DRUG INFORMATION PACK

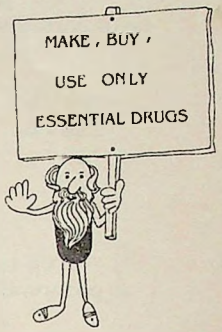
RATIONAL DRUG POLICY FOR RATIONAL DRUG USE

VOLUNTARY HEALTH ASSOCIATION OF INDIA

The World Health Organisation's Essential Drug List says:
The world needs only 200 drugs to cure all its ills.

The Hathi Committee Report of 1975 says:
India needs only 116 drugs.

Our drug companies vie with each other to thrust down our throats 63,000 formulations.



Hippocrates
Father of Medicine

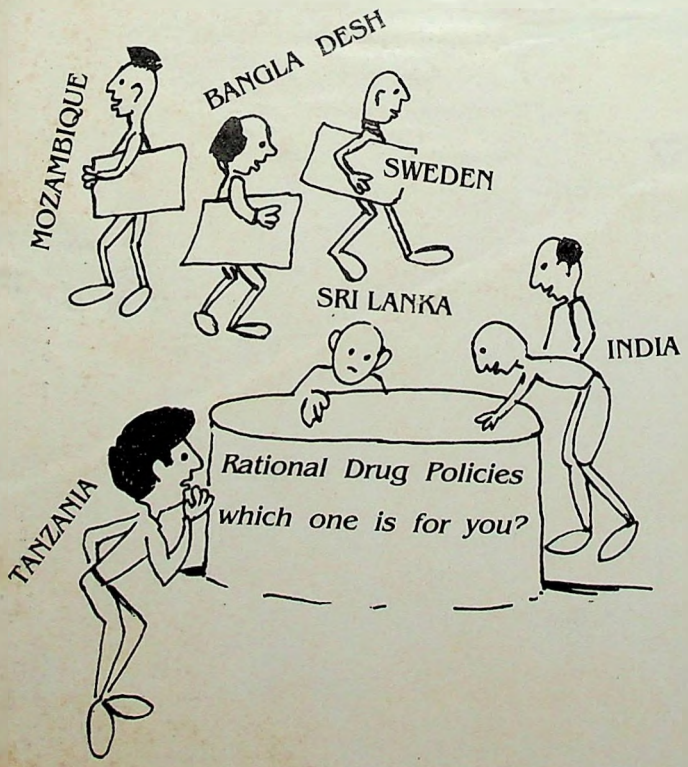
If 200 Kaniskhas crashed today

10 million Indians have T.B. 2.5 millions of these are infectious. More than 50,000 people die of T.B. every year. This is equal to the population of Simla, Udhampur, Kodagu, Wayanad, Panna, Khasi Hills, Kapurthala, Bundi, Dholpur, Sirohi, North Tripura, South Tripura, Lalitpur and Pithorgarh.

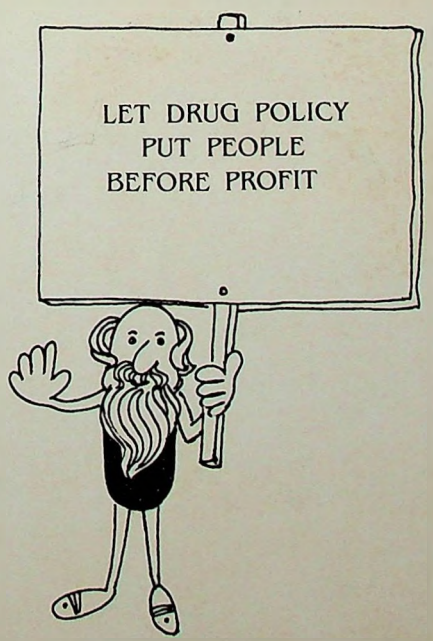
We need every year for T.B. and leprosy		We produced in 1984-85
* DDS (Dapsone)	60T	7.31T
* Clofazimine	650kg.	1.47T
* PAS and its salts	250T	19.07T
* INH	290T	192.57T
* Thiacetazone	55T	47.19T

We need every year 13,000MU of Tetanus Antitoxin. We produced in 1984-85 8291.02 MU.

(Source: Indian Drugs Statistics, 1984-85, M&E Section, Ministry of Chemicals and Fertilisers, Government of India).



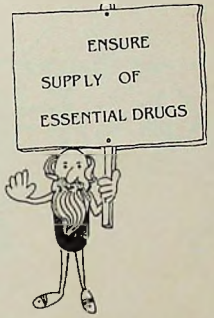
Our country has signed the Alma Ata Declaration of "Health for All by the Year 2000". This Declaration talks of drugs as related to Health. Our country has pledged itself towards formulating a Rational Drug Policy at the Summits of the Heads of Non-Aligned Nations both at SriLanka and at Havana.
Now is your chance to redeem this pledge. The Third World looks to you for guidance.



Who decides on drug policy?

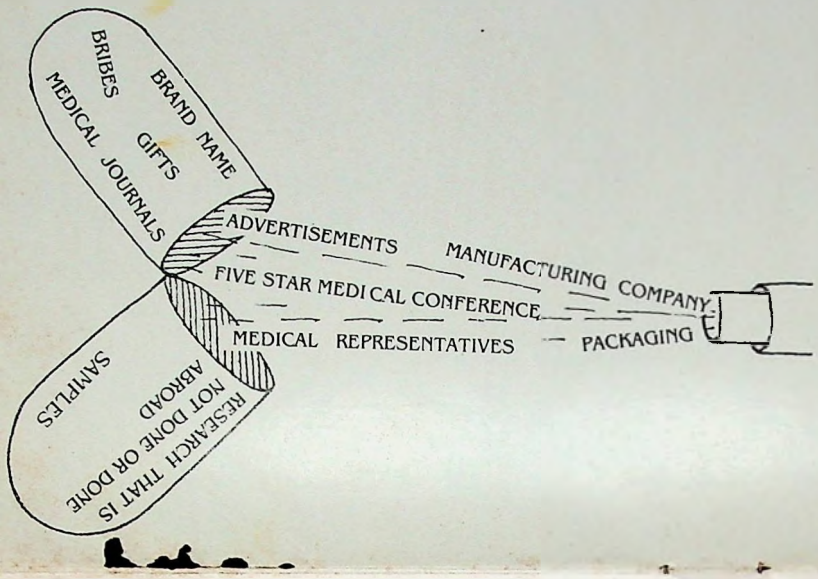
Every 13 minutes a child goes blind for want of Vitamin A.

We produced in 1984-85 60.58 mmu of Vitamin A when we needed 105 mmu.
(Source: Indian Drugs Statistics, 1984-85, M&E Section, Ministry of Chemicals and Fertilisers, Government of India).



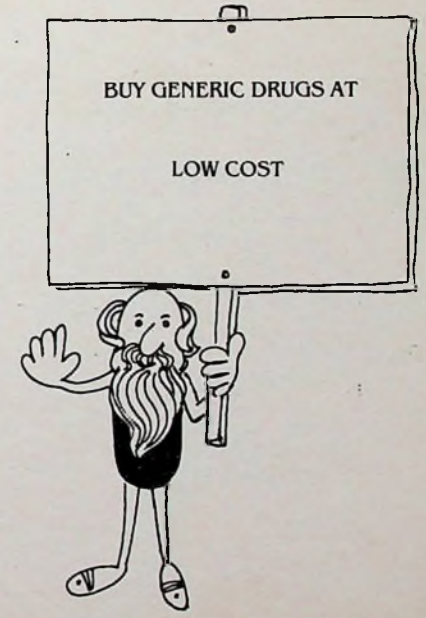
If 200 Kaniskhas crashed today

Why are medicines expensive?



Each of these contribute to the cost of drugs:

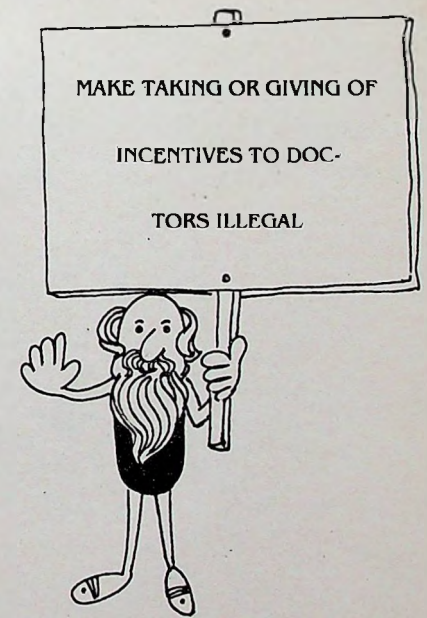
* Packaging
* brand name
* :manufacturing company
* advertisements
* medical representatives
* samples
* gifts
* medical journals
* bribes
* research that is not done or done abroad
* five star medical conferences



The cost of 'Health'?

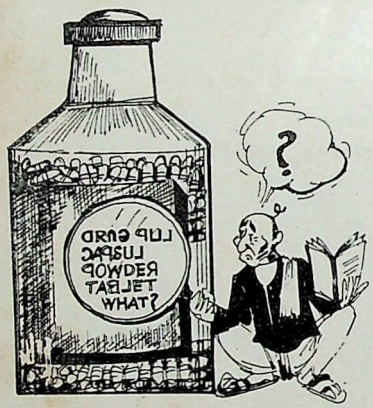
Most doctors and pharmacists in India do not have access to continuing education once they leave college. Their only source of information is often the medical representative of a drug company. As they have no way of checking the authenticity of his information, they often have no recourse but to accept it as gospel truth, and base their prescribing practice on this information.

The medical representative gives the doctor a beautiful brochure, free samples, discounts on bulk purchases, and gifts. Many drug companies spend much more on their advertising than on research and development.



Mexaform can make you blind

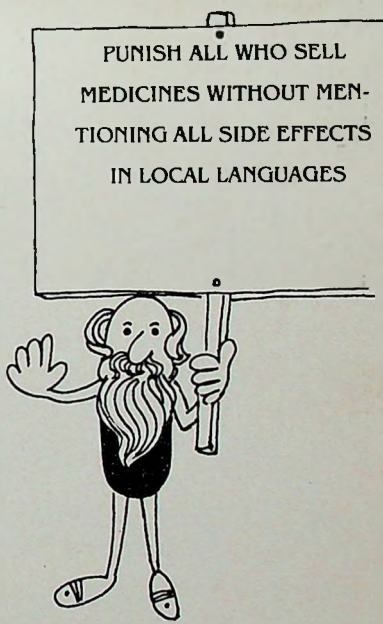
You can take Mexaform regularly to protect you from diarrhoea and dysentery



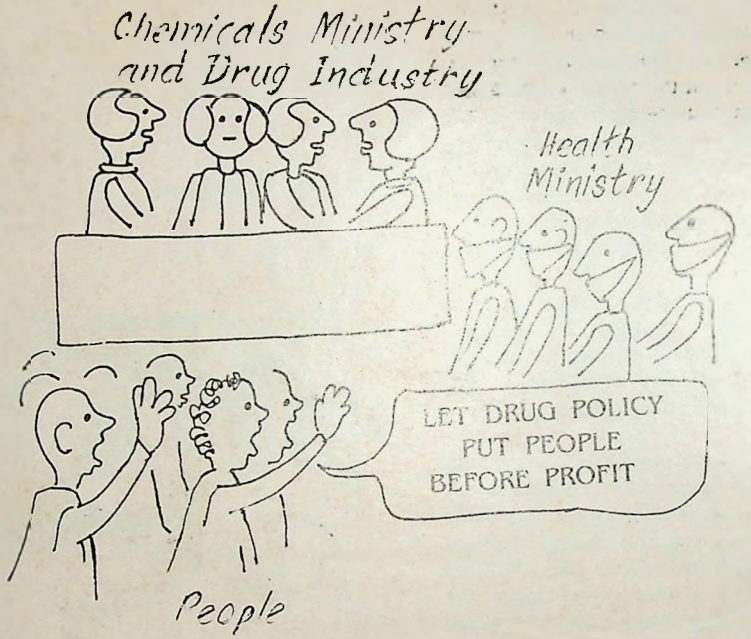
Drugs are important. They are life-saving, true. But all the information you have on drugs today is one-sided. Very often this information is untrue. This information is given to you by the drug company who has every thing to lose if the doctor does not prescribe their brand. They try their best to convince the doctor that their formulation is special, more effective, and really very necessary. To do this, they often distort the truth, and even lie.

Similarly, many drugs are sold without inserts. Again, inserts in developing countries often read differently than those in developed countries. Periactin, an antihistaminic, is marketed in the Third World as an appetite stimulant.

Hydroxyquinoline and clioquinol — available in India as Mexaform and Enterovioform — caused severe or partial blindness in over 10,000 patients in Japan. Ciba-Geigy, makers of Mexaform were forced to withdraw the brand from the world market, because of its severe side effects. This drug is still sold in India, under other names, over the counter, with warning of ocular toxicity written very small, and in English, which most people cannot understand in any case.



Who decides on drug policy?



Do you know that the drug policy is formulated by the **Chemicals and Industry Ministry** and **not** by the **Health Ministry?**
The overwhelming concerns that decide the issue are
"industrial" rather than "health"
"profit" rather than "people".

Bangladesh - Drug Policy

Criteria for recommended withdrawal of products from the Bangladesh market

The Expert Committee constituted by government Order No. S-DA/D-D-20/82/74 dated 27 April 1982 met at 10.00 a.m. on 28 April 1982 in the office of the Director, IPGMR, Dacca, under the Chairmanship of Professor Nurul Islam for evaluation of the pharmaceutical products available in the country and to draft a National Drug Policy, keeping in view the health needs of the country.

Consistent with the declared guidelines of Government to provide basic needs of life to the majority of the people through austerity, and to improve the economy of the country and prevent wastage of foreign exchange, the production and/or importation of unnecessary drugs or drugs of marginal value have to be stopped.

Almost any drug may produce unwanted or adverse reactions. The combination of two or more active ingredients not only makes the product costlier, it also increases the possibility of adverse reaction without increasing the efficacy over a single ingredient product. Hence, as a general rule, combinations of similar or disimilar drugs will be prohibited.

Combination drugs could be approved if the drug company can give definitive, approved scientific proof (ie WHO publications, British National Formulary, British Pharmacopeia, European Pharmacopeia, USA or other authoritative guidelines like Goodman's and Gilman's 'The Pharmacological Basis of Therapeutics', 'Current Medical Diagnosis and Treatment', etc.) of the drugs' synergistic action and increased efficacy. They

also have to prove conclusively that combining the elements creates no increase of toxicity or side effects nor instability of the compound or shortening of the life of the product.

One of the greatest sources of drainage of the country's financial resources is the irresponsible prescribing and marketing and inappropriate self-use of vitamins. Another great wastage of meagre resources is cough mixtures, gripe water, alkali preparations, and digestive enzymes which are of little or no therapeutic value.

It is unanimously decided that the following criteria will serve as the guidelines in evaluatiing all the registered/licensed pharmaceutical products manufactured and/or imported in Bangladesh.

i. The combination of an antibiotic with another antibiotic or antibiotics with corticosteroids or other active substances will be prohibited.

Antibiotics harmful to children (eg Tetracycline) will not be allowed to be manufactured in liquid form.

ii. The combination of analgesics in any form is not allowed as there is no therapeutic advantage and it only increases toxicity, especially in the case of kidney damage. The combination of analgesics with iron, vitamins or alcohol is also not allowed.

iii. The use of codeine in any combination form is not allowed as it causes addiction.

iv. In general, no combination drugs will be used unless there is absolutely no alternative single drug available for treatment or if no alternative single drug is cost effective for the purpose.

Certain exceptions will be made in the cases of eye, skin, respiratory and haemorrhoidal preparations, co-trimoxazole, oral rehydration salts, antimalarial, iron-folic, etc., as well as certain vitamin preparations, allowing combinations of more than one active ingredient in a product.

v. Vitamins should be prepared as single ingredient products with the exception of B complex. Members of vitamin B complex with the exception of B12 may be combined into one product. B12 always has to be produced as a single ingredient injectable product. Other members of B complex may also be produced as single ingredient products (eg B1, B2, B6 etc.). Vitamins will not be allowed to be combined with any other ingredient such as minerals, glycerophosphate, etc. It will be allowed to produce vitamins in tablets, capsules and injectable form only.

No liquid forms will be permitted because of wastage of financial resources and the tremendous misuse involved. However,

paediatric liquid multivitamin (with no B12, E, K and/or minerals) will be allowed to be manufactured in bottles of up to 15 ml. size with droppers. Paediatric liquid preparations of single ingredient vitamins will also be allowed to be manufactured in bottles of up to 15 ml. with droppers.

vi. No cough mixtures, throat lozenges, gripe water, alkalis, etc. will be allowed to be manufactured or imported as these are of little therapeutic value and amount to great wastage of our meagre resources.

vii. The sale of tonics, enzyme mixtures/preparations and so-called restorative products flourish on consumer ignorance. Most are habit-forming and with the exception of pancreatin and lactase these are of no therapeutic value. Henceforth local manufacture or importation of such products will be discontinued. However, pancreatin and lactase will be allowed to be manufactured and/or imported as single ingredient products.

viii. Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed.

ix. Products of doubtful, little or no therapeutic value and rather sometimes harmful, are subject to misuse and will be banned.

x. All prescription chemicals and galenical preparations not included in the latest edition of British Pharmacopeia or British Pharmaceutical Codex will be prohibited.

xi. Certain drugs, in spite of known serious side-effects and possibility of misuse, having favourable risk-benefit ratio may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.

xii. The same or close substitutes of a drug which is being produced in the country will not be allowed to be imported, as a measure of protection for the local industry. However, if local production is far short of needs, this condition may be relaxed.

xiii. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing it or its substitute to be imported if sufficient quantity is available in the country.

xiv. The role of multinationals in providing medicines for this country is acknowledged with appreciation. In view of the calibre of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will lie

solely with the National Companies, leaving the Multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller National Companies. Multinationals will, however, be allowed to produce injectable vitamins as single ingredient products.

xv. No foreign brands will be allowed to be manufactured under license in any factory in Bangladesh as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

xvi. No Multinational Company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on toll basis.

– After approval of these recommendations by Government, the licensing authority for drugs (Director, Drug Administration) will have to issue necessary orders withdrawing/cancelling the licensing/registration of the products, with the provision of a maximum period of six months grace for using up the present stock of corresponding raw materials. Henceforth no raw materials should be allowed to be imported for the manufacture of these products. All future licensing/registration should be given after evaluation of the products on the basis of the above criteria.

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VOLUNTARY HEALTH ASSOCIATION OF INDIA

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As Part Of Rational Drug Policy Campaign

WHO - Essential Drugs

Policies for providing essential drugs

The selection of essential drugs. Technical Report Series 615: WHO, 1977. Excerpt.

"While drugs alone are not sufficient to provide health care, they do play an important role in protecting, maintaining and restoring the health of people. In recent years, there has been a tremendous number of pharmaceutical products marketed; however, there has not been a proportionate improvement in health.

Many pharmaceutical products are marketed with little concern for the differing health needs and priorities of individual countries. Promotional activities of the manufacturers have created a demand greater than actual needs. Since up to 40% of the total health care budget in developing countries may be spent on drugs, the result has been an increase in the cost of health care or a reduction in funds available for other health services. The cost has affected even the affluent nations, and their governments are increasingly worried by the rising expenditure on pharmaceutical products. In developing countries, the problem is magnified by limited economic resources, shortage of trained health personnel, and lack of organised drug policies. In the least developed countries, where communicable diseases and lack of elementary health care are the major medical concerns, large segments of the population are in urgent need of essential drugs.

It is clear that for the optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential' drugs, indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population.

Drugs included in such a list would differ from country to country depending on many conditions, such as the pattern of prevalent diseases, the type of health personnel available, financial resources, and genetic, demographic and environmental factors.

Because of the great differences between countries, the preparation of a drug list of uniform, general applicability and acceptability is not feasible or possible. Therefore, each country has the direct responsibility of evaluating and adopting a list of essential drugs, according to its own policy in the field of health.

The list of essential drugs based on the guidelines put forward in this report is a model which can furnish a basis for countries to identify their own priorities and to make their own selection.

The notion that the number of necessary drugs is relatively small is supported by experience. Several developing countries that have adopted limited drugs lists report good aceptance, as well as favourable medical and economic results. Lists and formularies with a limited number of drugs are also successfully used in many developed countries.

A limited list may not provide for the needs of every person but certainly should meet those of the vast majority. Whether or not drugs or pharmaceutical products outside the list are available in the private sector should be a local decision.

Limited drug lists have several advantages:

1. Reduction in the number of pharmaceutical products to be purchased, stored, analysed, and distributed;
2. Improvement in the quality of drug utilisation, management, information, and monitoring;
3. Stimulation of local pharmaceutical industries;
4. Assistance to the least developed countries in urgent need of high-priority drug programmes to solve their primary health care problems.

An effective programme of drug selection coupled with

appropriate information and education may help to improve attitudes regarding the role of drugs in health and disease."

General principles for establishing a list of essential drugs

The following principles were considered by the Expert Committee to be a foundation on which to establish a list of essential drugs:

1. Adoption of a list of essential drugs is part of a national health policy. This implies that priority is given to achieving the widest possible coverage of the pop-ulation with drugs of proven efficacy and safety, in order to meet the needs for prevention and treatment of the most prevalent diseases.
2. Only those drugs for which adequate scientific data are available from controlled studies should be selected.
3. Each selected pharmaceutical product must meet adequate standards of quality, including when necessary bioavailability.
4. Concise, accurate and comprehensive drug information drawn from unbiased sources should accompany each list of essential drugs.

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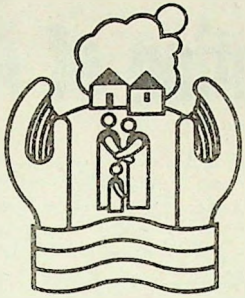

The Declaration of Alma-Ata

Primary Health Care is the key to health for all

In a world in which four-fifths of the population has no access to any permanent form of health care, and in which millions more are disenchanted with the service provided by conventional health systems, primary health care is the key to achieving an acceptable level of health for all. The International Conference on Primary Health Care, held at Alma-Ata in the USSR from 6 to 12 September 1978, drew up the fundamental principles of this far-seeing concept and embodied them in The Declaration of Alma-Ata. Urgent national and international action is needed now to translate these principles into dynamic, practical programmes.

WORLD HEALTH ORGANIZATION • UNITED NATIONS CHILDREN'S FUND

Declaration of Alma-Ata

The International Conference on Primary Health Care, meeting in Alma-Ata this twelfth day of September in the year Nineteen hundred and seventy-eight, expressing the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world, hereby makes the following Declaration:

I

The conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

II

The existing gross inequality in the health status of the people, particularly between developed and developing countries as well as within countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.

III

Economic and social development, based on a New International Economic Order, is of basic importance to the fullest attainment of health for all and to the reduction of the gap between the health status of the developing and developed countries. The promotion and protection of the health of the people is essential to sustained economic and social development and contributes to a better quality of life and to world peace.

IV

The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

V

Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures. A main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all peoples

of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life. Primary health care is the key to attaining this target as part of development in the spirit of social justice.

VI

Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.

VII

Primary health care:

1. reflects and evolves from the economic conditions and socio-cultural and political characteristics of the country and its communities, and is based on the application of the relevant results of social, biomedical and health services research and public health experience;

2. addresses the main health problems in the community, providing promotive, preventive, curative, and rehabilitative services accordingly;

3. includes at least: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs;

4. involves, in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors;

5. requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care, making fullest use of local, national and other available resources, and to this end develops through appropriate education the ability of communities to participate;

6. should be sustained by integrated, functional and mutually-supportive referral systems, leading to the progressive improvement of comprehensive health care for all, and giving priority to those most in need;

7. relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community.

VIII

All governments should formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health system and in coordination with other sectors. To this end, it will be necessary to exercise political will, to mobilize the country's resources and

to use available external resources rationally.

IX

All countries should cooperate in a spirit of partnership and service to ensure primary health care for all people since the attainment of health by people in any one country directly concerns and benefits every other country. In this context the joint WHO/UNICEF report on primary health care constitutes a solid basis for the further development and operation of primary health care throughout the world.

X

An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts. A genuine policy of independence, peace, detente and disarmament could and should release additional resources that could well be devoted to peaceful aims and in particular to the acceleration of social and economic development of which primary health care, as an essential part, should be allotted its proper share.

* *

The International Conference on Primary Health Care calls for urgent and effective national and international action to develop and implement primary health care throughout the world and particularly in developing countries in a spirit of technical cooperation and in keeping with a New International Economic Order. It urges governments, WHO and UNICEF, and other international organizations, as well as multilateral and bilateral agencies, non-governmental organizations, funding agencies, all health workers and the whole world community to support national and international commitment to primary health care and to channel increased technical and financial support to it, particularly in developing countries. The Conference calls on all the aforementioned to collaborate in introducing, developing and maintaining primary health care in accordance with the spirit and content of this Declaration. ▣

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Our Concern About Drugs

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

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

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

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

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

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

*DRUGS :

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

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

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

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

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

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

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

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

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

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

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

Other Activities to decrease health care costs :

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

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

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

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

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

This background paper is for discussion.

APPENDIX 1

Distribution of Essential drugs in Developing Countries

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

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

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

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

APPENDIX 2

The Primary purposes of the Pharmacy and Tnerapeutics Committee

a. Advisory

b. Educational

Functions and Scope

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

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

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

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

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

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

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

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

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

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

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

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

L. To review reported adverse reactions to drugs administered.

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

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VOLUNTARY HEALTH ASSOCIATION OF INDIA

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As Part Of Rational Drug Policy Campaign

Our Concern About Drugs

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

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

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

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

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

Essential Drugs

INTRODUCTION

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

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

The concept of essential drugs questions the health personnel who are supposed to safeguard the health of the people; it questions why their prescriptions include irrational, inessential,

costly combinations and often hazardous drugs. It questions the medical establishment for not demanding bans on bannable drugs, nor attempting to ensure and implement such bans. It focusses the attention on the present day medical services-private and government; the prescription patterns; the gross lack of accountability to the public or to any medical council.

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

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

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

How has the money been spent ? What are the disparities existing? What has been the role of the policy makers? What has happened to the various recommendations mentioned earlier? The perspective should have been set when we attained independence. The direction being pursued now hasn't changed verymuch from the pre-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.

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

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

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

COURAGEOUS EFFORTS

A Brief Review

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

CHILE :

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

SHRI LANKA :

In 1971 under the guidance of Seneka Bibile, Sri Lanka had formed the State Pharmaceutical Committee to launch its **people oriented new Drug Policy.** The number of drugs in the market were slashed down from 2100 to 600 and made available mostly under generic names and obtained by calling international tenders.

Within six months there were savings of about 40% in relation to expenditure incurred earlier.

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 healthand consumer groups no copies of the Hathi Committee recommendations are available, from the health ministry. These recommendations are shrouded in cob-webs. The difference between the Indian experience withessential 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.

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 to 430 medicines in 1977. Essential drug list was revised in 1980 and contained only 343 drugs. ONLY THESE DRUGS COULD BE PRESCRIBED.

The result of streamlined contracts was that the **drug prices of many essential drugs came down to 1/3 of their orginal 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.

WHO

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 bythe Technical Report Series 685 which dealt with

the "Use of Essential Drugs" and gave the essential drug list for emergencysituations 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. Dr. Zafrullah Chowdhury admits that the Hathi Committee and its recommendations held great inspiration for evolving and for implementation of the Bangladesh drug policy. In Bangladeshthe 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. There is also list of 76 supplementary drugs for restricted use.

ZIMBABWE :

Zimbabwe's Government has selected 376 essential drugs to be used in the public health system. The Government will not make foreign exchange available for importing drugs outside this list.

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As Part Of Rational Drug Policy Campaign

Hazardous, Bannable and Dumped Drugs

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

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

Realising all this, the question arises as to how much can we, as citizens of India, expect our drug control authorities to safeguard our interests. The pressure from the drug industry is immense. In spite of knowing this, our expectations from the drug control authorities is high. After all our pharmaceutical industry is the most developed in the Third World. According to UNIDO, it belongs to Category V -- developed enough to be self-sufficient.

We have demanded that our imports, production and sales should give priority to essential, life-saving drugs over irrational and hazardous drugs, as per WHO's guidelines for Essential Drugs. The drug industry and its supporters allege that the concept of essential drugs is only for struggling, less developed countries of the Third World and not for a country like India, with its well-developed industry and its high and advanced level of medical expertise. However, this same lobby puts India in the category of less developed countries when it comes to the issue of banning drugs and drug control. The lobby claims that consideration of hazards over efficacy, is a luxury which we cannot afford.

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

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

SOME BANNABLE DRUGS -- WHAT IS THE POSITION NOW

Under Section 23 P of the Drugs and Cosmetic Act of 1940, the Central government has the power to issue such directions to the State Governments as required to execute the Drug Act. under Section 18 of the Act the State Government has the power to prohibit manufacture, distribution and sale of drugs by a gazette notification.

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

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

SOME BATTLES

Halogenated Hydroxyquinoline

Ban of fixed dose combinations of halogenated hydroxyquinoline

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

High Doses of EP Drugs

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

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

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

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

Paediatric Tetracycline

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

Aspirin and Vitamin C

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

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

This has resulted in the FDA -- Maharashtra (which is supposed to be having the best drug control mechanism in India) informing the Drug Controller of India that, in the light of the ruling given by the Bombay High Court, "it would not be possible for him to take any action to stop the manufacture and sale of any of the fixed dose combinations in question". (Letter dated 9.6.1984 by the Drug Controller of India to the Voluntary Health Association of India).

Gazette Ambiguities

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

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

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

- or to yomhimbine and strychnine with testesterone or vitamins

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

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

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

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

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

Dear Member of Parliament

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

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

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

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

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

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

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

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

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

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

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

India has signed the Alma Ata Declaration of "Health for All By the Year 2000". India has pledged to formulate a rational drug policy at the fifth and sixth summits of the Heads of Non-Aligned Countries both in Sri Lanka (1976) and in Havana (1979).

India is considered as a leader of the Third World and of Non-aligned countries. They look to us for guidance. Can we make this leadership concrete ? Can we redeem our pledge now ?

Can we formulate a drug policy where people matter more than profits.

It depends on you .... now.

Signed by the citizens of India
and
All India Drug Action Network

The World Health Organization says:

"A number of medicines, which are of no value and are even dangerous, are often given to treat diarrhoea. Money and time are wasted in their use." So . . .

WHO says LOMOTIL has NO VALUE?

LOMOTIL (diphenoxylate/atropine) is made by the US multinational drug company, G.D. Searle; and promoted to physicians all over the world in terms such as "established success", "good tolerance", "excellent value" and "ideal for every situation". This leaflet — prepared and published by Social Audit Ltd. and friends* — calls into question these claims.

LOMOTIL may be of value in giving *symptomatic* relief for non-specific "travellers' diarrhoea" in adults. But experts say Lomotil — and other products like it [2] — have little or no place in the treatment of young children — especially in developing countries, where infective diarrhoeas are the major cause of death in children aged under three.[1] Lomotil's limitations include:

POTENTIAL DANGERS

"Lomotil, which is widely used in the treatment of diarrhoea in the paediatric age group, is dangerous and unwarranted . . . we urge that all physicians treating infants and children avoid the potentially dangerous use of Lomotil for the treatment of diarrhoea."
(Clinical Notes [1974])[3]

"Lomotil can relieve the symptoms of acute gastroenteritis in children, but it can also mask the signs of dehydration and cause fatal toxic reactions . . . use of this combination for treatment of diarrhoea in children is hazardous."
(The Medical Letter [1980])[4]

"Lomotil is a dangerous combination of drugs contra-indicated for children under 2 years of age and probably never indicated in childhood diarrhoea."
(Pediatrics [1980])[5]

QUESTIONABLE USEFULNESS

"The use of Lomotil as an antidiarrhoeal agent in children is difficult to justify . . . we doubt if it has any place in the treatment of diarrhoea in children."
(Arch. of Dis. in Child. [1979])[6]

"A diarrhoea that needs 4 such tablets to be cured would probably have been cured without it too. A more prolonged diarrhoea needs proper investigation and specific therapy rather than a blindly harmful stopcock."
(Leb. Med. J. [1974])[7]

ECONOMIC WASTE

Lomotil costs up to 25 times more than other widely-used symptomatic treatments for diarrhoea.
(AMREF [1980])[8]

"Lomotil (no value)." (WHO [1976])[1]

Lomotil

HOW USEFUL . . .

"The management of acute diarrhoea in childhood is essentially dietary . . . Unnecessary drug prescription for these chidren should be vigorously opposed."
(The Lancet [1976])[9]

. . . Against Dehydration?

"The cause of death in diarrhoea is DEHYDRATION . . . Diarrhoea is the most common cause of death in children under three years of age . . ."
(WHO [1976])[1]

LOMOTIL is not a treatment for dehydration. It may reduce the loss of fluid from the body but can also allow fluids to accumulate in the paralysed gut.

"LOMOTIL can mask fluid losses without diminishing them, and the drug itself can cause fatal adverse effects . . . there is no evidence that reduced motility diminishes the loss of fluid and electrolytes into the lumen of an inflamed intestine."
(The Medical Letter [1975])[4]

The accumulation of the body's vital fluids within the intestine can be just as dangerous as the more obvious dehydration:

"In diarrhoea, life-threatening situations are reached . . . so long as fluid and electrolytes are excessively lost into the lumen whether they are expelled from the lumen to the outside of the body or not . . ."
(J. of Singapore Ped. Soc. [1976])[10]

Small feeds of water (or a weak electrolyte solution) given frequently by mouth is the *only* first-line treatment against serious childhood diarrhoea. If this fails after 24 hours, intravenous therapy and hospitalisation may be needed.

. . . Against Infection?

"Acute diarrhoea in children is usually infective, but antibiotics and anti-diarrhoeal drugs rarely help."
(Drug and Ther. Bulletin [1978])[11]

LOMOTIL is widely and often successfully used by adults as a symptomatic treatment of bothersome, non-specific "travellers' diarrhoea" (which is rarely serious). But in children infective diarrhoea is serious. LOMOTIL prevents the child from getting rid of the infective agent and may prolong the period of infection.[12]

"In patients with infective diarrhoea, the use of constipating agents make the carrier state last longer by stopping the organism from being excreted."
(AMREF [1980])[8]

A comparison between LOMOTIL and a placebo in treatment of an infective diarrhoea reported that:

"Febrile volunteers receiving Lomotil alone experienced over a day more fever than those in other treatment groups," suggesting that "drugs that retard gut motility may facilitate intestinal infection . . ."
(JAMA [1973])[13]

HOW SAFE?

"Because of its depressant effects it is no longer recommended for children."
(Brit. Med. J. [1976])[14]

LOMOTIL poisoning in children can include atropinism, respiratory depression, coma, and even death. Symptoms can appear even at near therapeutic doses:

"Lomotil ingestion is a cause of serious poisoning in young children, especially those aged under five. It is always hard to assess the dose in patients suffering from poisoning, but it seems that young children may develop pronounced symptoms after taking only one to five tablets."
(Brit. Med. J. [1977])[15]

The difference between therapeutic and toxic dose is unpredictable:

"We were unable to find a correlation between the severity of symptoms and the dose ingested. Because of this it is not possible to predict what dose will be toxic in children, and while some may have only the mildest symptoms with relatively large doses, others develop severe toxicity on ingesting an amount near the normal dose."
(Arch. of Dis. in Child. [1979])[6]

"There is a very narrow range between allegedly therapeutic and toxic dosages, and many cases of toxicity in children have been reported."
(Pediatrics [1980])[5]

"The narrow margin between therapeutic and toxic doses, and the high incidence of atropine hypersensitivity, make Lomotil a potentially dangerous therapeutic agent."
(Clinical Notes [1974])[3]

"The dangers of this drug to children have not been well recognised. The narrow range between therapeutic and toxic doses, and also the possibility of a child being abnormally sensitive . . . may account for the severe toxicity sometimes seen with low dosage."
(Clinical Pediatrics [1973])[16]

DESPITE THE DANGEROUSLY VARIABLE RESPONSE, SEARLE'S RECOMMENDED DOSES FOR INFANTS AND CHILDREN AND THE PACKAGE WARNING INFORMATION VARY AROUND THE WORLD.

In the US, LOMOTIL is contra-indicated for children under two years old.

"This warning by the manufacturer is not because there has been inadequate paediatric testing of the drug but rather because severe life-threatening reactions (which are not rare) occur in this age group."
(Am. Fam. Phys. [1976])[17]

In Britain, however, the makers recommend it for one-year-olds; and in Hong-Kong, Thailand, and the Philippines it is offered for infants of three months old.

Special circumstances in developing countries compound the potential danger of treating infants with Lomotil in this way. In developing countries:

- children are relatively lighter than those of the same age elswhere;
- the amount of medical supervision is greatly lower;
- typically, no adverse reaction reporting systems exist; and
- drugs such as LOMOTIL (available only on prescription in the West) are in practice freely available over the counter.

HOW EXPENSIVE?

The cost of the smallest available size of LOMOTIL would for many people in developing countries be equivalent to at least one day's income. Other effective preparations for symptomatic treatment of diarrhoea[18,19] cost much less.

According to the African Medical and Research Foundation (AMREF), the cost of treatment with LOMOTIL is about twice the cost of treatment with codeine syrup orcodeine phosphate. Treatment with a kaolin mixture, which may also give relief[20], costs about 25 times less.[8]

LOMOTIL WITH NEOMYCIN (an antibiotic) is recommended by Searle for the treatment of "diarrhoea of bacterial origin." This is unacceptable:

"Antibiotic and sulphonamide preparations should be avoided for the treatment of diarrhoea even when a bacterial cause is suspected because they may prolong rather than shorten the time taken to control diarrhoea and carrier states."
(BNF [1981])[21]

"Neomycin not only can cause renal damage, but also it makes diarrhoea, dehydration, and nutritional losses worse and could interfere with oral rehydration therapy."
(Population Report , 1980)[22]

"Medicines which should not be used in the treatment of diarrhoea: . . . Neomycin . . ."
(WHO [1976])[1]

Treatment with LOMOTIL plus NEOMYCIN costs about three times more than treatment with LOMOTIL alone.

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*SOCIAL AUDIT AND FRIENDS

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War on Want, 467 Caledonian Rd., London N7 9BE, and The International Organisation of Consumers Unions, Regional Office for Asia and the Pacific, PO Box 1045, Penang, Malaysia.

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VOLUNTARY HEALTH ASSOCIATION OF INDIA

C-14, Community Centre, S. D. Area,

New Delhi - 110016

AS PART OF THE RATIONAL DRUG POLICY CAMPAIGN.

BAD INFORMATION MEANS BAD MEDICINE...

Dear Doctor,

So many different brands of clioquinol recommended for the prevention or treatment of non-specific diarrhoeas. How does a doctor choose between them?

A brand of clioquinol from an unknown local firm? Or Mexaform or Entero-Vioform - world leading brands from a trusted Swiss name, CIBA?

The choice is immaterial. This is because all brands have this in common: In the treatment of non-specific diarrhoeas, their benefits have not been proven. Their dangers clearly have.

Whatever the brand - with clioquinol there is no choice. Thank you for not prescribing it.

Yours faithfully,

SO WHY AREN'T THERE MORE 'DEAR DOCTOR' LETTERS LIKE THIS?

This 'Dear Doctor' leaflet puts patients first. It was prepared and is published by Social Audit and friends*.

BENEFITS OF CLIOQUINOL: UNPROVEN

The CIBA-GEIGY products *Entero-Vioform* and *Mexaform* are among the many brands of clioquinol that have long been promoted[1] for the prevention and/or treatment of a wide variety of non-specific/travellers' diarrhoeas — e.g. for 'summer diarrhoea', 'food intolerance', 'non-specific diarrhoeal disorders' — and even for 'all forms of gastro-intestinal disorders'.

But authoritative, independent assessments have concluded that the evidence for such claims is trivial. The evidence that has been offered has been described in terms such as: 'inadequate', 'scanty', 'unconvincing', 'insubstantial' and 'non-existent'. For example:

'The claims for the value of clioquinol in the prevention and treatment of that nebulous ragbag "travellers' diarrhoea" do not withstand critical examination.'
(The Lancet [1977])[2]

'There is no evidence to suggest clioquinol (is) effective in the prophylaxis of travellers' diarrhoea.'
(British National Formulary [1981])[3]

'The Committee (on Safety of Medicines, UK) has reviewed the data relating to the efficacy of clioquinol in the treatment of diarrhoea, and considers "that there is inadequate evidence to support this claim".'
(Pharmaceutical Journal [1977])[4]

'. . . in the 40 years that (clioquinol) has been available, only one study, which is not entirely convincing, has shown it to be effective in preventing travellers' diarrhoea, whereas one other prospective study has shown it to be no more effective than a placebo.'
(JAMA editorial [1972])[5]

This lack of evidence has not deterred CIBA-GEIGY, BAYER and other drug manufacturers from vigorously promoting their brands of clioquinol for the treatment of non-specific diarrhoeas. If there has been less emphasis recently on such promotion, it has been largely the result of successful legal action against CIBA-GEIGY and other firms — and of government regulation.

But, for the future, is it sufficient merely to delete any reference to 'non-specific diarrhoeas' in the prescribing literature? No:

'A quiet change in the indications is not enough. Drug regulatory authorities, manufacturers and distributors . . . should now emphasise to the public that these drugs should no longer be used for travellers' and other non-specific diarrhoeas.'
(The Lancet [1978])[6]

Other uses for clioquinol

Clioquinol is used in the treatment of intestinal amoebiasis — though other effective and safer drugs are available for treatment of both the symptomatic and carrier state of this disease.[16]

Clioquinol has been used in the treatment of the rare childhood skin condition, acrodermatitis enteropathica. It has been established since 1973 that treatment with zinc salts is more effective and safer.[17]

Clioquinol is of no value in the treatment of acute cholera.[18]

Ciba-Geigy and the law

In 1978, after 8 years of litigation over the claims of Japanese victims of SMON, the Tokyo District Court reached two decisions — the first of several similar rulings. The Court found first that clioquinol caused SMON. Secondly, it was found that CIBA-GEIGY et. al. were liable, in failing to pass on information about the dangers of clioquinol.

Since then, the SMON victims and their representatives have put CIBA-GEIGY under considerable pressure, if not to withdraw its clioquinol products, then to include appropriate instructions and warnings with them. In defending its position the Company has argued: 'It is, however, not possible to achieve complete uniformity of the information for the doctors and patients because in different countries there are different rules which are usually laid down by the local health authorities.'[19] Though this is true, any implication that such regulatory requirements would prevent a company from including more than the minimum warnings required is wholly unacceptable.

DANGERS OF CLIOQUINOL: PROVEN

The benefits of using clioquinol against diarrhoea have not been proved. But the dangers have — and they clearly compare with the thalidomide catastrophe in severity.

Clioquinol has caused thousands of cases of SMON — subacute myelo optic neuropathy — a condition involving continuous pain, paralysis, blindness and, in extreme cases, death.

In Japan, cases of SMON reached epidemic proportions — affecting an estimated 10,000-30,000 people — before the drug was banned there, in 1970. But what of the situation elsewhere?

'. . . the companies deny that the neurological damage from clioquinol is a serious risk outside Japan. This denial is unconvincing because cases of clioquinol damage have been observed outside Japan, and identical abnormalities of the nervous system have been reproduced in animals.'
(The Lancet [1976])[7]

'The absence of epidemics in other countries does not invalidate the conclusion that (clioquinol) is neuro-toxic. Clinicians from England, Australia, Switzerland, Sweden, Denmark, the Netherlands and the US have described patients who developed neurologic symptoms while taking (these compounds). The clinical symptoms of these patients were like the ones that characterised SMON.'
(JAMA [1973])[8]

Incapacitating neurological damage has been associated with high doses of clioquinol in prolonged treatments. But limiting the dose or duration of treatment is not necessarily an appropriate response:

'In fact, since it now seems almost certain that large doses of (clioquinol) produce severe, clinically obvious neurological damage, it must be suspected that the accepted smaller dose schedules may cause sub-clinical neurological damage.'
(Pediatrics [1974])[9]

IS THIS DRUG CLIOQUINOL WORTH THAT ADDITIONAL RISK?

CONTROL OF CLIOQUINOL: INADEQUATE

Several governments have concluded — as the World Health Organisation has stated — 'that the risks of treatment outweigh the potential benefits'.[10] In some countries — they include the United States, Japan, New Zealand, Sweden, Denmark and Norway — clioquinol has been withdrawn or altogether banned. Other governments have restricted the availability or applications of this drug.[11]

But in many developing countries, and elsewhere, clioquinol is still widely available:[12]

'Worldwide, these preparations are still available in at least 100 countries and, in some instances, on a scale comparable to that existing in Japan at the height of the SMON epidemic.'
(World Health Organisation [1977])[13]

A survey of 107 samples of clioquinol obtained from 34 different countries (International Organisation of Consumers Unions [1975])[14] established that 'Clioquinol is widely available as an over-the-counter drug for the prophylaxis and treatment of travellers' diarrhoea'. The investigators reported serious inadequacies in the prescribing information supplied, with 'wide variation in the doses, duration of treatment, contraindications, side effects and warnings listed'.

In a more recent survey (IOCU [1980])[15] an examination was made of the instructions given with twelve brands of clioquinol sold in Indonesia, Malaysia, the Philippines and Thailand. Of the 20 samples obtained:

- all but one was bought *without* a prescription
- four contained no instructions for use
- eleven recommended use for 'non-specific diarrhoeas'
- ten omitted any warning to stop using the product immediately on the first signs of neuritis, damage to nerves.

The need for control is underlined by the fact that products containing clioquinol cannot readily be recognised as such. There is not only a multiplicity of brand names — but many products are also identified only by a confusing chemical name, such as 'iodochlor-hydroxyquinoline' or '5-Chloro-7-iodo-8-quinoline'.

BAD INFORMATION. IT MEANS BAD MEDICINE.

'Do you think a big multinational company would continue sales of a compound, of a product, if this would mean a danger to human lives?'
(Ciba-Geigy representative [1980])[20]

REFERENCES:

1 CIBA-GEIGY has stated (letter to Social Audit dated 6 May, 1981) that 'the indication "non specific diarrhoea" was recommended for elimination from the package leaflets for these drugs in 1978. This policy has been implemented worldwide, with the exception of one European country'. However, see section on 'Controls' in this leaflet, and references 14 and 15.
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11 For instance, in France, Switzerland and other countries, clioquinol is available only on prescription. In Venezuela and Australia, use of clioquinol is restricted to severe cases of amoebic dysentery and acrodermatitis enteropathica.
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13 World Health Organisation. Op. Cit.
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20 Dr. J. Sobotkiewicz. Ibid. p. 23.

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AS PART OF THE RATIONAL DRUG POLICY CAMPAIGN.

DRUG ACTION FORUM, KARNATAKA

57, "SONI" Tejaswinagar, Dharwad-580 002
KARNATAKA INDIA

Date 5 Jan 1993.

PLEASE REPLY TO
Dr Gopal Dabade,
Khan's building,
Sanmati Marg,
Dharwad 580001.

To,

Dr Benjamin V, Tel no 569087.
Dr Tekur SP, Tel no 531518.
Dr Saraswathy Ganapathy Tel no 630463.
Dr Vanaja Ramprasad Tel no 644963.
Dr Prakash Rao C. Tel no 369016.
Mr Sebastain MA, Tel no 575852.
Mr Philip Goerge, Tel no 223229.
Ms Ammu Joseph, Tel no 541875.
Dr Arun K, Tel no 569527.
Dr Sudarshan H,
Mr Natraj DR,

Dear friends,

Wish you all a happy new year.

December 1992 has left several scars on us.When the whole country was shaken and tattered by Ayodhya issue, we at Kittur had to face uphills. The Kittur landlord filed a police complaint on some of us and the villagers. We really had to struggle and strive to come out of it.To cut the long story short, we came out ultimately with flying colours, but that meant one and half month intense stratagesing and organising.I hope you will excuse me for not being able to communicate to you.And amidst all this we have shifted to our our new house at Dharwad.Note change in address.

So let us get back to our work. Drug Action Forum-Karnataka will meet on 12th Jan 1993 at 3.30 pm at SCM House,Bangalore. Agendas for discussion

1)Future action and reorganising of DAF-K.
2)Natraj's study and how DAF-K will use it.

Hoping to meet you on 12th Jan.

Yours Sincerly

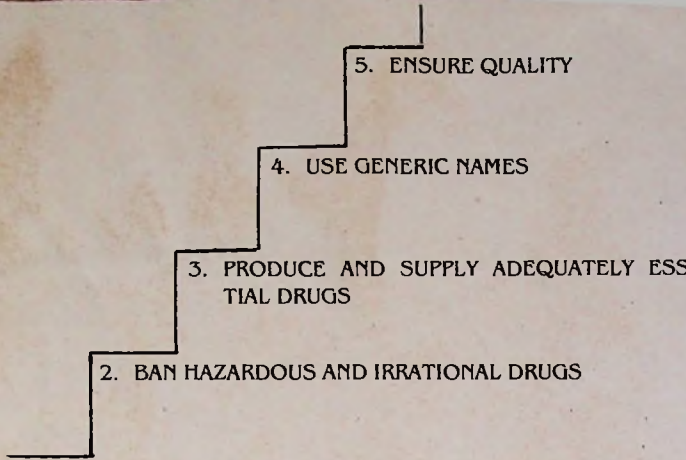
(Dr Gopal Dabade)

Remember Gandhi

When you formulate the Drug Policy, remember Gandhiji's words:

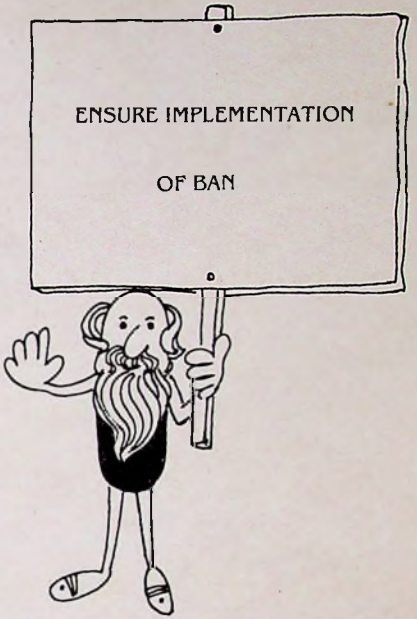
"Recall the face of the poorest and the most helpless man whom you may have seen and **ask yourself if the step** you contemplate **is** going to be **of any use to him."**

Remember Gandhi


5. ENSURE QUALITY
4. USE GENERIC NAMES
3. PRODUCE AND SUPPLY ADEQUATELY ESSENTIAL DRUGS
2. BAN HAZARDOUS AND IRRATIONAL DRUGS
1. ASSESS DRUG NEEDS
NOT MARKET DEMAND

The Drug Controller of India's DO No. X 11014/7/83 banned liquid preparations of oral tetracycline so that its misuse in children could be prevented. This issue was side stepped by the production of Ledermycin tablets of 30mg. for children.

Most doctors, particularly in smaller towns and rural areas, do not know about the ban. The banned drugs are availabe, and the doctors prescribe them.

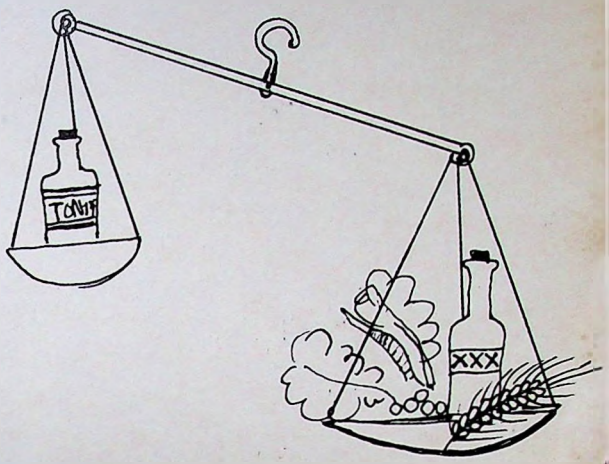


What you pay for health and energy

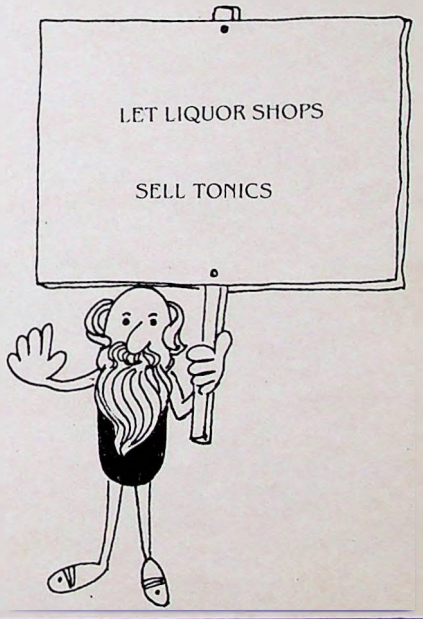
One teaspoon of Waterbury's Compound gives you 3 mg. of iron and 8-9.5% v/v alcohol.
A child needs daily 15 to 20mg of iron — at least 5 teaspoons of Waterbury's compound or 100g. methi (fenugreek leaves)
An adult needs daily 20 to 30mg. iron — at least 7 teaspoons of Waterbury's compound, or 200mg. of methi leaves daily.

Neither need the alcohol.

For the same price



Most gripe waters given to infants contain large amounts of alcohol. More than 20 years ago, the Kefauver Committee on drugs in USA reported:
"The incidence of disease cannot be manipulated and so increased sales volume must depend on at least in part on the use of drugs unrelated to their utility or need, or in other words, improperly prescribed. Human frailty can be manipulated and exploited and this is fertile ground for anyone who wishes to increase profits."



Liquor is cheaper than tonic

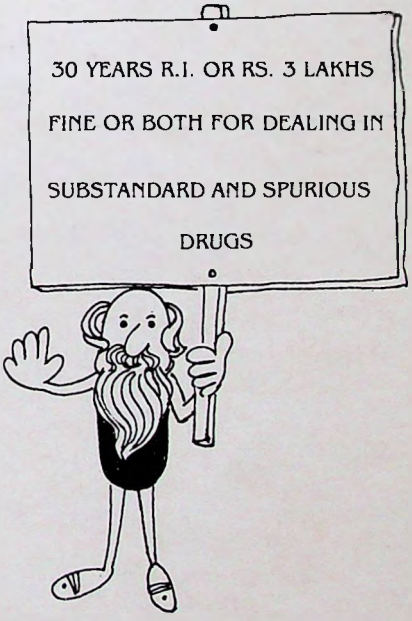
Japan, considered to be the seat of small-scale industry, has 1000 drug manufacturing units.
USA with 16 percent of the drug market has 700 units.

India with just 1 per cent of the drug market has over 8000 formulators.

5 quality control laboratories and 600 drug inspectors attempt to maintain quality control of over 60,000 drugs.

20 per cent of the drugs available in the Indian market are substandard. That is, 1 out of every 5 medicines you buy is uneffective.

India has numerous spurious drugs in the market, and their number is increasing. This is due to the high profit margin there is in drugs. The spurious drugs are naturally not quality controlled. They can even cause death.



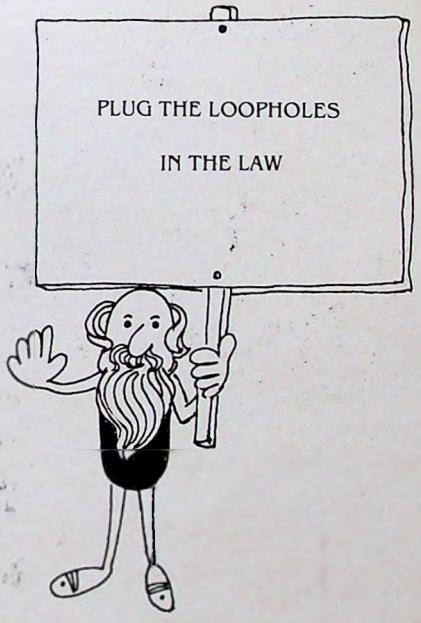
There are numerous instances where the laws have provided enough loopholes for manufacturers of hazardous and irrational drugs to escape.

When the Drug Controller of India banned high-dose estrogen-progesterone combinations, because they were being used for pregnancy testing and could harm the unborn babies, the manufacturers managed to get a stay order against the ban.

When the Drug Controller of India banned paediatric tetracycline in liquid oral preparations, the manufacturers are making tablets of the same for children.

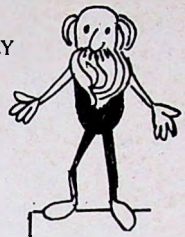
Every time the drug control authorities have made a decision favouring health of the people over the drug industry, the industry has managed to find enough loopholes in the law to escape. Today, you can do something.

Something for the public whose interests you have promised to safe guard. And health is one of those interests.



Steps for survival

YOU NOW HAVE A RATIONAL DRUG POLICY



10. PLUG LEGAL LOOPHOLES

9. PROMOTE INDIGENOUS RESEARCH AND DEVELOPMENT

8. ENSURE REASONABLE PRICE

7. ENSURE ETHICAL MARKETING

6. ENSURE CORRECT INFORMATION

- Availability of essential and life saving drugs
- Withdrawal of hazardous and irrational drugs
- Availability of unbiased drug information
- Adequate quality control and drug control
- Drug legislation reform
- Use of generic names

ALL INDIA DRUG ACTION NETWORK