a long time, it caught the attention of the public after the J J Hospital tragedy of 1986, in which 14 patients died due to contaminated glycerol. The findings of the Justice Lentin Commission which went into the causes of the tragedy are too known well to be repeated.

Over the years a number of studies have established that a substantial number of drugs sold in the market are either sub-standard or are not up to the mark. Thirty years ago the Drugs Equipment Standard Committee found that one out of every five (20 per cent) drugs are either sub-standard or spurious. In 1986-87, over 26000 drugs drawn by drug inspectors of various states revealed that nearly 4000 samples were of low quality.

The Joint Council of Pharmacists of Delhi alleged that as many as 16 per cent of indigenously produced drugs could be sub-standard. However none of these figures are palatable, to the Drugs Control officials or the FDA. The reason, apart from others, lie in the concept of sub-standard or spurious drugs.

The definition of sub-standard drugs is wide and includes all drugs which do not meet the prescribed standards like improper colouration in tablets and chipped tablets. However, from the common man's point of view, sub-standard drugs are those which do not conform to the standards as specified by the Drugs and Cosmetics Act 1940.

While sub-standard drugs can be manufactured by licensed manufacturers, spurious drugs are those which may be manufactured and sold by unlicensed manufacturers. Stated in simple words spurious drugs are those which are (a) manufactured without license (b) manufactured/ sold without testing (c) the content of active ingredient is lesser than that mentioned on the label (d) drugs sold on the basis of false laboratory analysis report. Many drugs available in the market will fit into one of these definitions.

Patients have been put into great difficulty by contaminated eye solutions and IV fluids. It is feared that hundreds of elderly people may have turned completely blind because of a contaminated eye solution used during cataract surgery. It has now come to light that a batch of 20000 vials of the Balance Salt Solution (BSS) sold in 1992 contained a chemical preservative that causes the cornea to turn opaque.

In another case, at least five persons lost their eye sight due to administration of contaminated solution after eye surgery in a private hospital at Kochi. When complaints of eye sore, blurred vision etc,. came in, tests were conducted which showed that Irgasol, used intraoccularly had fungus called Aspergillus which infected the eye leading to loss of vision.

Perhaps more than drugs and medicines, it is contaminated IV fluids that has had sent patients into unnecessary trouble. If Bombay leads in spurious drugs, New Delhi has the dubious distinction of more cases of contaminated IV fluids.

During 1989, life saving IV fluids reportedly claimed seven lives in Delhi of which two were in the Safdarjung Hospital. In the same year, at the All-India Institute of Medical Sciences, a highly contaminated bottle of IV fluid was found by a doctor just before it was to be injected. The CBI registered a case against the Drug Controller of Delhi and a pharmaceutical firm of Coimbatore which had supplied contaminated bottles of IV glucose to a Delhi based dealer.

A study conducted in 1989 by the Voluntary Health Association of India, came out with several unpleasant facts. As per medical norms, IV fluid should be manufactured in sterile, automatic units with no physical contact. But the study found that due to lack of contamination test units, in several states, the fluid is taken to other places, which may lead to contamination.

Again, the temperature limit for these fluids (maximum 35 degrees celcius) is also often ignored even during summer months. The study has pointed out that since many storage depots lack adequate air conditioning facilities, the solution expires much before the scheduled date.

With Ayurvedic and Homeopathic medicines gaining popularity, there are reports of selling sub-standard or adulterated traditional drugs. It was reported that in the Delhi liquor tragedy of November 91, in which 175 people died, liquor was sold under an Ayurvedic label. Such labels are used because traditional medicines can be sold by anybody and can also avoid Excise Duty.

When the Centre received many complaints of sellers misusing Ayurvedic labels for liquor, the Health Ministry set up a committe under Prof. Nam Joshi which suggested that Ayurvedic drugs which contain alcohol should be in small 30 ml bottles, so that it should not be possible to consume them in large quantities. It also suggested that no color should be added to drugs so that consumers should know by the transparency that they contain alcohol.

Unethical business practices does not end here. There are also cases of fake syringes, saline etc., being sold as 'sterilised' and 'non-toxic'. With the spread of AIDS, disposable syringes is now mandatory. But these disposed syringes are collected by unscrupulous scrap dealers and are sold with labels of reputed pharmaceutical companies. In one case the West Bengal police found that one seller had sold contaminated syringes worth Rs.12 lakh to the Burdwan District Hospital. They also seized lables which said that the syringes were gamma ray sterilised, while there is no gamma ray machine in the whole of Eastern India.

Innocent consumers have been taken for a ride by scrap dealers who sell drugs by recycling rejected and expired capsules, tablets etc., discarded by the multinational pharmaceutical companies. According to the guidelines issued by the Drugs Control authorities, the manufacturer is expected to grind pills, crush bottles, shred lables and foil wrappers before any of the rejected material is handed over to the scrap dealer. But very rarely the manufacturer follow these guidelines. Otherwise how could Bombay's 'Dawa Bazar' be a centre for fake drug business? In a massive raid, the Bombay drug inspectors seized 5.75 lakhs of recycled capsules of which 3.75 lakhs were intended to be life saving drugs.

A recycling trade in drugs exist because of faulty systems of waste destruction, allowing rejects to be smuggled out of the factories instead of being destroyed. Drugs which expire are supposed to be returned by the distributors to the manufacturer in time. It is here the scrap dealers play their trick. Drugs are smuggled out of gowdons and sold to unsuspecting consumers.

In India we have the Drugs and Cosmetics Act 1940, which provides for the Government to control the manufacture of drugs and cosmetics. The Act also lays down principles of fixation of prices of drugs. In addition to this, the Drugs Control Act 1950, The Drugs and Magic Remedies (Objectionable Advertisement) Act 1956, Drugs Price Control Rules have been framed to protect the health of the consumers. Yet consumers interest is in jeopardy many a time.

The existence of sub-standard drugs may be attributed to several factors. Firstly, there is no organised effort equal to that of the turnover, to check and ensure the quality of pharmaceuticals. At present, testing facilities are available only in Bangalore, Calcutta, Ghaziabad and Kasauli. As a result, these centres are overburdened and are unable to check required lot of samples.

To overcome this problem partly, the Drug Rules (1977) was amended according to which every drug manufacturing unit, big or small should set up an 'in-house' laboratory for testing drugs. While this is a right step in right direction, it has its pitfalls. While multinational companies obliged without any effect on their sales, small units had their own problems. Secondly, the Government health schemes like CGHS, ESI etc., which are the largest purchasers of drugs (around Rs.30 crore) have few testing facilities. The inadequate number of drug inspectors is another reason for unchecked growth of spurious drug sales. It is estimated that just five per cent of drugs are subjected to quality tests. The Hathi Committee recommended that proper check could be maintained if there was one drug inspector for every 25 manufacturing units and one inspector for every 100 sales outlets. However, even now not even one-fourth of the required inspectors are available. There are nearly 20000 manufacturing units and two lakh sales outlets in the country with 680 to 700 drug inspectors. This figure is grossly inadequate even as per the recommendations of the task force set up in 1990-91 which suggested 2690 drug inspectors. As such the first step to ensure quality is to enhance manpower.

Secondly, steps are to be taken to implement the rules and regulations under the Good Manufacturing Practices (GMP) which India as a member state has agreed to. The practices as laid down in the GMP are designed to ensure that the drugs received by the consumers have been subjected to stringent control from the begining to the end of the manufacturing cycle involving the operations of processing, compounding, formulating, filling, packaging and labelling.

Again the responsibility of the drug company does not end with the manufacturing of a drug. The manufacturer has to take care that the drug is stored under prescribed appropriate storing conditions in the factory warehouse and the same has to be followed by the dealer and the chemist who is the last point before the drug is passed on the consumer.

Ultimately it is the duty of the consumer to be careful while buying the medicines.

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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 and 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 drugs 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. **Drug Nomenclature**

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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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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DR - 1.

Drugged policy

Senseless, it lets people die of dangerous pills

PERSISTENT fever dogged N. Narasimhan, managing director of Crystal Cab Pvt Ltd., Bangalore. Doctors put him on an oral 'Ultragin' course for five days. On the sixth day, however, his condition took a turn for the worse and he developed purpuric rashes. Eventually, he had to be shifted to the intensive care

The massive doses of Ultragin, an analgin-based antipyretic had induced a life-threatening condition known as 'thrombocytopenic purpura'. The drug, banned in several countries, had severely affected Narasimhan's bone marrow and caused the platelet count to fall drastically. Timely medical intervention saved his life but many others may not be so lucky.

For, India, which has no rational policy, is a dumping ground for many banned drugs.

Take the case of Clioquinol, an anti-diarrhoeal that has partially blinded many Japanese. Ciba-Geigy withdrew the drug from Japan in 1976 after the victims went to court and banned it in 1986. Yet it is still prescribed in India.

The story of estrogen-progesterone drugs used for pregnancy tests is not very different. Safety to the unborn child cannot be ensured and the users face an increased risk of clotting and stroke. However, India banned them only in 1988, seven years after the WHO issued a warning.

The Drug Controller of India had, in fact, called for a ban on them in 1982, but two companies—Unichem in Bombay and Organon in Calcutta—went to court and obtained a stay order. Drug companies invariably go to court whenever a ban is announced.

The fact is that the world can do without thousands of drugs in the market. All it needs to treat the diseases is just 250 drugs, according to the WHO. Since disease patterns vary in different countries, each country has to choose the drugs it needs most.

The Jayasukhlal Hathi committee appointed by the government in 1975 reviewed the overall medicational needs of India, and recommended guidelines for its future drug policies. The report pointed out that the Indian pharmaceutical industry was capable of manufacturing all the essential drugs needed by the country and that the multinational companies were hindering the growth of the Indian drug industry.

The committee recommended the nationalisation of the multinational drug companies and use of generic names instead of brand names. Use of generic names, it said, would make the manufacturers reduce expenditure on promotion of brand names and cut the drug prices. Among the other recommendations were priority production of 116 essential drugs, elimination of irrational drug combinations and improved quality control.

Most of the recommendations have not yet been implemented in India. But the report did not go waste. It inspired the drug policy of Bangladesh, which banned many unessential and hazardous drugs. There are under 3,500 drug formulations in Bangladesh today while India has nearly 70,000. In Norway and Sweden, there are hardly 3,000 formulations representing about 300 essential drugs.

According to Dr Shirdi Prasad Tekur of Community Health Cell of Bangalore, "Every fifth drug tested in India is substandard; yet half of the drugs in India are sold without prescription." India's drug policy, he says, is a mere pricing policy.

The doctors who demand a rational drug policy point out that India produces only a third of anti-TB drugs it requires; the country has half the world's TB patients. Be-

Fighting a tough battle. Members of the Community Health Centre, Bangalore, who advocate a rational drug policy

Banned but available

A few drugs which are banned in other countries, but still manufactured and sold in India:

Analgin and Analgin combinations. (Ultragin, Baralgan, Buscopan, Oxalgin, Novalgin, etc.)

Clioquinal, Hydroxyquinoline, Vioform, etc. (anti-diarrhoeals)

Phenyl Butazone and Oxyphenbutazone. (Bestophen, Butalgin, Butaproxyvon, Esgipyrin, Reducin, Suganril, Zolandin, etc.)

came. Now we have reached a stage where we can't cope with more," elaborates Birinder.

She changes the potted plants in every establishment every week. The flower arrangements are done either every other day or twice a week depending on the client's needs. "But Mondays are busiest days as everyone wants to start the week with a new flower arrangement. Over a thousand pots are rotated every week, and a very large number of flower arrangements are done by us."

With her home garden and farm not enough to meet the demand she started buying flowers from outside. "I buy the flowers from growers in Chail, Dochi, Shimla and other parts of Himachal," she says. Among her suppliers is an army officer-turned-flower grower from Fatehgarh Sahib district of Punjab.

THE business has clearly grown. "In fact,we have reached saturation point. I started with less than a thousand rupees, now the investment is about Rs 60,000 to 70,000 a month. Where I had one gardener, I have almost 50 employees now, and an outlet at a hotel here. But all these things happened so gradually, step by step, that it is difficult to quantify the income and expenditure, turnover, net profit and so on. Also, it being an agricultural activity meant no income tax."

Happiest with Birinder's business are perhaps the potters of Mani Majra village in Chandigarh. They owe their newfound prosperity to her as she keeps designing pots for them, and constantly goads them to improve the quality of pots.

AT a glance, her tightly centralised venture is more in the class of a small shop rather than an institutionalised business, but Birinder is emphatic that she cannot grow more. "I don't even take orders for flower arrangements and pot rotations in Panchkula or Mohali (both about 5 km from the city periphery)," she points out. Nor does she try out new strains and varieties sought to be popularised by flower growers collaborating with counterparts in Holland, Israel, etc. "I do them the traditional way, stick to our own varieties with the philosophy of maximum utilisation of inputs. These are the best suited to our climatic conditions," says she.

Her work involves the whole day, the whole year with seed sowing beginning in September, and going on up to January. The new year begins with planting of seedlings, and growing the flowers, picking of seeds in April, drying and packing them. Then the time for summer seedlings begins, and before that is over, it is time for chrysanthemums.

There is no lean period for her. "For me being in the garden is holidaying, so I don't need to go out anywhere." Nor does she read books on gardening and flowers, for the garden and flowers directly teach her more than books, she believes.

The judge at the rose festival may or may not acknowledge it, but it is generally believed in this city that a number of those determined to walk away with prizes in fact buy the plants and flowers at Birinder's nursery and pass them off as the flowers of their efforts. Her businessman husband does not even know the name of one flower from another, but her children have taken keen interest. They too have been entering the rose festival, though the hobby-turned-business is exclusively Birinder's.

—VIJAYA PUSHKARNA

■ **Maintain quality:** Her winning flower arrangements remain unbeaten in Le Corbusier's city. In fact, she acquired many of her clients when people who had seen her work passed on details to others by word of mouth. In a way her quality ensured free advertisements for her products.

■ **Expand gradually:** Her business has grown slowly but surely. Do not rush into expansion without checking whether the market can take your production.

Goodwill: The prosperity of many small businessmen like the flower grower in Fatehgarh and the potters in Mani Mara is linked to her venture. A very important asset in any business.

START YOUR OWN BUSINESS

INFORMATION on the various types of loans is continued from the previous column. We had mentioned how entrepreneurs could raise funds for their equity and venture capital, working capital and loans against the borrower's assets.

We give below other sources which small-scale industries can tap to raise funds:

■ **Hire-purchase:** This loan is usually given when the SSI unit wants to purchase plant or equipment. Source: Financial institutions, National Small Industries Corporation, State Small Industries Corporations. Some private finance companies too have entered the field now. Terms: The machinery bought with the loan is generally hypothecated to the institution which has advanced the loan. The interest is charged at a flat rate over the duration of the loan. In certain cases borrowers are required to furnish collateral security.

■ **Leasing finance:** If an entrepreneur wants to lease some equipment or the plant itself, he can approach banks, financial institutions or leasing companies for leasing loans. The amount and the duration of the loans are based on the economic life of the machinery. The interest rate is usually higher than the short and medium term loans but payments are fully deductible from pre-tax income.

(To be continued)

sides, drugs like streptomycin which are needed for the treatment of TB are marketed in unnecessary and hazardous combinations.

For the last two years, the Supreme Court has been hearing a public interest litigation which, the medical fraternity hopes, will lead to the weeding out of hazardous drugs and to a more rational use of drugs. Dr Sridhar of Community Health Cell has already launched a programme to educate people about hazardous, banned and bannable drugs.

The Indian myopia is clear from the fact that the government has clubbed drugs and pharmaceutical products with industrial products. It is no surprise then that the minister of chemicals and fertilisers—not the health minister—announced the new drug policy on September 15 last year.

If the Hathi committee had sought nationalisation of multinational companies, the new drug policy promised automatic clearance for any new company with 51 per cent foreign equity. The plight of Indian companies will worsen when GATT laws and the Dunkel draft replace the Indian Patent Law of 1970. Since Dunkel draft stipulates product patent, Indian companies which have developed inexpensive drugs under the process patents will have to close shop.

Recently, Eli Lilly of the US and Novo of Denmark obtained the 'product patent' for insulin. This means Indian companies which know how to make insulin will not be allowed to make it. Naturally the price of insulin will increase.

The medical fraternity, too, can do with better awareness. That is why doctors like C.M. Francis, coordinator of the Community Health Cell, Bangalore, feel the need for a national formulary modelled on the British National Formulary published by the British Medical Asscian and the Pharmaceutical Society of Great Britain. Updated every six months, it gives a range of costs for rational drugs and helps doctors avoid prescribing irrational combinations. Dr Francis also wants the government to provide a medical auditing system to monitor over prescribing, costly prescribing and wrong prescribing.

An authentic source for information on prescriptive drugs in India. P.V.V. Krishnan, editor of CIMS (left) depends on information from trade journals

Currently, the doctors rely on the tri-annual *Current Index of Medical Specialities* (CIMS), published by the Bangalore-based Biogard Medical Services, for information on drugs, their formulations, brand names, prices and contraindications.

It recently introduced a column 'Alert Index' that offers data on drug interactions and adverse reactions. "CIMS gets its information from the pharmaceutical industry and trade magazines. It keeps track of the international drug scene through the British pharmaceutical manual, *Scrib*," says P.V.V. Krishnan, director of Biogard.

Noting that there are 20,000 pharmaceutical units in India, producing nearly 70,000 formulations," Dr Tekur says that the drug controlling and inspecting apparatus is grossly inadequate. Drugs banned in India are sold over the counter by unscrupulous pharmacists, claims another doctor. Anand Rajashekar, drug controller of Karnataka, says that hardly any such case came to the notice of drug controllers last year. "The drug control act (1940) has been quite stringent," he says.

Many doctors do not agree. In the absence of a rational drug policy in the new liberalised and competitive era, they fear it would be easier for medical horrors like the thalidomide tragedy to recur. Taken by pregnant women, thalidomide caused birth deformities in 10,000 children during the early sixties in West Germany. Irrational use of drugs cannot but give birth to such medical holocausts.

—DR VEENA BHARATHI

Required, a new policy

COMPONENTS of a rational drug policy prepared by the All-India Drug Action Network and Voluntary Health Association of India.

- **Drug availability/production in consonance with health needs of the people.**
- **Elimination of irrational, useless and hazardous drugs.**
- **Low cost drugs in adequate quantities particularly essential/priority drugs.**
- **Adequate quality control and drug control.**
- **Availability of unbiased drug information and ethical marketing of drugs.**
- **Drug legislation reform.**
- **Generic prescribing.**
- **Technological self-reliance.**
- **Increase drug availability through fair price shops and government health infrastructure.**
- **Training of health personnel in rational therapeutics and rational drug policy.**

INDUSTRY

MARCHING ON

■ Indian industry is marching ahead, going by the trends in the month of March. The index of industrial production went up by as much as 11.7 per cent for the month—the highest monthly growth seen since May 1990.

The fiscal year 1994-95 ended with industrial production growing by 8.4 per cent as against the 5.6 per cent growth in the previous year, says the July review of the Indian economy published by the Centre for Monitoring Indian Economy Private Limited. During 1994-95, the biggest growth was witnessed in the manufacturing sector which grew by 8.8 per cent. Power generation which grew by 8.5 per cent was followed by the mining and quarrying segment with a 6.3 per cent growth.

When viewed from the use-based classification of industries, the capital goods industry contributed more than 50 per cent to the growth in the overall industrial sector during 1994-95.

Meanwhile, the overall foodgrains production is expected to be around 191 million tonnes during 1995-96, showing a nominal increase of 0.7 per cent over and above the 4 per cent increase recorded in 1994-95.

COMPUTERS

A TIE-UP

■ Informix, the world leader in parallel processing database technology, and Netscape have signed a world-wide web agreement. The Informix database servers will now be available in the Netscape Internet Applications (TM) family of turnkey solutions. Netscape Communications is a giant in open software for electronic commerce on the Internet.

"Through this agreement, we can bring the parallel processing power of online dynamic server and the simplicity of Informix-Se to that essential group of users who are laying the foundations for electronic commerce on the Internet," says Govind Nangrani, Informix general manager.

Informix had opened its India business office and software development centre for product development in Bombay in July.

The 'green' rubber

A Malaysian-born Indian chemist has answers to the tyre mountains

THE "Canadian fire" lasted for 12 years: Virginia fire earned its notoriety in 1993; there was another tyre mountain fire in Australia. These are the tiring problems encountered by environmentalists today. India, ten years from now, will have tyre mountains too.

B.C Shekar, a Malaysian Indian, nick-named the 'rubber ambassador', has an answer to this mountainous problem. He has developed a reactant called De Link, using which rubber with 75 per cent of its orignal properties can be reclaimed from tyre crumbs.

Efforts are on to link the De Link reactant to the whole rubber world across the continents. Shekar, heading the STI Corp Sdn Bhd, headquartered in Kuala Lumpur, plans to go in for joint ventures globally to put the process to optimum use. He is eying the growing Indian market to widen the product's scope. Already companies have been set up in the US, Asia and Australia.

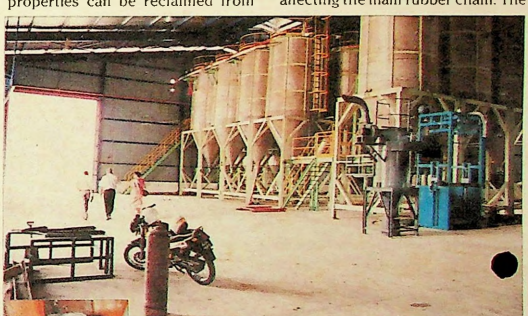
Shekar has undone what the US Goodyear had done with the invention of sulphur vulcanisation. "Burning tyre is environmently hazardous. Discarded tyres when recycled give raw material in plenty and the cost efficient source is ensured," says Shekar.

The De Link process begins with the removal of metal, fibre and non-rubber parts from the scrap tyres. The tyres are then treated with a mixture of sulphur and organic additive degradents in a high temperature reactor. The resultant polymer resembles a miniature fish net and the De Link reactant is used to break it down. This it does by breaking up the sulphur cross links without affecting the main rubber chain. The end product obtained contains 75 per cent of natural rubber that can be reused for vulcanisation.

The Ramon Magsaysay award winner has been lauded by premier R&D institutions and top scientists for his pioneering work. A top polymer scientist, Sir Geoffery Allen, has termed Shekar's work as innovative. Shekar had hit upon this idea at a seminar in Ottawa, Canada, where the Russian scientist Vitaly Kormer talked about a method of reclaiming rubber using a toxic chemical.

This 'rubber man', being an authority on natural rubber, is flexible enough to stretch his vast experience.

—R. KESAVA MALLIA in Kuala Lumpur



PICS: R. KESAVA MALLIA

Innovative. The De Link plant. (Inset) Shekar