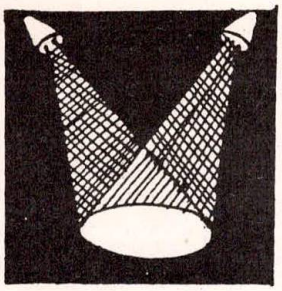



# The New Drug Policy

## What does it have in Store for the People

Dr. Anil Pilgaonkar

EVER since the 1978 Drug Policy was announced, both the consumer forums and the drug industry have been seeking changes in that policy, albeit for diametrically opposite reasons. The drug industry had consistently put pressure on the government for allowing, a) greater mark-up on the formulations and b) greater freedom from controls. The people-i.e. consumer groups, health groups and science groups had, on the other hand, sought for i) availability of essential drugs (as drawn by the World Health Organisation), at very reasonable prices, ii) restricting the drug list to include only the rational drugs and exclude all irrational and harmful drugs and iii) the marketing of drugs and formulations under generic names only. Further, they had also pressed for people's participation in the formulation of the drug policy. In fact, many of the proposals of the Hathi Committee, 1975, were in consonance with these very demands.

The present New Drug Policy pretends to make an attempt at pacifying both the groups, though even the most naive would be able to see through this move and make out that the policy is very much against the interests of the consumers and is heavily tilted in favour of the industry. Virtually all the demands of the people—drawing out of the essential drugs list, weeding out and banning irrational and harmful drugs—have been placed in the hands of the as yet to be constituted National Drugs and Pharmaceutical Authority (NDPA). This inevitably means delays and perhaps distortions, depending on the composition of the NDPA. Secondly, everything that the drug industry has been pressing for, has been conceded in ample measure—higher mark-ups and greater freedom from controls. It is therefore necessary to look into each of the proposals available from the summary (which is all that is available at the moment) and see how they would affect the people on the one hand and the drug industry on the other.

1) A National Drugs and Pharmaceutical Authority (NDPA) will be created. This will have representatives from all concerned agencies, *including those from the industry* (emphasis added). While the question of who these 'all concerned agencies' are, is left open, the summary of the text makes it amply clear that 'those from the Industry' will be represented.

This authority would function as an advisory body on the development of the pharmaceutical industry. Among other things, it would go into the question of rationalisation of the existing formulations in the market, including the banning of harmful formulations and better control over the introduction of new drugs. While representation of the industry in NDPA in some matters is understandable, that in respect of the question of rationalisation of the formulations in the market, including banning of irrational and harmful drugs is both surprising and unwarranted as they would have vested interest in this issue, and this is more than likely to defeat the aim. It is as ill-conceived as making a quality control manager report to the production manager, and is therefore unacceptable to the people.

2) Quality control: It is proposed to give statutory effect to good manufacturing practices and also to introduce a certification system under which, recognised institutions with proven expertise and testing facilities would certify the adoption by formulators of good manufacturing practices and the quality of the formulations manufactured. It is common knowledge that these have been the responsibilities of the Food and Drug Administration. The questions that therefore arise are: What would be the role of the FDA vis-a-vis that of this new certification system? and (b) if these responsibilities are *not* clearly demarcated, wouldn't that allow room for manipulation and the playing of one authority against the other?

3) Pricing: As against the existing three categories (viz. category I—40 per cent mark-up, category II—55 per cent mark-up and category III—100 per cent mark-up) of drugs and pharmaceuticals, hereafter there would be only two categories. The first category will consist of drugs necessary for the national health programme (some 40 drugs) and the second category, of essential drugs. Formulations of the first category would have a MAPE (maximum allowable post-manufacturing expense, virtually the same as 'mark-up' used earlier) of 75 per cent, and those of the second category of 100 per cent. This implies that the rest of the formulations (and very likely a very large number of them) would be out of the purview of price control.

A High-level committee would draw up the list of drugs to be included in the second category. Who would be in this high-level committee? What would be the criteria for deciding the essential drugs? There has been no attempt to answer these questions—another area of studied ambiguity.

It will be recalled that after the last (1978) drug policy, the formulations of the I and II categories were scarcely available whereas those of the III category and those out of the purview of price control were in abundance. The reason forwarded for this situation was that, because the last two categories were the ones that were profitable, they were the ones that were manufactured. If this is the case, and if the intentions of those in authority were to reduce the drug list to conform with rational drugs only, then one would expect that the MAPE on formulations *not included* in categories I and II should have been even lower than 75 per cent; but instead, the authorities have left them out of the purview of price control (which would mean high margin and high profits). The outcome of this

*(continued on page 8)*

# AIDS: If Slogans were Vaccines...

Dr. Nerges Mistry

THE dramatic advent of the acquired immunodeficiency syndrome (AIDS) since 1978, may well have provided to religious fundamentalists another clue of approaching Armageddon; however it has had a remarkable effect on the mobilisation of medical resources and scientific acumen hitherto unknown.

The vast pool of information gathered on the somewhat unique tissue tropism of the virus, its molecular structure, and facets of the immune response towards it, has paradoxically been instrumental in creating a fear psychosis, since despite the considerable inroads made in the understanding of the disease, full blown AIDS remains a 100 per cent fatal condition. The treatment is either symptomatic or hypothetical. The course of events after exposure to the virus begin with extremely innocuous symptoms such as fever, anorexia, weight loss, which, in the absence of a diagnostic test, would abet the evasion of a correct diagnosis. Indeed the pattern of immunodeficiency in AIDS resembles, to varied degrees, patterns noted in different diseases such as viral infections, malignancies, Burkitt's lymphomas, infectious mononucleosis, tropical splenomegaly, nutritional immunodeficiencies (IDS) and leprosy. In third world countries therefore, acquired immunodeficiency syndromes probably exist in vast numbers but remain unlabelled in the right context.

Little information exists towards the recognition or measurement of a protective immune response (ImR). Epidemiological observations bear out that only 10 per cent of those infected with the virus progress to active disease, a positive indication that a protective ImR against the virus exists. Investigators were also elated when it was computed that homosexual men exhibiting both antibody positivity (an indication of Human Immunodeficiency Virus infection) and abnormalities in blood cell numbers for a prolonged period, reverted to antibody negativity without exhibiting signs of AIDS related disease. This disappearance of the virus coincided significantly with a measurable increase in a critical sub-population of blood cells termed as suppresser lymphocytes.

In our "vacciphilic" era, it is inconceivable that any control measures against AIDS would exclude the development of a viral vaccine to AIDS. At this juncture, only optimism abounds. Attenuated or live vaccines are considered too risky for any proposed trial. The favoured approach lies in isolation and cloning of a viral structure that may induce the formation of a protective ImR. Variation in viral structure either through environmental pressures or genetic mutation provides another obstacle to the development of a homogenous vaccine. The natural history of Human Immunodeficiency Virus (HIV) infections in Africa, where the virus is believed to originate, must necessarily be different from that of other groups. Adjustment to the virus over generations must play a role in natural immunity/tolerance to the virus. This introduces the question of the differential response to the vaccine in various ethnic groups.

With AIDS claiming its first victim in India in 1986, public fear over the disease has descended on this country as well. This has been compounded by unprecedented announcements in Parliament, intensive media coverage and the setting up of an elaborate surveillance network practicable principally on paper. Nevertheless, because of the very nature of the superefficient pattern of global travel and communication prevalent, and the existence of high risk groups in every society, control of the spread of infection remains an urgent priority.

IN a special article in a recent issue of the New England Journal of Medicine, it was reported that a million new cases of gonorrhoea are reported in the United States of America every year, despite the fact that penicillin has been available as a single—shot treatment for several decades. Since there is now an emergence of resistance to antibiotics, they have recommended research in recombinant DNA techniques for developing a vaccine.

China has successfully eradicated sexually transmitted diseases including gonorrhoea and syphylis.

This is the result of the revolution which has changed the social and sexual mores. Penicillin was only an additional tool to deliver the coup de grace. The eradication of STD therefore lies more in social change than in mere medical technology.

Epidemiologists feverishly grapple with "transients" (anomalies due to the rate of spread of virus and the long incubation period) to predict estimates for new AIDS cases in the subsequent years. Even with a minimum of pessimism and with a hope that new infections may be eventually preventable, it is estimated that the epidemic in countries such as the USA will be five times larger than the number of cases observed so far.

Because of the identification of HIV as the causative agent in AIDS and the consequent development of culture techniques and serologic methods for detecting antibody to the virus, it is possible to identify both, symptomatic and asymptomatic infected persons. Paradoxically again, this very widespread availability of simple, inexpensive and sensitive screening tests for antibody to HIV has further complicated the development and implementation of infection control procedures. The question becomes.. who to screen. This is a particularly important issue in health care facilities where frequent and intensive exposure to infected patients may occur. Protection to health personnel would also have serious repercussions in clinical management of AIDS' patients as well as in early reporting of AIDS cases.

It is not feasible to identify all infected patients even with the availability of screening tests. The risk of

nosocomial (relating to a hospital) transmission of HIV is extremely low even after accidental parenteral innoculations. Again, special infection control precautions for patients known to be infected are not necessary in most health care settings at least in the developed countries. The existing guidelines for reducing exposure to blood and other body fluids will protect workers who care for AIDS afflicted patients. The procedures recommended to prevent contact with body fluids would reduce exposure not only to HIV but also to other sexually transmitted pathogens.

This is also the general tack of Prof. V. Ramalingaswami, the former Director General of the Indian Council of Medical Research, who claims that though sexually transmitted disease (STD) is widely prevalent, its prevention and control have been largely neglected: "The opportunity of AIDS should be used to monitor and prevent STD in general".

The remarkable mobilisation of scientific resources in the US towards development of quick and relatively inexpensive screening procedures was largely due to the transmission of AIDS through Blood Bank transfusions to hemophiliacs or to the users of blood products. Even though they constituted about two per cent of the total AIDS patient population, their impact on the control measures was very significant. By a massive screening programme, where within 3 years, 20 million units of blood were screened, not only for antibody but also for viral particles themselves, the risk of contracting AIDS through transfusions in the US was reduced to a minimum −1.77/1000 units of blood.

Given the prevalent condition of blood banking in this country, screening for AIDS samples would appear meaningless when screening for Hepatitis−B or VDRL for syphilis is still not carried out routinely in a majority of institutions despite being made mandatory since 1976.

The highest incidence of AIDS is reported to have occured in homosexual men, subversion of immune system probably occuring through the introduction of sperm through an abnormal route. The recognition of the heterosexual mode of contraction of AIDS has been identified as an important way of introducing the virus into populations not generally considered at risk. This single fact may play a key role in the final containment of the disease. Slogans such as "Give a Gift—Not Aids", "Stick to your partner" are common sights in Western cities where generally the level of sexual promiscuity is said to be high and indiscriminate sexual practices, socially condoned or even legalised. Given the relatively conservative sexual mores and practices in societies like ours, the likelihood of the problem acquiring similar dimensions everywhere is remote; AIDS cannot be caught easily from a dirty toilet!

If the trend of incidence continues, a study proclaims, over 50 per cent of all populations at risk will have contracted AIDS by the year 1990. However, persuasive induction of behavioural change, and accurate public information have already begun to have an important impact in markedly reducing the incidence of AIDS long before a vaccine is available. Far from any sense of helplessness that may arise from scientific means to control this affliction, there are a multitude of alternative levels on which things can be done and multiple cultural factors that will directly affect the progress of technological advances in hand.

# Amniocentesis Update

**Dr. Sanjeev Kulkarni**

A Committee to study the problem of sex determination and female foeticide was formed by the government of Maharashtra, under the chairmanship of Mr. Bhai Sawant, the Minister for Public Health and Family Welfare in September 1986. The Committee was formed as a response to the raging public debate, due to the consistent campaign by the Forum against sex-determination and sex pre-selection, and also because of the private members' bill presented in the legislative assembly. The Secretary to the government of Maharashtra, department of public health and family welfare, commissioned Dr. Sanjeev Kulkarni of the Foundation for Research in Community Health to conduct a short study of prenatal sex determination tests and female foeticide in Bombay city.

Some of the important findings of this study are:—

* About 84 per cent of the gynaecologists interviewed for the study are performing amniocentesis for sex-determination tests. These doctors together perform on an average 270 amniocentesis tests per month.
* According to this study, some doctors have been performing amniocentesis for 10-12 years. But a majority of the doctors (over 85 per cent) have started performing these tests in the last 5 years.
* About 74 per cent of the doctors said that over *50 per cent* of the women who come for the tests are from the "*middle class*". More than 85 per cent of the doctors said that *no lower class women* had come to them for sex-determination tests, though the areas selected had a substantial lower class representation.
* A *majority* of the women have *2 or 3 daughters* when they come for sex determination tests and the percentage of women coming for sex-determination tests when they have 4 or more daughters is relatively small. Significantly enough, about 24 per cent doctors said that in *20 per cent* of the cases, the women had *only one daughter*, when they came for the sex determination tests.
* About 29 per cent of the doctors said that upto *10 per cent* of the women who come for s.d. tests *already have* one or more *sons*.
* A majority of the doctors see the s.d. tests as a humane service to the women who do not want any more daughters. Some doctors also feel that s.d. tests are an important family planning method in our country.

The study also reveals some other interesting features. For example, one doctor advocates *pre-planning* of sex by a method based on the characteristics of the x and y-bearing sperms. Another doctor performs s.d. by a non-allopathic, non-ayurvedic, spiritual method.

This report is now ready and is available at the FRCH.

# Overpopulation and Poverty

**Dr. Ramesh Awasthi**

That overpopulation is the root cause of India's poverty is an absolute myth. What is the meaning of overpopulation? Is it the staggering total figure (1000 million by 2000 AD) that raises a spectre of despair? In that case, will our reaction be different if India is divided into 25 independent states each having a population of only about 30 million, even less than that of UK or France?

That India supports 15 per cent of the world's population with only 2.4 per cent of the world's total land area is often cited as a major handicap in solving the problem of poverty. If population-land ratio is the criteria for overpopulation, let's have a look: some of the most *overpopulated countries* are also among the *richest.*

| Country | Population (Mid 1984) Million per 100 sq. km land area |
|---|---|
| South Korea | 4.09 |
| Holland | 3.51 |
| Japan | 3.23 |
| Belgium | 3.19 |
| West Germany | 2.46 |
| U.K. | 2.30 |
| India | 2.28 |
| China | 0.01 |

All these countries have a population-land ratio which is larger than that of India. On the other hand a large number of countries with a favourable population-land ratio are among the poorest in the world.

| | |
|---|---|
| Ethiopia | 0.345 |
| Zaire | 0.127 |
| Thailand | 0.973 |
| Indonesia | 0.828 |
| Uganda | 0.636 |
| Pakistan | 1.15 |

(Source: World Development Report 1986, pp 180-181)

Is poverty a question of there not being enough for so many people? Let us consider the consumption of resources or the expenditure on food, health, education, clothing and housing of the poor *vis-a-vis* that of the rich. From the consumption expenditure data we know that the top 10 per cent consume 7-8 times as much as consumed by the lowest 10 per cent. Hence averting a birth in the rich families will save 7-8 times the resources that would be saved by a poor family having 1 child less. Extending the same logic, if it was a question of limited world resources, all population control effort should be aimed at the industrial market economies where, considering only in terms of energy consumption per capita (in kilograms of equivalent oil) the consumption level in 1984 was 26 times that of India and 13.5 times that of India and China together.

Another myth harboured by most educated elites is that the poor remain poor because they have more children. Without going into the rationale why the poor need to have more children (high infant mortality, more hands to earn the family's food, lack of illness/oldage security etc), let us put the question a bit differently—If the poor start having lesser children, will they be better fed and clothed, will they have access to good education, better health care and adequate housing? The honest answer is 'NO'.

How much the poor will get is determined not by the number of children they have but by the level of distributive justice in society. The poor can get more if they consciously use the power of their numbers to enforce distributive justice.

We are not disputing the need to control the high rate of population growth in India and in other developing countries. What we have tried here is to put the relation between poverty and population straight. We cannot find excuses for the persistent poverty in high population growth rate; rather the socio-economic factors have a stronger bearing on the persisting high rate of population growth.

# Practice of Medicine

**Dr. Mukund Uplekar**

## TOXICITY of vitamin overdose

OUR every day diet contains most of the vitamins that our body requires. Additional vitamin intake is only necessary in a very few specific conditions. For these, single vitamin preparations are necessary—B-1 in case of beri-beri, B-12 for pernicious anaemia. The habit of indiscriminate prescription of multivitamins is unnecessary and expensive. This habit is based on the *false* presumption that vitamin can only do good but no harm.

However, excessive intake of vitamins can be harmful and often produces toxic effects.

| Vitamin | Average Daily Requirement | Toxic Effects of Overdoses |
|---|---|---|
| A | 750 micro grams. | cerebral edema resulting in headache, nausea and vomiting. Chronic liver disease. Skin changes including dryness, eruption and rash; fissures, depigmentation, itching, loss of hair. Ingrowing toenails resistant to treatment. Tenderness of bones. Psychiatric symptoms. |
| B 3 | 9-20 mgm. | Peptic ulcer, loss of hair; itching; liver toxicity, abnormal heart beats, hypotension. |
| B 6 | 2-3 mgm. | Dependency, peripheral sensory neuropathy and failure of muscular coordination. |
| C | 35-60 mgm. | Oxalate stones, possible teratogenesis and carcinogenesis in very high doses, multiplicity of minor idiosyncratic symptoms. |
| D | 400 I.U. | Possible mental deterioration due to excess of calcium, hypertension, hardening of organic tissues due to deposition of calcium salts. |
| E | 5-15 mgm. | Increased anticoagulant action of Warferin (an oral anticoagulant drug). |
| K | 100 mgm. | Hemolytic anemia, neonatal jaundice. |

ORIGINAL ARTICLE

# Drug Prescription Preferences of Medical Officers

— *M.K. Vasundhara**

Key words : Prescription survey.

**Summary :** Study of 47 Medical Officers in Management of common ailments revealed polypharmacy, violation of standing order and aggressive treatment of self-limiting disorders. These practices would contribute towards iatrogenicity.

**Introduction :** The incidence of iatrogenic disorders is high ranging from 20 to 30 per cent among in-patients[1]. It is indeed tragic to note that the patient who seeks relief for one disorder leaves with one or more disorders, probably more serious in nature than the original one.

A study was thus conducted to study the preference of medical officers for use of drugs in management of common ailments.

**Methodology :** A pre-tested schedule was used to elicit the information from 47 medical officers in government services about management of common disorders usually encountered during their practice.

**Observations :**

i) It was observed that the "drug pool" tapped for treatment of each disorder consisted of 6-23 drugs.

ii) The medical officers preferred to treat the disorders aggressively including even the self-limiting disorders like diarrhoea. Most of them preferred to use 2 to 3 drugs per condition and preference for combination drugs was marked. The "shot-gun" therapy preferred was more evident in case of fever, urinary tract infection and pain in abdomen (Table 1).

iii) Irrational therapy was suggested for treatment of common conditions e.g. use of i.v. fluids for fever and chloramphenicol for treatment of fever and diarrhoeal disorders (Table 2).

iv) A disturbing feature was the violation of standing order i.e. "correct drug and correct dose" was of high order particularly regarding management of convulsions and diarrhoea (Table 2).

v) Only a few doctors suggested need for investigations prior to institution of treatment.

**Conclusion :**

Though the observations pertain to a small number of medical practitioners, the findings are shocking regarding the irrational preference of drugs and likelihood of resultant iatrogenicity. Polypharmacy, violation of standing order and aggressive treatment of self-limiting disorder suggest an alarming situation calling for an urgent action.

**Suggestion :**

i) Introduction of limited drug formulary with drugs available only under generic names[2].

ii) Training of medical personnel at all levels including undergraduate and post graduate students, interns and inservice doctors through workshops, seminars and continued medical education programmes.

**Table I**

**Number of drugs prescribed per doctor for each ailment (n=47)**

| S.No. | Ailment | Number of Drugs 0 | 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|---|
| 1. | Fever | - | 7 | 20 | 20 | - |
| 2. | Diarrhoea | 6 | 18 | 16 | 5 | 2 |
| 3. | ARI | - | 9 | 20 | 15 | 3 |
| 4 | Headache | - | 12 | 25 | 10 | - |
| 5. | Pain in abdomen | - | 10 | 20 | 15 | 2 |
| 6. | UTI | - | 14 | 17 | 15 | - |
| 7. | Convulsions | - | 18 | 12 | 5 | |
| 8. | Insomnia | - | 37 | 3 | 4 | |
| 9. | Backache | - | 22 | 18 | 7 | |
| 10. | Arthritis | 4 | 11 | 22 | 10 | |

* Professor and Head of Dept. of Preventive and Social Medicine, Bangalore Medical College – Paper presented at 2nd workshop on essential drugs organised by National Institute of Public Co-operation & Child Development - June 1990.

**Table 2**
Doctor v/s standing order
N=47

| Sl. No. | Clinical Condition | Standing Order Status | | | | | |
|---|---|---|---|---|---|---|---|
| | | Correct drug + Correct dose | | Correct drug & Wrong dose | | Wrong drug | |
| | | No. | % | No. | % | No. | % |
| 1. | Fever | 41 | 87.23 | 6 | 12.76 | - | - |
| 2. | Diarrhoea | 21 | 44.68 | 6 | 12.76 | 20 | 42.55 |
| 3. | Headache | 36 | 76.59 | 7 | 14.89 | 4 | 8.51 |
| 4. | Pain in abdomen | 42 | 89.36 | 5 | 10.63 | - | - |
| 5. | Asthma | 36 | 76.59 | 11 | 23.40 | - | - |
| 6. | Insomnia | 32 | 68.05 | 9 | 19.14 | 6 | 12.76 |
| 7. | Worm infestation | 39 | 82.97 | 4 | 8.51 | 4 | 8.57 |
| 8. | Backache | 39 | 82.97 | 8 | 17.02 | - | - |
| 9. | Scabies | 35 | 74.46 | 10 | 21.27 | 2 | 4.25 |
| 10. | Convulsion | 18 | 38.29 | 19 | 40.42 | 10 | 21.27 |

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"Good leadership consists of motivating people to their highest level by offering them opportunities, not obligations. That is how things happen naturally. Life is an opportunity and not an obligation."
— *Lao Tzu*

## Rational Use of drugs

*Dr Halfdan Mahler, Director-General, WHO. WHO Drug Information, Vol. 2(2), 1988.*

The indivisibility of "care" and "cost" has implications not for industrial interests, but for everyone involved in the delivery of health care in the public sector. Socioeconomic as well as health-oriented responsibilities impinge at every level. Standards of individual care must remain sacrosanct, but health care professionals who neglect to provide cost-effective treatment are as culpable in their duties as those who fail in their immediate responsibilities to their patients.

# 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 volunarily by doctors, nurses, para-professionals and others in their attempt to contribute to a solution of the problem.

Readers of this note are requested to think over the following facts, observations, conclusions taken from WHO, ICMR, ICSSR, Earthscan, VHAI, Govt. of India and other source 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[2,3] believes that health needs would be met by only 116 drugs.

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[5] has prepared a list of 200 drugs needed for health care.

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

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

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

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

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

A study of UNCTAD has shown that bio-availability argument for branded drugs ie., therapeutic difference[6] based on formulation is not very valid for most drugs.

p.t.o... ...2

Could we accept generic prescribing? ie., Ry 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 and 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 lsector?

(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." [1]

"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." [1]

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

Packaging increases the cost of drugs very greatly because the trend is to make it attractive and highly[1] 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[6], there was no therapeutic rationale for their marketing. The Government of India issued a notification in July 1983, banning 22 fixed drug combinations.

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?

Do we know which are these banned drugs? Why were they banned? Can we stop prescribing them?

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

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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' and 'vitamin' practice?

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

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 INDUCEMENT 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[2,6] in journals collect dust in reference libraries.

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 overtreated.

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 introduce use of traditional medicine and non-drug therapies in our practice after scientific enquiry?

(9) Health Care is becoming increasingly a quest for priorities. "Clean water before anti-biotics, 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[2] for the affluent suburbs of capital cities.

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

- ravi narayan
background paper, mfc Annual Meet 1982

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CONSUMER ALERT--CONSUMER ACTION*

ravi narayan

The problem

The Indian Council of Medical Research (ICMR) and the Indian Council of Social Science Research (ICSSR) have, in a joint study group report entitled 'Health for All - An alternative Strategy' warned that '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 drug does not become a vested interest in ill-health'. This warning is a serious indictment of the drug industry and the medical profession in the country. It confirms the growing evidence that drugs are being pushed on an unsuspecting public by devious methods which masquerade as 'sales promotion' of drug companies and 'professional prescribing practice' by doctors.

A spate of reports have been appearing in our newspapers and periodicals of late, on drug-related issues and a review of these highlight that many of the following practices are not at all uncommon in India:

i) Sale of drugs banned in other countries eg: Lomotil and Clioquinol preparations.

ii) Sale of irrational combinations and formulations eg., Hathi Committee has suggested weeding out of atleast 23 such preparations.

iii) Sale of drugs without adequate precautionary product information

iv) Sale of drugs at highly inflated costs eg: it is reported that Analgin is being sold at 20 to 30 times the cost of production.

v) Promotion of drugs for indications that are not clinically proved and are often potentially dangerous eg: Promotion of EP forte combinations for pregnancy testing and induction of abortion. There is well documented scientific evidence that the risk of foetal deformity is increased by the use of these hormonal preparations.

vi) Sale of spurious, adulterated or poor quality drugs eg: Turmeric powder in tetracycline capsules and poor quality and reaction producing intravenous fluid preparations have been reported.

vii) Sale of old, expired and unused drugs. There is the double danger of effects of denatured drugs as also of inadequate dosage.

viii) Over-prescription and misuse of tonics, high-protein foods, hormonal preparations and baby foods that are both superfluous and a drain on the family economy.

ix) Sale of drugs over the counter without doctor's prescriptions or the necessary statutory checks.

x) Production of drugs for profits rather than health needs of people - eg: The ICMR/ICSSR report highlights that drugs for diseases like leprosy and tuberculosis which affect millions are produced at one-third

Bull. Scs. Vol.1 No.2 Dec83--Jan84 page 11-15.

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and one-fourth of the actual requirements while tonics, vitamins and high protein substitutes are being produced in wasteful abundance.

It is evident then, that what is needed in the country today is a consumer awakening and awareness building process that will sensitise people to the realities of the drug industry, mobilise public opinion, sensitise policy makers, confront the medical establishment and challenge the drug industry. This process will have to lead to the initiation, promotion and sustenance of consumer action to ensure that the drug policy in India is more 'people' and 'health' oriented. Is there any evidence of such an awareness?

Consumer alert and action

Beginning in the late seventies, there is an increasing number of organisations, associations, projects and action groups who have begun to create an awareness of drug-related policy issues. These groups are predominantly if not exclusively urban-based, consisting of young professionals and intellectuals from different ideological backgrounds.

Since the Medical Profession is the 'instrumental consumer' ie., they prescribe the drugs, many of these groups have directed their efforts particularly towards them. Many others are health or development associations, science popularising movements and consumer associations who are increasingly taking up drug-issues as one of their many activities. The list of groups which makes interesting reading are -

- Voluntary Health Association of India (VHAI), New Delhi
- medico friend circle (mfc) Pune
- Arogya Dakshata Mandal (AIM), Pune
- Delhi Science Forum (DSF), New Delhi
- Society of Young Scientists (SYS), New Delhi
- Lok Vignyan Sangathana (PSM), Maharashtra
- Kerala Sastra Sahitya Parishad (KSSP)
- Concern for Correct Medicine (CCM), New Delhi
- Consumer Action Front (CAF), New Delhi
- Consumer Education and Research Centre (CERC), Ahmedabad
- Centre for Education Development (CED), Bombay
- Federation of Medical Representatives Association of India (FMRA), Patna.

All India Women's Conference (AIWC) and so on. It is impossible to document all the efforts of these groups but the main types of action they have been involved in are:-

1. Publications

mfc published two anthologies of their bulletin articles 'In Search of Diagnosis' (1977) and 'Health Care Which Way to go' (1982) which included many articles on drug policy

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related issues. VHAI's special issue of the bi-monthly 'Health for the Millions' was entitled 'Medicines, as if people mattered' (1981). It covered many aspects of drug use and abuse and tried to stimulate voluntary initiatives from the public and the medical profession. CED published an exhaustive, well-researched report on "Aspects of Drug Industry in India" (1982) to stimulate further interest.

2. Meetings

These were organised by many of the groups to bring together people interested in the problem to share views and discuss action plans. The Drug Industry and the Indian People (DSF, SYS, FMRA and others, November 1981), Drug Issues and Feasible Alternatives (VHAI, Pune, Jan '82), Drug use and Abuse (mfc, Tara, Jan '82) were three such meetings. The Seminar on National Health Policy (New Delhi, VHAI, AIWC, CCM, April 1983) also discussed drug issues and stressed the need for information dissemination and consumer action.

3. Educational Campaign through letters and media

AIM launched a movement called 'Operation Medicine' in July 1977 with letters to medical practitioners and articles in the press requesting for a stop in prescription of forte vitamin preparations, irrational B-complex formulations, tonics and tinned foods and boycotting of certain drugs being sold at inflated costs.

VHAI launched a campaign in March 1982 (International Women's Day) against the misuse of hormonal preparations for pregnancy testing. Letters were sent to doctors and chemists informing them about the dangers and requesting them not to misuse these products. Articles were published in leading newspapers and periodicals. The movement snowballed and the government decided to ban EP forte combinations. The movement continues to challenge government action which has given a lag period of six months to drug companies to move stock before ban becomes effective.

mfc launched a campaign early this year about the rational management of diarrhoeas in children with a hope to prevent misuse of various available preparations that do not have much therapeutic value. Press releases, informative articles and letters to drug controllers have been major constituents of this campaign.

4. Newsletters/Bulletins

One of the best examples of continuing education of doctors on drug issues is the Pune Journal of Continuing Health Education published by AIM. This bulletin sensitises its subscribers to the half-truths of medical advertising apart from providing reliable information on latest drugs. The Drugs Bulletin of Pharmacology Department of Post-Graduate Institute, Chandigarh, is another example. mfc bulletins have also regularly featured articles on drug issues.

5. Information net-work among voluntary action groups

To maintain this growing interest, VHAI has set up a special cell on 'Low Cost Drugs and rational Therapeutics'. This Cell has been keeping groups all over India informed about new problems and follow up action of campaigns. Other groups have also initiated informal network exchanges.

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6. Low Cost Drug Ventures

The Bangarapet Medical Mission Tablet Industry has been a very successful small scale venture in providing low cost, good quality formulations to a limited group of mission hospitals in the country. Recently in Gujarat a new project called LOCOST has been initiated. This is a collective voluntary endeavour for rational therapeutics through promotion of low cost, quality, generic named medicines. An important dimension of the project will be an educational effort addressed to the voluntary sector for minimum use of drugs and the socio-economic implications of irrational therapeutics.

7. Drug Issues in Science Movements

With the growing interest on drug related issues well-known science movements in the country like KSSP and PSM have also decided to coordinate with other agencies in joint campaigns. At the All India convention of the People's Science Movement at Trivandrum convened by KSSP in February 1983, a health group was formed which drew up a joint action programme having the following four components.

a. Ban on EP Forte combinations
To oppose the wrong arguments of drug companies being used to pressurise government to lift ban order on these combinations.

b. Campaign about Anemia in Women and Irrational anti-anaemic drug preparations in the market. PSM Maharashtra included it as a topic for their yatra in May 1983.

c. Campaign against irrational Diarrhoea Management in Children. mfc would initiate campaigning from June 1983.

d. Campaign against multinational in Indian Drug Industry. A campaign by FMRA would be organised in October 1983, to coincide with the annual Jatha of KSSP and to make people aware of the role of multinational corporations in India.

Towards a people's movement

All the above efforts are small steps towards a much more wide based consumer movement against drug use and abuse and profit oriented drug policies. However, it must be remembered that in a country like ours when a very large percentage of people are below the poverty line and when more than 75 percent of the people have little access to basic health science a consumer action programmeonly on drug matters will continue to be cut off from the needs and aspirations of the majority.

Dr Norman Bethune, favour for his work in China wrote, "The best form of providing health care and health protection would be to change the economic system which produces ill health to liquidate ignorance, poverty and unemployment".

One hopes that eventually drug-related issues will become part of a much wider people's campaign for health development and socio-political change because at the root of the entire problem of drug production and availability lies what Ivan Illich has aptly described as "Socialiatrogenesis - ie., health policies reinforcing an industrial organisation which generates ill-health'.

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# THE DRUG SITUATION IN INDIA

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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. WELL 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.13.17 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 3 yrs have witnessed a steady increase in the requirements of imported raw materials by nearly 100 percent. Thus while our

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.<br>Caffeine 16.2mg.<br>Quinine sulfate 8 mg. | Anacin | 8 |
| Avedanplus | Aspirin 350 mg.<br>Acetyl Aminophenol 125mg.<br>Caffeine 30 mg. | | 8 |
| Powerin | Aspirin 350 mg.<br>Caffeine 65 mg.<br>Codeine 8.125 mg.<br>Paracetamol 65 mg.<br>Salicylamide 65 mg. | | 20 |

(Analysis of Painkillers done by Dr. Anant Phadke in his paper) Scientific Scrutiny of Over the Counter drugs)

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 on Category I, II and III after a study of the

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 prescription 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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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.

<u>What does the 6th Five Year Plan require regarding drug production?</u>

| | | |
|---|---|---|
| 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.

<u>What's the situation?</u>

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 - 1821.05 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 defiency.

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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% Indian Private Sector, 6% Public Sector

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# Changes in drug policy

THE following is the text of the official release on the modifications effected in the drug policy:

Over the years, through the successive drug policies, the Government has sought to meet the requirements of medicines for catering to the health needs of the people. The existing drug policy was formulated in 1986. Implementation of the main policy provisions has been through the I (D&R) Act in regard to the industrial licensing aspects and through the Drugs (Prices Control) Orders under the Essential Commodities Act for giving effect to the pricing mechanism. The drug policy has also provided the policy framework in regard to quality control and rational use of drugs. Enforcement of quality and standards in medicines is done through the provisions contained in the Drugs and Cosmetics Act which is administered by the Ministry of Health and Family Welfare.

In view of the experience gained over the years, the Government had felt the need to modify the existing drug policy, 1986, so as to bring it in consonance with the industrial policy, 1991, and the present EXIM policy as also to remove the anomalies/aberrations observed in its working.

After having considered the viewpoints of the various interest groups, viz. consumers and voluntary health associations, the medical profession, trade and industry associations, including small-scale manufacturers, and after broad-based discussions at various levels, including discussions in the consultative committee, the standing committee on petroleum and chemicals in the Rajya Sabha and Lok Sabha, the Government has finalised the modifications required to be made in the drug policy, 1986. The main objectives of the drug policy continue to create conditions for adequate availability of medicines of good quality at reasonable prices. The salient features of the new modifications being made in the policy are as follows:

1. Industrial licensing for all bulk drugs and their formulations, and for intermediates stands abolished, except for (i) five identified bulk drugs reserved for the public sector, (ii) drugs involving use of recombinant DNA technology and (iii) specific cell/tissue targeted formulations.

2. Companies with foreign equity up to 51 per cent would be at par with wholly Indian companies. 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.

3. In the case of manufacture of drugs from the basic stage, a rate of return higher by 4 per cent over the existing rates which are 14 per cent on net worth or 22 per cent on capital employed would be allowed in fixation of prices for drugs under price control.

4. It has been decided to keep the drugs having an annual turnover of Rs. 400 lakhs or more under price control. However, the monopoly situation in the cases of drugs with comparatively lower turnover has also been decided to be kept in view. For this purpose, if for any bulk drug having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90 per cent or more market share in the retail trade (as per ORG), a monopoly situation would be considered as existing. Drugs in which there is sufficient market competition viz. at least five bulk drug producers and at least 10 formulators and none having more than the 40 per cent market share in the retail trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would be kept in check by the forces of market competition.

With these measures the number of drugs under price control will get reduced to about 73 from the present 142 and the span of control to about 50 per cent from the present 70 per cent.

The Government will keep a close watch on the prices of medicines which are taken out of price control. In case the prices of these medicines rise unreasonably the Government would take appropriate measures, including reclamping of price control.

5. A uniform maximum allowable post-manufacturing expense of 100 per cent will be allowed in all cases of drugs under price control.

6. To achieve uniformity in prices of widely used formulations there would be ceiling prices for commonly marketed standard pack sizes of price controlled formulations and it would be obligatory for all, including small-scale units, to follow the prices so fixed.

7. Special emphasis will be laid on encouraging R & D in the pharmaceutical sector. Apart from existing incentives available for R & D, including tax incentives, an inter-ministerial committee will be set up under the chairmanship of the Secretary, Department of Chemicals and Petrochemicals, to go into the question of providing further incentives and impetus for R & D in this sector within a set time frame.

8. The Government would set up an independent body of experts, to be called the National Pharmaceutical Pricing Authority (NPPA), to do the work of price fixation. NPPA would take decisions on the applications of price approvals within a set time limit of two months for formulations and four months for bulk drugs. The NPPA would also oversee the enforcement of the provisions of DPCO.

9. In order to provide a more efficient mechanism for ensuring quality control and rational use of medicines, a National Drug Authority (NDA) would be set up by a separate Act of Parliament. NDA, in addition to the work related to effective implementation of the provisions of the Drugs and Cosmetics Act and of the rules made thereunder, would also be responsible for monitoring standard practices in drug promotion and use and to clearly identify those which are acceptable and prohibit those which are unethical and against the consumers' interest. NDA would prepare and publish a national formulary and also the formularies relevant to various levels (like district hospital, community centre, primary health centre) for the guidance of consumers as well as doctors.

10. Besides the need to undertake upgradation and augmentation of the existing infrastructural facilities, in terms of drug testing laboratories and enforcement staff under the Central and State organisations, there is need for establishing more zonal and sub-zonal offices under the Central Drug Standards Control Organisation as well as additional regional drug testing laboratories. The implementation of these proposals would require additional funds which are proposed to be mobilised by levying a cess of 1 per cent on production of drugs and pharmaceuticals by a special legislation to be piloted by the Ministry of Health and Family Welfare. The funds mobilised through the cess would be utilised also for encouraging research and development in the drug sector.

11. To provide better focus to the development and promotion of ayurvedic, unani, siddha, homeopathic and other traditional systems of medicines, a separate department, to look after all matters related to the development and promotion of these systems of medicine, would be created under the Ministry of Health and Family Welfare.

12. An inter-ministerial coordination committee will be set up under the chairmanship of the Secretary, Department of Chemicals, for monitoring areas of key concern and for taking effective and timely action in respect of issues facing the pharmaceutical industry.

DR 22.6

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# DANGEROUS PROFITERING

-Dr.GOPAL DABADE
and SHARADA GOPAL

The pioneers in establishing the drug industry in the country were P.C. Ray and T.K.Gujjar. At the time of Independence, the total pharmaceuticals sale was Rs.10 Crore.

Over the years, the multinationals have gained strong roots in the Indian drug omdustry and repatriate huge amounts out of this country. For example, Glaxo, which during 1975-76 had remittances of Rs.62.84 lakh built their empire to Rs.120.82 lakh in 1978-79.

On the whole, the contribution of these drug manufacturing units towards producing life-saving and essential drugs has been very little The Indian drug industry floods the market with about 70,000 formulations, yet 40,000 children go blind every year because of Vitamin A deficiency. Hardly has the industry anything to contribute to preventive medicine.

The Hathi Committee has commented that the firms have reduced life to disease, "to be cured in those countries by their sales propaganda technique". What are these 70,000 formulations that our drug industry is producing?

Most of these drugs produced are unessential and many of them have been banned in developed countries. The Government regularly receives information regarding banning of drugs from the World Health Organisation.

Recently, the US Senate sub-committee passed a bill that permits export of drugs which are not approved by that country's Food and Drug Administration. The laws of the European Economic Community also do not prevent export of hazardous drugs banned in their countries.

The Indian Government had hardly taken note of this until serious concern was expressed in and outside Parliament, when it took steps to ban the production and sale of certain drugs. The Drug Technical Advisory Board recommended banning of 18 fixed-dose combination drugs and accordingly, the Drug Controller of India issued a notification banning their manufacture from September 30, 1982, and sale from April 1, 1983.

But a stay was brought by by the Retail and Dispensing Chemists' Association of Bombay, in the Bombay High Court, which ordered that the list of the drugs banned should be published in the gazette as per the Drugs and Cosmetic Act.

Another drug company, Boehringer Knoll, challenged the order and got an interim stay restraining the Drug Controller from publishing it in the gazette.

Ultimately, the Ministry of Health and Family Welfare issued a notification banning some drugs, which are listed below. But it will be disheartening to note that the drug companies have found lacunae even in some of these bans, as will be mentioned later.

Under section 26(a) of the Drugs and Cosmetic Act G.S.R 578(e) dated 23/7/1983 (as amended by G.S.R. 1057(e) dated 3/11/88 - the following drugs have been banned in the country.

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1. Amidopyrine.
2. Fixed-dose combinations of vitamins with anti-inflammatory agents and transquilisers.
3. Fixed-dose combinations of Atropine in analgesis and anti-pyretics.
4. Fixed-dose combinations of strychnine and caffeine in tonics.
5. Fixed-dose combinations of strychnine and yohimbine with testosterone and vitamins.
6. Fixed-dose combination of sodium bromide/Chloral hydrate with other drugs.
7. Fixed-dose combinations of iron with strychnine, arsenic and yohimbine.
8. Phenasetin.
9. Fixed-dose combinations of anti-histaminics with analgesics.
10. Fixed-dose combinations of Penicillin with sulphanamides.
11. Fixed-dose combinations of vitamins with analgesics.
12. Fixed-dose combinations of tetracycline and Vitamin C.
13. Fixed-dose combinations of Hydroxyguinoline group of drugs, except preparations which are used in the treatment of diarrhoea and dysentry and for external use only.
14. Fixed-dose combinations of corticosteroids with any other drug for internal use, except combinations of steroids with other drugs for treatment of Asthma.
15. Fixed-dose combinations of chloramphenicol with any other drug for internal use, except combinations of chloramphenicol and Streptomycin.
16. Fixed-dose combinations of Ergot.
17. Fixed-dose combinations of vitamins with anti-TB drugs, except combinations of isonizid with pyridoxine hydrochloride (B6).
18. Pencillin skin eye ointment.
19. Tetracyline liquid (oral) preparations.
20. Nialamide.
21. Practolol.
22. Methapyrilene as salts (G.S.R.49(c) 3/5/84).
23. Methaqualone (G.S.R. 322(e) 3/5/84).
24. Oxytetracycline (oral) preparations.
25. Democlocycline liquid (oral) preparations (G.S.R. 86(e) 22/11/85).
26. Combination of anabolic steroid with other drugs (G.S.R.700(e) 15/6/88).
27. Fixed-dose combinations of oestrogen and progestin (other than oral contraceptives) containing pertablet estrogen content of more than 50 mg and of progestin of more than 3 mg.
28. Fixed-dose combinations of corticosteroids with any other drug for internal use.
29. Fixed-dose combinations of Chloramphenicol with any other drug for internal use.

But drug manugacturing companies have found adequate loopholes in in these notifications.

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Manufactures of fixed-dose combinations of oestrogen and progestin, for example, were given a notice on June 13, 1982, saying that the production of the drug should be banned from Dec.31, 1982 and sale from June 30, 1983. The order was challenged by Organon, Cibageigy and Unichem, and they obtained a stay from Calcutta and Bombay High Courts.

This drug was advocated for ban as it was known to produce congental deformity of the unborn child. The drug had already been banned in the 70's in Europe, America and Australia. The ICMR had recommended that the drug be banned.

The Supreme Court urged the Government to take action in six months and deplored the lack of interest in the issue by IMA, the Medical Council of India, and Drug Controllers of various States, as they had shown complete lack of interest in public health and welfare.

Ultimately, a public hearing was conducted, as a result of which the Drugs Controller banned it again on June 15, 1988. However, the drug was sold in several places in Karnataka and Maharashtra even after the ban, as evident from the receipts of purchase.

The companies producing the drug had mischievously interpreted this ban order as one which applied to the tablet form only and not injections. The drug companies continue to enjoy profits, at the cost of the health of people.

Tetracycline syrup has been banned on the groung that it can cause permanent damage to teeth and bone marrow. So also oxytetracycline and demeclocyline syrups.

But the injection form of the same drug does not even carry a warning, that the drug should not be injected in children. Even though syrups have been banned, so that children below 14 years do not concume it, the same is injected into the body.

Tetracycline (which is an essential drug) combination with Vitamin C is also banned. But pfizer, a leading drug company, now combines oxytetracycline with Vitamin C.

Oxytetracycline is pharmacologically no different from tetracycline. Hence, pfizer enjoys defying the ban, right under the nose of the law.

Atropine combination with analgesics and antipyretics are banned but the drug company, IDPL, uses the same combination. Instead of atropine, it uses homatropine, which has the same action and effect in the body.

Fixed-dose combination of steroids has been banned,but the drug company, Roussell, has already brought a stay order for its products, Cortasmy. So has another drug company, Lyka.

The scientific facts remain in the text books of medicine that such combination of drugs have no role to play, and that they can be dangerous. Inspite of the fact that the Drug Controller has issued ban orders on these, the drugs still find place in the market.

There are several drugs that should be banned, or their availability restricted.

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Phenylbutazone or Oxyphenbutazone is a drug that is restricted for use as per the circular by the Drug Controller and Directorate General of Health Services (dated 20 May, 1988, No.12-4-04-DC), but many drug companies flaunt the circular. In fact, this circular dated 20 May, '88 states that none of the companies insert cautionary printed statement as per an earlier circular.

This drug has been banned or restricted for use in several countries, but in our country it continues to be prescribed even for any injury.

Such restrictions on drugs have no use at all. In fact, in a recent issue of a guide book for professional medical world, the drug phenylbutazone is advocated by several drug companies for children.

Analgin is another notorious drug which is indiscriminately used in our country. It is difficult to convince our doctors about dangerous side effects of analgin. Prof.B.C.Mehta, a leading haematologist from Bombay, has estimated that in India, one person develops analgin induced agranulocytosis per day.

Agranulocytosis is a serious condition wherein the white blood cells (the defensive mechanism of body) loses its function, hence the body becomes susceptable to any infection. Analgin is available in every pan shop of our country and Baralgan, which also contains Analgin, is used by college girls to suppress menstrual pains.

Cliquinols or enteroyioform tablets are another illustration. They were known to produce SMON (Subacute Mayelo Optic Neurophathy) in Japan in 1969, where 2,340 cases were reported. After a hard fought litigation in that country Ciba Geigy ultimately withdraw the drug from the world market.

But in our country, the production of this group of drugs rose from 230 tonnes in 1982-83.

Third World countries are easy prey to the dangerous drugs, as they do not have strict regulations on drug control.

The range of unessential drugs flooding the Indian market is very wide, ranging from Gripe water mixture and baby food to cough syrups and combination drugs. At the outset, it may seem that these drugs produce no harm to the body.

But the economic waste is huge. For example,pfizer's Becosules, the second ranked product with retail sale in 1985 worth Rs.11.93 crore, is an unessential drug.

India is fortunate enough to be a country that possesses the technology for production of all essential drugs, as certified by UNIDO. According to a survey, the total sale of drugs in 1985 was Rs.1.777 crore.

Of this, essential drugs were worth Rs.632 crore (53.12%) and sales of non-essential drugs was Rs.552 crore (46.88%).

An artificial demand for these non-essential drugs has been created by the multinationals for over a decade. They earn fabulous profits and are desperate to maintain the market.

Unlike other commodities in the market for which the market is open and common through the mass media, the drug companies main concern are doctors, wholesalers and retail chemists.

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It is obvious that the drug companies use high pressure marketing techniques, and thus non-essential drugs are sold. An analysis shows that 52 multinationals in 1978-79 spent only Rs.1.56 crore on research, but Rs.15.34 crore was spent for marketing.

Though the drug companies approach the doctors through medical representatives, they extensively advertise in professional medical journals also.

The Indian Council of Medical Research and the Indian Council of Scial Sciences Research set up a joint study group to study the health situation in India and in the report have rightly said, "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".

Regarding the drug-pushing strategy of drug companies, the ICMR and ICSSR study states, "It is 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".

After having known about banned drugs, bannable drugs, unessential drugs and the promotional techniques of drugs companies, let us see what our drug policy has to offer. The following observations are worth noting.

1. The drug policy of our country is prepared by the Ministry of Petroleum and Chemicals, and the Health Ministry is in no way involved.

2. The policy announced as on January 3, 1986, did make a brief mention about banning of drugs. But no thought had been given to the ban orders.

3. No attempt has been made by the policy about abolition of brand names and introducing generic names.

4. No attempt was made to make a list of essential drugs.

5. The 1986 drug policy increases the cost of essential drugs. The increase in price is even one hundred percent for some products.

6. The policy encourages more formulations by delicensing certain drugs and also its formulations.

7. The drug policy makes no mention about restriction that need to be put on the promotional material of drugs companies.

In short, the drug policy is more a pricing policy than making it a people's policy.

A committee set up under the guidance of Jaisukhlal Hathi made certain useful recommendations. None of these has been fully implemented. The following are the highlights of the recommendations.

1. All multinational companies should be nationalised.
2. Generic names should be used, instead of using trade names/brand names.
3. Production of single drugs.
4. Elimination of irrational drug combinations.
5. Indian National Formulory must be revised in order to keep the medical profession well informed.

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6. Distribution of drugs being an important factor, a National Drug Authority of India (NDA) should be set up.
7. A list of 117 essential drugs were drawn up by the committee.
8. The Indian sector of drug industry should be helped to obtain self-sufficiency.

Former judge of the Supreme Court Justice Krishna Iyer is on record as stating: "Government is allergic to the Hathi Committee report .. and dithers, delays, shies and even retreats, allowing the hefty drug industrialists to hold to ransom people's health. Pharmaceutical imperialism practised by covert and overt disinformation, trade terrorism and brainwashed professionalism is a menace to a patriotic drug policy".

In the context of the entire drug issue, a lesson has to be learnt from a small neighbour, Bangladesh. In fact, the country took up the entire idea of a drug policy from the Hathi Committee.

The Indian drug industry should cease to exist as a profit-making industry and the concern should be for health of the people. Drugs have a role to play in the health care system, and people will have to raise their voice to claim it.

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India has committed itself to "Health for all" by 2000 AD. But to think of health as being deliverable by drugs and doctors is far from being practical. Despite the rise in the number of medical colleges, hospitals, doctors, paramedics and drug production; Malnutrition, mortality and disease rates in the country continue to evade a solution. However, since drugs form only a part of the health programmes, this aspect is usually ignored. GOPAL DABADE and SHARADA GOPAL take a look at the Indian drug scene, and the continuing use of harmful drugs.

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From

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# Drug situation - Comparative study of India and Bangladesh

FOR thousands of years, mankind has devised and employed a variety of ways to deal with diseases, each suitable to the climatic and social conditions prevailing. In all societies there have been people to advise on how to deal with disease and its consequences.

Unlike those trained in the allopathic system, traditional healers, at least in India, have treated body, mind and social relations as an indivisible unit. Allopathic system gained importance and spread in the Third World countries during the colonial period, but was generally limited to a very small group usually the white population residing in cities. In the countryside, traditional medicines largely remained the only source of treatment. In later years, however, both the systems began to be used at the same time.

Now-a-days, physicians applying the traditional system of curing disease, are employing to an increasing extent modern allopathic drugs in their therapies to attract patients. This can be a cause for concern, because these healers have no training in the use of pharmaceuticals, their information regarding drug indications, contraindications and side-effects. Their knowledge is mostly devised from informal non-medical sources or from drug retailers having extremely limited knowledge.

## Wide consumption gap

Despite this, the gap in per capita consumption of drugs between the developed and developing nations, which was already very considerable continued to grow in subsequent years. While in terms of value, each inhabitant of a developed country consumed in 1976, on an average, 8.5 times as many drugs as an inhabitant of a developing country, in 1985 he consumed drugs costing 11.5 times as much.

This worsening of the situation is due to both the slower growth of drug consumption in developing countries and the faster growth of population. Whereas the growth rate of the population in developing countries reached 201 per cent per year in the period 1976-85, in developed countries it was less than one per cent.

The pattern shows the low effective demand in developing countries for drugs of the highest health priority for the majority of the population, namely, those for tropical infections and parasitic diseases, and a relatively high demand for drugs that do not meet the basic needs and are chiefly consumed by a small segment of the population. This is so because, whether in developed or developing countries, medical personnel, other prescribers, and the public are not rational in their use of drugs.

When a Drug Policy and supplementary Drug Legislation were promulgated in neighbouring Bangladesh after 1962, much was written in this country about the pragmatic approach of the neighbour and it was even suggested that India should learn from its neighbour how to administer a drug policy. It was overlooked that the drug situation in India with its enormous size as compared with Bangaladesh and its large population was far more complex and that no single and simple policy was suitable for all countries.

## Drug industry

Many developing countries have a substantial drug industry, but it is largely made up of the local affiliates of foreign companies and employs the production of active ingredients and the development of new products taking place elsewhere. Thus in most of international trade in drugs the developing countries play only a marginal role while the transnational corporations generally play the dominant one. Their share of the market ranges

from 30 per cent in Egypt, 50 in Argentina, 70 per cent in India, 78 in Brazil and 90 in Ecuador, to nearly 100 per cent in many African countries.

Subsidiaries of the major pharmaceutical companies may or may not have national capital participation, depending on the law of each country, generally they produce pharmaceuticals developed by the parent firms and buy the raw materials also from them. In some cases, for reasons of taxation and profit, it is in the interest of the companies to sell the active ingredients to the subsidiary at a high price, thus increasing the cost of production. This practice is called transfer pricing.

A large number of domestically owned pharmaceutical firms, engaged mainly in formulation and packing, compete for the remaining share of the market. These may be privately owned or state owned but because they are not equipped to carry out research and development, often market a wide range of drugs which are combination or duplicate products.

## Indian paradox

In 1977, the World Health Organisation published the first model list of essential drugs and in 1981 an Action Programme on essential drugs was launched. Since then a large number of countries have adopted an essential drugs policy to

- make effective, safe, low cost drugs available to meet the needs for essential drugs of the entire population.

- ensure that drugs are used rationally, and

- develop, where economically and technically possible, national pharmaceutical production that will support economic growth and the overall development strategy of a country.

India provides a paradoxical example where overproduction of non-essential drugs is allowed to co-exist with shortage of essential drugs for curing major diseases. This is all the more pitiable because the country does have a strong pharmaceutical industry capable of manufacturing nearly all the drugs needed and according to UNIDO, falls in category 4 of countries technologically developed enough to be totally self-reliant, with research capabilities for the discovery of new chemical entities.

Attempts were made by the Hathi Committee to elaborate a policy geared to meeting the health needs of the people. The policy has not, been followed completely however, and economic and political priorities have often been allowed to take precedence over health priorities.

The situation is further confounded by allowing the responsibility for the development of the pharmaceutical sector to be shared by two different ministries at the Centre. The Department of Chemicals and Petrochemicals, Ministry of Industry deals with the new drug policy, prices and profits technology and other matters while the Ministry of Health and Family Care deals with such matters as registration of units, quality controls and others.

## Hathi Committee

With the advent of independence, the government planned an orderly integrated growth of the pharmaceutical industry. The 1956 Industrial Policy Resolution set the tempo for industrialisation, with


emphasis on self -reliance. On the basis of some of the recommendations made by the Hathi Committee in 1975, a national drug policy was proclaimed in 1978 with the objectives of developing self-reliance in drug technology; according a leadership role to the public sector; achieving self sufficiency in the production of 117 essential drugs and thus reducing the level of imports; encouraging the growth of the domestic sector; ensuring that drugs are available in abundance and at a reasonable price to meet the health needs of the people, maintaining high standards of production and promoting research and development.

Among other measures it was decided that imports of the necessary raw material would be carried out on behalf of drug manufacturers by the State Trading Corporation (STC), a process known as "drug

canalisation" and the pooled stock of imported raw materials was to be distributed among the manufacturers in both the public and the private sectors. The objectives of canalisation were to prevent transfer-pricing and to ensure a reliable supply of raw materials to indigenous manufacturers at a fair price.

Since the report of the Hathi Committee in 1975 and the promulgation of the 'drug policy in 1978, there have been significant changes in the pharmaceutical industry. The production of finished products has reached a value of Rs.20 billion in 1985-86, and that of bulk drugs to Rs.four billion rupees. A cumulative growth of 19.6 per cent from 1971-72 to 1978-79 in formulations and 22 per cent in bulk drugs has taken place, imports of finished formulations (tablets, injections, and so on ready-packed for retail sale) have been virtually eliminated, and exports have increased. All this has produced net savings in foreign exchange.


## Policy failures

However, the 1978 policy has not achieved all the intended results. Between 1952 and 1983 the number of production units grew three-fold, investment 24-fold, and bulk drug production 18-fold. Yet, the production of essential drugs in 1980 accounted for only Rs.3.5 billion of an overall total production worth Rs.12.6 billion. Imports of bulk drugs, mostly essential, reached a record Rs.1.78 billion in 1984-85, about half of the indigenous production. In the five years between 1978-79 and 1983-84 the industry's sales of essential drugs with the lowest price mark-up actually dipped from Rs. 554.7 million to Rs. 493.5 million, while sales of other drugs for which the government permits higher mark-ups grew by over 25 per cent from Rs. 1544.4 million to Rs 1983.8 million.

In the absence of any specific requirement that essential drugs should be produced, companies concentrated on the more profitable non-priority end of the market. As a result, essential drugs are in short supply in many parts of the country and in 1980 they constituted 16.8 per cent of the total of drugs consumed. Tonics, vitamins, restoratives, and enzyme preparations constitute 25 per cent of the drugs in the market.

## New drug policy

To set up production in general and give a boost to stagnating drug exports, the goverment adjusted its policy in 1986. Among the changes brought about were the introduction of a new comprehensive pricing system; changes in licensing policy; decanalisation of imported new materials and intermediates, and the maximum priority to making essential drugs available.

Requirements for the registration of new drugs were to be revised and the marketing of new drugs was not to be allowed unless they could be demonstrated to possess distinct advantages over existing products. However, because of the complexity of implementing national drug policies, although India has strict and comprehensive legislation on the import, manufacture and sale of drugs, much remains to be done to implement the reforms.

To improve the availability of essential drugs, measures to regulate prices have previously been taken by the government, culminating in the Drug Price Control Order (DPCO) of 1970. However, pharmaceutical firms took advantage of some aspects of the Order and increased the prices of unregulated drugs to compensate for the control.

To remedy the situation, a new order was issued in 1979, dividing formulations or finished products of 37 bulk drugs into three categories according to their "essentiality", with a different price mark-up for each category .Unfortunately the policy led to the adoption of price control measures that proved difficult to implement in practice.

With the 1986 Drug Policy, all bulk drugs and their formulations have been freed from price control except for a priority list of 166 bulk drugs, which fall into two price-control categories. The mark-up on finished drugs in controlled categories is to increase from 40 per cent to 75 per cent for drugs in Category I and from 55 per cent to 100 per cent for Category II drugs of their manufacturing costs.

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As for the critical question of ensuring the prices are under control, a monitoring system, National Drug and Pharmaceutical Authority (NDPA), will be set up, but is not likely, to be functional for at least a year and at best will be only an advisory body. The new pricing policy could improve the availability of essential drugs, though at a higher cost - anything from 0.43 to 13 per cent above current prices. Some sources though predict a possible increase in cost of 50-300 percent.

On the other hand, the argument has been put forth that a differential mark-up for finished products combined with price controls for a selected few (leaving the rest to be sold in the open market without strict price control) will encourage the industry to produce more non-essential drugs and also increase their prices.

Already, prior to the new Drug Price Control Order, the prices of all drugs showed a 30 per cent mark-up and drug company shares were selling at high premia. This was despite the fact that the drug controllers were instructed to ensure that there was no price increase before the issuance of the Order.

Although drug prices have not risen as much as the prices of other commodities in India, the increase has been substantial. The drug price index rose from 135.2 in 1979-80 to 167 in 1982- 84. Thus, despite price control and the phenomenal growth of the drug industry during the last three decades, the availability of modern drugs was still very low.

For example, in 1984 only five to six per cent of the population were able to afford or procure the modern drugs they needed; another 25 per cent had limited access to essential drugs. A majority of the people living in rural areas and urban slums, the main victims of endemic and epidemic diseases, had no or very little access to modern drugs. With the predicted increase in the cost of drugs, the problems are likely to be accentuated.

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As well as the lack of the most basic drugs for entire groups of the population, there is a proliferation on the market of formulations without adequate therapeutic rationale. Concern has been expressed in several Indian newspapers regarding harmful and/or ineffective formulations, in particular combination drugs such as antibiotics plus vitamins, penicillin plus streptomycin, chloramphenicol plus stremptomycin, and various cough syrups containing ingredients with opposing effects.

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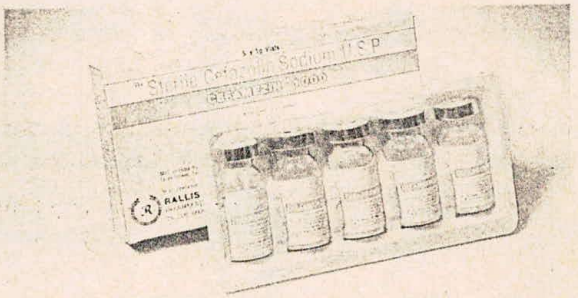

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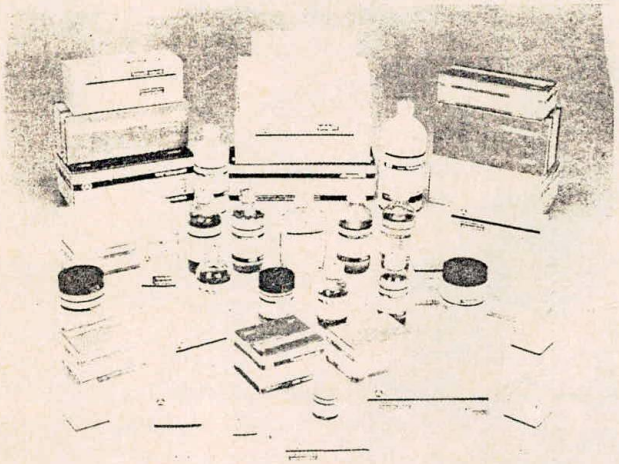


to redress the situation and ensure availability of essential medicines for everyone. It is, however, too early as yet to assess its impact.

## On to Bangladesh

In Bangladesh in 1982, a new drug policy and supplementary drug legislation (the Drug Control Ordinance, 1982) were promulgated to provide inter alia, administrative and legislative support for ensuring the quality and availability of essential drugs, reducing the price of drugs and raw materials, eliminating useless, non-essential and harmful drugs from the market, promoting local production, and developing a drug monitoring and information system.

A committee appointed by the Ministry fo Health developed a set of guidelines to evaluate all registered/licensed pharmaceutical products manufactured in or imported into Bangladesh. Nearly all combination products and harmful drugs were to be withdrawn, unless there was absolutely no alternative single drug available for treatment. The sale of tonics and of some duplicate drugs was to be prohibited. Drugs and raw materials produced in Bangladesh were not allowed to be imported and multinational companies were not to be allowed to produce antacids and vitamins. Under these guidelines, out of a total of about 4000 brands of registered allopathic drugs, the registration or licence of 1701 brands of locally manufactured or imported drugs was cancelled. This procedure took longer than planned because of the pressures put on the government by a number of interested parties. A list of 150 essential drugs by generic name was drawn up for the national health system. A supplementary list of 100 was established for restricted use by specialists.

As a result of the new policy, in 1984 over 80 per cent of the country's requirements for drugs were produced locally but almost all raw materials were imported. About 2300 locally manufactured products and 1600 foreign products were registered and authorised for marketing. Only drugs approved and registered by the Bangladesh Drug Administration could be imported into the country.

## Saving foreign exchange

One of the objectives of the drug policy was to save foreign exchange previously spent on the import of irrelevant, dangerous, or overpriced products. This was achieved by removing certain products from the market, purchasing products in the world market at competitive prices, and carrying out careful investigation of requests for registration of imported drugs by pharmaceutical companies.

The total cost of imports of raw materials in local currency appoximately doubled between 1981 and 1985, from 451 to 982 million taka (approximately 22.5 million US dollars to 32.7 million dollars) but the average price paid in 1986 for a number of raw materials was lower than in 1981. For instance, the price of ampicillin was 75 dollars per kg. in 1985 against 120 dollars. In 1981, doxycycline cost was 175 dollars instead of 1500 dollars, rifampicin 230 dollars against 473 dollars and mebendazole 52 dollars against 287 dollars. Thus far more drugs were produced per dollar spent on imports. Imports of finished products (284 million taka in 1981 and 337 million in 1985) did not rise as fast as raw materials, and more products were manufactured locally.

In 1982 the market was dominated by eight multinational companies producing about 75 per cent of the market share, followed by 25 medium-sized companies producing 15 per cent while other companies accounted for the remaining 10 per cent. The government today has a larger share in the pharmaceutical industry, as full or part owner. The share of production by Bangladeshi corporations rose from 35.3 per cent of total local production in

1981 to 54.2 per cent in 1985. Production of first 45 essential drugs doubled between 1981 and 1983 and represented 56 per cent of total local production in 1983 as against 30 per cent in 1981. The share of this production by national companies was 80 per cent.

## Industry's welcome

The monopoly existing in certain therapeutic classes was to a certain extent broken by the new drug policy. When many of the most profitable drugs were banned, the multinational companies were forced to compete in terms of both prices and products. The restriction imposed on the manufacture of vitamins and antacids by the multinational companies provided an opportunity for local companies.

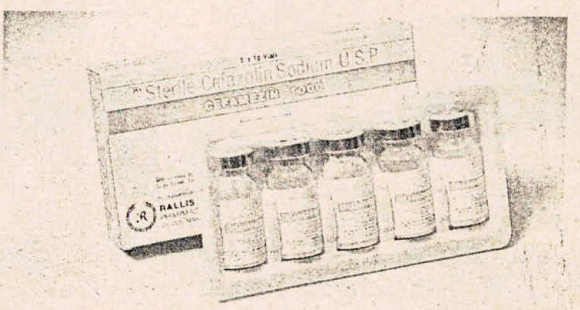
Following initial reservations, the national pharmaceutical companies now have a more positive attitude towards the new drug policy, as reflected in an article by the Bangladesh Association of Pharmaceutical Industry in the newspaper New Nation, detailing the benefits the industry has reaped from the policy. A letter from the Association in 1986 approved ratification of the Drug Control Ordinance.

Nor have the multinational companies suffered drastically from the new policy. Their output has not declined, and some firms have actually benefitted. In all, 170 drugs produced by the multinationals were banned by the Ordinance, but several new drugs produced by them have been approved and others reformulated; more than 136 of these new products are now on the market. The attraction of the pharmaceutical market in Bangladesh has not declined: local companies have expanded, while at the same time the entire pharmaceutical market has grown, thus leaving ample room for the multinational companies too. Since the new drug policy was introduced one more multinational company has entered the market, and there have been no reports of companies intending to leave.

## Progress insufficient

Although there has been remarkable progress in the production of essential drugs, it is still insufficient. Between 70 and 80 per cent of the population are without access to even basic essential drugs and, while antibiotics may be available, other fundamental drugs are not. About 10 per cent of drugs are distributed free of charge in the public sector. Only small amount of drugs reach the health system under the thana health complexes, but supplies are irregular, and even the health complexes are frequently short of essential drugs. An essential drugs programme has been established in one province, with DANIDA support, and will be extended to larger areas.

The remaining 90 per cent of drugs are sold by 14000 retailers. The Drug Ordinance states that all retail sales of drugs must be under the supervision of a pharmacist, but owing to the lack of pharmacists and the understaffing of the drug administration this has proved difficult in practice. The maximum retail price of drugs is decided by the government under the Essential Commodities Act. But the enforcement of the Act is weak. However, despite the pressure of inflation, the market price of some essential drugs has been reduced since the




new policy came into force because of increased competition, control of prices of raw materials, and the prohibition of the manufacture of a drug by a company under another company's brand name. Even so,prices are still too high for the majority of the population, whose annual income is less than 100 dollars per capita. The average spending on pharmaceuticals was 1.25 dollar per capita in 1985 one of the lowest in the world.

Only the wealthier 20 per cent of the population have easy access to drugs and health care. Polypharmacy is widespread, the average number of drugs on each prescription being four. Doctors'knowledge of drugs still often depends on information provided by companies and their representatives; loyalty to brand-name products is strong and prevents essential drugs, especially generic ones, from being used more widely.

## Areas of concern

Two other areas are of concern in Bangladesh namely quality control and traditional medicines. Quality control capacity is very limited and the drug administration is too understaffed to exercise adequate control. Drug sample tests in 1983 and 1985 showed some improvement in the quality of products, 18.6 per cent of the samples being unacceptable in 1983 as against 10.75 per cent in 1985. Nevertheless, the number of substandard products is high. DANIDA with WHO assistance, is supporting the Ministry of Health in this field.

Before the introduction of the new drug policy, traditional medicines were uncontrolled. Under the ordinance, a large number of these medicines were banned, but enforcement of the policy on Ayurvedic and Unani drugs was postponed several times because the Ministry of Health had only slight control over the producing companies. As a result the manufacture of traditional medicines have become an attractive investment proposition and the number of units manufacturing Unani and Ayurvedic drugs increased from 151 in 1978 and 1981 to 336 in 1986. This has led to the production of drugs of doubtful efficacy, several of which are claimed to have the same curative potential as banned drugs. Evidence shows that some of these drugs have been packaged and marketed in such a way as to appear to be substitutes for the banned drugs.

## Future concerns

In conclusion, the Bangladesh drug policy has in a few years permitted several steps forward to be taken in lowering prices, controlling transfer pricing, increasing essential drug production, stimulating local companies and removing dangerous drugs from the market, However, the government still faces a number of obstacles to the success of the policy.

While it is making efforts to ensure that essential drugs are made available to the majority of the population, the government realises that it needs to strengthen the health sector and, in particular the drug administration, including quality control. There is also an awareness of the need to improve control of the production of traditional medicines. Attempts to overcome the various obstacles are hampered by the scanty resources available to the government. In the future research and development are likely to continue to become more complex, time-consuming and costly. Greater emphasis is now being put on research efficiency.

Although some experts estimate that 75-85 per cent of all the new chemical entities currently awaiting approval by the FDA belong to the imitative category, advances in the biological and biochemical sciences in recent years are likely to foster the development of major new therapeutic agents, more specifically the product of what some have called the "second pharmacological revolution". They include neurotransmitters, mood-altering drugs, prostaglandis, and products to treat the health problems of the elderly (the fastest-growing population group in the major world markets.)

## Newer technology

Many of the drugs of the future will also be products of recombinant DNA technology. Until now, genetic engineering has mainly offered ways of making and improving old products (e.g.human insulin)but new products are on the way, though their appearance on the market may take longer than expected.

Novel drug delivery systems and techniques for carrying agents to specific receptor sites will also be a new field for expansion and one of the responses of research and development firms to the threatening growth of the generic producers. The goal will be to replace current "peak and trough"dosing systems with ones that provide the medicinal effect when and where needed.

Both the cost of research and the time required to transfer a drug from the laboratory to the market have increased in the last 15 years. In 1963 in the United Kingdom, according to industry analysts, it took about three years and two to three sterlings to develop and market a new drug but now it is estimated to take seven to ten years and 50 million pounds sterling

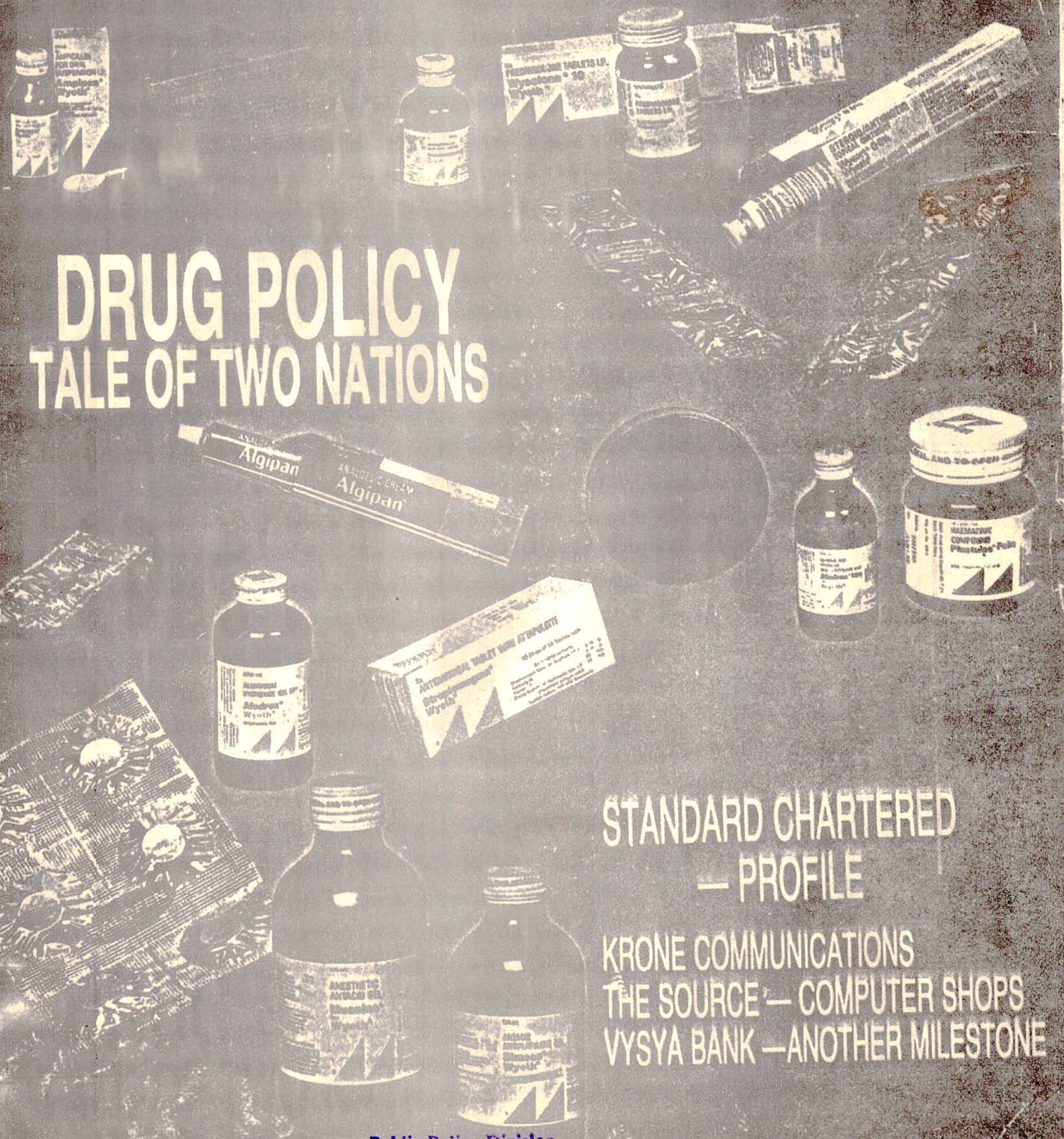
When we talk of Health For All by 2000 A.D, I feel we in India shall have to put a lot of endeavour to encompass a wide variety of activities, such as - developing a system of primary health care that reaches the whole population and promoting the health of mothers and children; combating malnutrition;controlling malaria and other communicable diseases including tuberculosis and leprosy, promoting mass immunization against a number of other preventable diseases, improving mental health, providing safe water supplies, and training health personnel of all categories and concern for health care by the government as well as people at large. ☆

— L.K. ACHARYA

DR 22.8

# FORTUNE:INDIA

ECONOMIC & BUSINESS AFFAIRS AND INVESTMENT




## DRUG POLICY
## TALE OF TWO NATIONS

STANDARD CHARTERED
— PROFILE

KRONE COMMUNICATIONS

THE SOURCE — COMPUTER SHOPS

VYSYA BANK —ANOTHER MILESTONE

# Drug situation - Comparative study of India and Bangladesh

FOR thousands of years, mankind has devised and employed a variety of ways to deal with diseases, each suitable to the climatic and social conditions prevailing. In all societies there have been people to advise on how to deal with disease and its consequences.

Unlike those trained in the allopathic system, traditional healers, at least in India, have treated body, mind and social relations as an indivisible unit. Allopathic system gained importance and spread in the Third World countries during the colonial period, but was generally limited to a very small group usually the white population residing in cities. In the countryside, traditional medicines largely remained the only source of treatment. In later years, however, both the systems began to be used at the same time.

Now-a-days, physicians applying the traditional system of curing disease, are employing to an increasing extent modern allopathic drugs in their therapies to attract patients. This can be a cause for concern, because these healers have no training in the use of pharmaceuticals, their information regarding drug indications, contraindications and side-effects. Their knowledge is mostly devised from informal non-medical sources or from drug retailers having extremely limited knowledge.

## Wide consumption gap

Despite this, the gap in per capita consumption of drugs between the developed and developing nations, which was already very considerable continued to grow in subsequent years. While in terms of value, each inhabitant of a developed country consumed in 1976, on an average, 8.5 times as many drugs as an inhabitant of a developing country, in 1985 he consumed drugs costing 11.5 times as much.

This worsening of the situation is due to both the slower growth of drug consumption in developing countries and the faster growth of population. Whereas the growth rate of the population in developing countries reached 201 per cent per year in the period 1976-85, in developed countries it was less than one per cent.

The pattern shows the low effective demand in developing countries for drugs of the highest health priority for the majority of the population, namely, those for tropical infections and parasitic diseases, and a relatively high demand for drugs that do not meet the basic needs and are chiefly consumed by a small segment of the population. This is so because, whether in developed or developing countries, medical personnel, other prescribers, and the public are not rational in their use of drugs.

When a Drug Policy and supplementary Drug Legislation were promulgated in neighbouring Bangladesh after 1962, much was written in this country about the pragmatic approach of the neighbour and it was even suggested that India should learn from its neighbour how to administer a drug policy. It was overlooked that the drug situation in India with its enormous size as compared with Bangaladesh and its large population was far more complex and that no single and simple policy was suitable for all countries.

## Drug industry

Many developing countries have a substantial drug industry, but it is largely made up of the local affiliates of foreign companies and employs the production of active ingredients and the development of new products taking place elsewhere. Thus in most of international trade in drugs the developing countries play only a marginal role while the transnational corporations generally play the dominant one. Their share of the market ranges

from 30 per cent in Egypt, 50 in Argentina, 70 per cent in India, 78 in Brazil and 90 in Ecuador, to nearly 100 per cent in many African countries.

Subsidiaries of the major pharmaceutical companies may or may not have national capital participation, depending on the law of each country, generally they produce pharmaceuticals developed by the parent firms and buy the raw materials also from them. In some cases, for reasons of taxation and profit, it is in the interest of the companies to sell the active ingredients to the subsidiary at a high price, thus increasing the cost of production. This practice is called transfer pricing.

A large number of domestically owned pharmaceutical firms, engaged mainly in formulation and packing, compete for the remaining share of the market. These may be privately owned or state owned but because they are not equipped to carry out research and development, often market a wide range of drugs which are combination or duplicate products.

## Indian paradox

In 1977, the World Health Organisation published the first model list of essential drugs and in 1981 an Action Programme on essential drugs was launched. Since then a large number of countries have adopted an essential drugs policy to

- make effective, safe, low cost drugs available to meet the needs for essential drugs of the entire population.

- ensure that drugs are used rationally, and

- develop, where economically and technically possible, national pharmaceutical production that will support economic growth and the overall development strategy of a country.

India provides a paradoxical example where overproduction of non-essential drugs is allowed to co-exist with shortage of essential drugs for curing major diseases. This is all the more pitiable because the country does have a strong pharmaceutical industry capable of manufacturing nearly all the drugs needed and according to UNIDO, falls in category 4 of countries technologically developed enough to be totally self-reliant, with research capabilities for the discovery of new chemical entities.

Attempts were made by the Hathi Committee to elaborate a policy geared to meeting the health needs of the people. The policy has not, been followed completely however, and economic and political priorities have often been allowed to take precedence over health priorities.

The situation is further confounded by allowing the responsibility for the development of the pharmaceutical sector to be shared by two different ministries at the Centre. The Department of Chemicals and Petrochemicals, Ministry of Industry deals with the new drug policy, prices and profits technology and other matters while the Ministry of Health and Family Care deals with such matters as registration of units, quality controls and others.

## Hathi Committee

With the advent of independence, the government planned an orderly integrated growth of the pharmaceutical industry. The 1956 Industrial Policy Resolution set the tempo for industrialisation, with


emphasis on self -reliance. On the basis of some of the recommendations made by the Hathi Committee in 1975, a national drug policy was proclaimed in 1978 with the objectives of developing self-reliance in drug technology; according a leadership role to the public sector; achieving self sufficiency in the production of 117 essential drugs and thus reducing the level of imports; encouraging the growth of the domestic sector; ensuring that drugs are available in abundance and at a reasonable price to meet the health needs of the people, maintaining high standards of production and promoting research and development.

Among other measures it was decided that imports of the necessary raw material would be carried out on behalf of drug manufacturers by the State Trading Corporation (STC), a process known as "drug

canalisation" and the pooled stock of imported raw materials was to be distributed among the manufacturers in both the public and the private sectors. The objectives of canalisation were to prevent transfer-pricing and to ensure a reliable supply of raw materials to indigenous manufacturers at a fair price.

Since the report of the Hathi Committee in 1975 and the promulgation of the drug policy in 1978, there have been significant changes in the pharmaceutical industry. The production of finished products has reached a value of Rs.20 billion in 1985-86, and that of bulk drugs to Rs.four billion rupees. A cumulative growth of 19.6 per cent from 1971-72 to 1978-79 in formulations and 22 per cent in bulk drugs has taken place, imports of finished formulations (tablets, injections, and so on ready-packed for retail sale) have been virtually eliminated, and exports have increased. All this has produced net savings in foreign exchange.


## Policy failures

However, the 1978 policy has not achieved all the intended results. Between 1952 and 1983 the number of production units grew three-fold, investment 24-fold, and bulk drug production 18-fold. Yet, the production of essential drugs in 1980 accounted for only Rs.3.5 billion of an overall total production worth Rs.12.6 billion. Imports of bulk drugs, mostly essential, reached a record Rs.1.78 billion in 1984-85, about half of the indigenous production. In the five years between 1978-79 and 1983-84 the industry's sales of essential drugs with the lowest price mark-up actually dipped from Rs. 554.7 million to Rs. 493.5 million, while sales of other drugs for which the government permits higher mark-ups grew by over 25 per cent from Rs. 1544.4 million to Rs 1983.8 million.

In the absence of any specific requirement that essential drugs should be produced, companies concentrated on the more profitable non-priority end of the market. As a result, essential drugs are in short supply in many parts of the country and in 1980 they constituted 16.8 per cent of the total of drugs consumed. Tonics, vitamins, restoratives, and enzyme preparations constitute 25 per cent of the drugs in the market.

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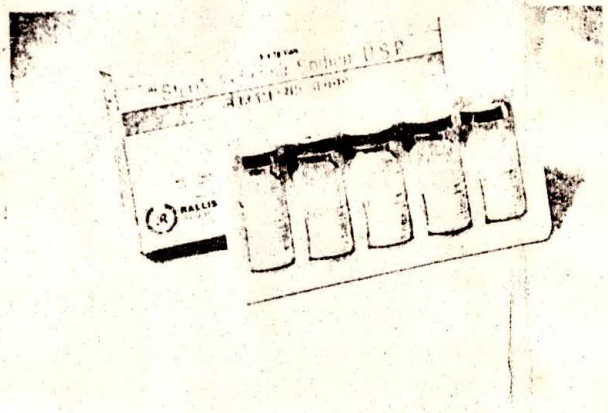

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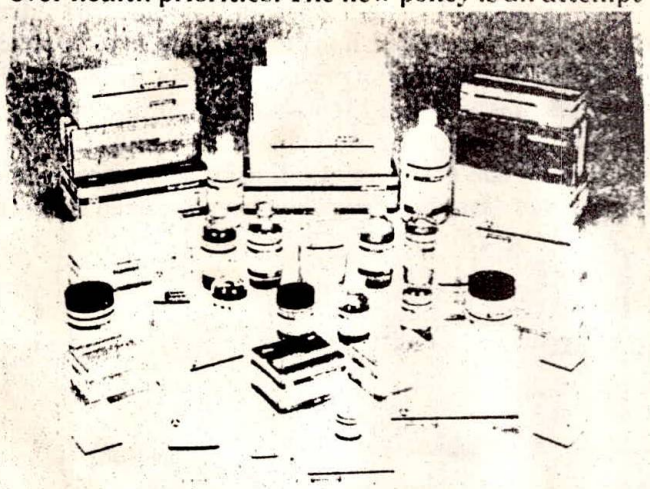

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## Saving foreign exchange

One of the objectives of the drug policy was to save foreign exchange previously spent on the import of irrelevant, dangerous, or overpriced products. This was achieved by removing certain products from the market, purchasing products in the world market at competitive prices, and carrying out careful investigation of requests for registration of imported drugs by pharmaceutical companies.

The total cost of imports of raw materials in local currency appoximately doubled between 1981 and 1985, from 451 to 982 million taka (approximately 22.5 million US dollars to 32.7 million dollars) but the average price paid in 1986 for a number of raw materials was lower than in 1981. For instance, the price of ampicillin was 75 dollars per kg. in 1985 against 120 dollars. In 1981, doxycycline cost was 175 dollars instead of 1500 dollars, rifampicin 230 dollars against 473 dollars and mebendazole 52 dollars against 287 dollars. Thus far more drugs were produced per dollar spent on imports. Imports of finished products (284 million taka in 1981 and 337 million in 1985) did not rise as fast as raw materials, and more products were manufactured locally.

In 1982 the market was dominated by eight multinational companies producing about 75 per cent of the market share, followed by 25 medium-sized companies producing 15 per cent while other companies accounted for the remaining 10 per cent. The government today has a larger share in the pharmaceutical industry, as full or part owner. The share of production by Bangladeshi corporations rose from 35.3 per cent of total local production in

1981 to 54.2 per cent in 1985. Production of first 45 essential drugs doubled between 1981 and 1983 and represented 56 per cent of total local production in 1983 as against 30 per cent in 1981. The share of this production by national companies was 80 per cent.

## Industry's welcome

The monopoly existing in certain therapeutic classes was to a certain extent broken by the new drug policy. When many of the most profitable drugs were banned, the multinational companies were forced to compete in terms of both prices and products. The restriction imposed on the manufacture of vitamins and antacids by the multinational companies provided an opportunity for local companies.

Following initial reservations, the national pharmaceutical companies now have a more positive attitude towards the new drug policy, as reflected in an article by the Bangladesh Association of Pharmaceutical Industry in the newspaper New Nation, detailing the benefits the industry has reaped from the policy. A letter from the Association in 1986 approved ratification of the Drug Control Ordinance.

Nor have the multinational companies suffered drastically from the new policy. Their output has not declined, and some firms have actually benefitted. In all, 170 drugs produced by the multinationals were banned by the Ordinance, but several new drugs produced by them have been approved and others reformulated; more than 136 of these new products are now on the market. The attraction of the pharmaceutical market in Bangladesh has not declined: local companies have expanded, while at the same time the entire pharmaceutical market has grown, thus leaving ample room for the multinational companies too. Since the new drug policy was introduced one more multinational company has entered the market, and there have been no reports of companies intending to leave.

## Progress insufficient

Although there has been remarkable progress in the production of essential drugs, it is still insufficient. Between 70 and 80 per cent of the population are without access to even basic essential drugs and, while antibiotics may be available, other fundamental drugs are not. About 10 per cent of drugs are distributed free of charge in the public sector. Only small amount of drugs reach the health system under the thana health complexes, but supplies are irregular, and even the health complexes are frequently short of essential drugs. An essential drugs programme has been established in one province, with DANIDA support, and will be extended to larger areas.

The remaining 90 per cent of drugs are sold by 14000 retailers. The Drug Ordinance states that all retail sales of drugs must be under the supervision of a pharmacist, but owing to the lack of pharmacists and the understaffing of the drug administration this has proved difficult in practice. The maximum retail price of drugs is decided by the government under the Essential Commodities Act. But the enforcement of the Act is weak. However, despite the pressure of inflation, the market price of some essential drugs has been reduced since the

new policy came into force because of increased competition, control of prices of raw materials, and the prohibition of the manufacture of a drug by a company under another company's brand name. Even so,prices are still too high for the majority of the population, whose annual income is less than 100 dollars per capita. The average spending on pharmaceuticals was 1.25 dollar per capita in 1985 one of the lowest in the world.

Only the wealthier 20 per cent of the population have easy access to drugs and health care. Polypharmacy is widespread, the average number of drugs on each prescription being four. Doctors'knowledge of drugs still often depends on information provided by companies and their representatives; loyalty to brand-name products is strong and prevents essential drugs, especially generic ones, from being used more widely.

## Areas of concern

Two other areas are of concern in Bangladesh namely quality control and traditional medicines. Quality control capacity is very limited and the drug administration is too understaffed to exercise adequate control. Drug sample tests in 1983 and 1985 showed some improvement in the quality of products, 18.6 per cent of the samples being unacceptable in 1983 as against 10.75 per cent in 1985. Nevertheless, the number of substandard products is high. DANIDA with WHO assistance, is supporting the Ministry of Health in this field.

Before the introduction of the new drug policy, traditional medicines were uncontrolled. Under the ordinance, a large number of these medicines were banned, but enforcement of the policy on Ayurvedic and Unani drugs was postponed several times because the Ministry of Health had only slight control over the producing companies. As a result the manufacture of traditional medicines have become an attractive investment proposition and the number of units manufacturing Unani and Ayurvedic drugs increased from 151 in 1978 and 1981 to 336 in 1986. This has led to the production of drugs of doubtful efficacy, several of which are claimed to have the same curative potential as banned drugs. Evidence shows that some of these drugs have been packaged and marketed in such a way as to appear to be substitutes for the banned drugs.

## Future concerns

In conclusion, the Bangladesh drug policy has in a few years permitted several steps forward to be taken in lowering prices, controlling transfer pricing, increasing essential drug production, stimulating local companies and removing dangerous drugs from the market, However, the government still faces a number of obstacles to the success of the policy.

While it is making efforts to ensure that essential drugs are made available to the majority of the population, the government realises that it needs to strengthen the health sector and, in particular the drug administration, including quality control. There is also an awareness of the need to improve control of the production of traditional medicines. Attempts to overcome the various obstacles are hampered by the scanty resources available to the government. In the future research and development are likely to continue to become more complex, time-consuming and costly. Greater emphasis is now being put on research efficiency.

Although some experts estimate that 75-85 per cent of all the new chemical entities currently awaiting approval by the FDA belong to the imitative category, advances in the biological and biochemical sciences in recent years are likely to foster the development of major new therapeutic agents, more specifically the product of what some have called the "second pharmacological revolution". They include neurotransmitters, mood-altering drugs, prostaglandis, and products to treat the health problems of the elderly (the fastest-growing population group in the major world markets.)

## Newer technology

Many of the drugs of the future will also be products of recombinant DNA technology. Until now, genetic engineering has mainly offered ways of making and improving old products (e.g.human insulin)but new products are on the way, though their appearance on the market may take longer than expected.

Novel drug delivery systems and techniques for carrying agents to specific receptor sites will also be a new field for expansion and one of the responses of research and development firms to the threatening growth of the generic producers. The goal will be to replace current "peak and trough"dosing systems with ones that provide the medicinal effect when and where needed.

Both the cost of research and the time required to transfer a drug from the laboratory to the market have increased in the last 15 years. In 1963 in the United Kingdom, according to industry analysts, it took about three years and two to three sterlings to develop and market a new drug but now it is estimated to take seven to ten years and 50 million pounds sterling

When we talk of Health For All by 2000 A.D, I feel we in India shall have to put a lot of endeavour to encompass a wide variety of activities, such as - developing a system of primary health care that reaches the whole population and promoting the health of mothers and children; combating malnutrition;controlling malaria and other communicable diseases including tuberculosis and leprosy, promoting mass immunization against a number of other preventable diseases, improving mental health, providing safe water supplies, and training health personnel of all categories and concern for health care by the government as well as people at large. ☆

— L.K. ACHARYA

# SURYA

MARCH, 1991

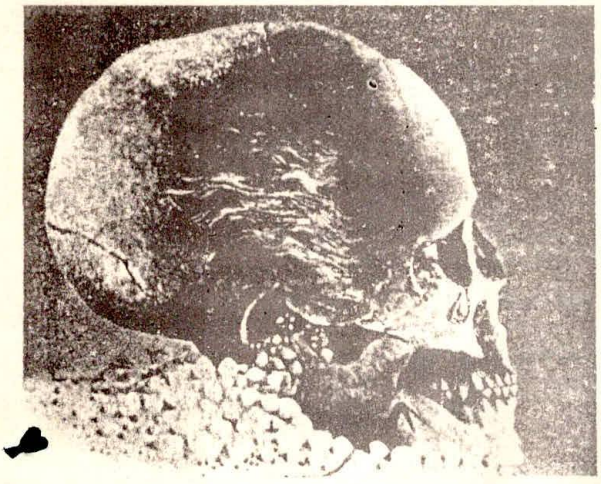
Rs. 6

# ARE YOU BEING DRUGGED TO DEATH?




CONGRESS (I) THE AGE OF THE PYGMY

MEDICAL FORMULATIONS



# ARE YOU BEING DRUGGED TO DEATH?

**There are 60,000 to 75,000 drug formulations available on the Indian market, many of them hazardous, most of them irrational.**

**Do you know what's being prescribed?**

**Does your Doctor?**

In an age of aggressive marketing and sales strategies, the consumer seldom knows what is hidden behind the well packaged product he's saddled with. But where the product is as important, and as complex, as a prescribed, even life saving drug, user ignorance is intensified by the levels of expertise needed to understand the significance or the suitability of a particular combination. Dependence on expert, and sometimes pseudo-expert opinions is absolute, the latter particularly in case of supposedly harmless across-the-counter drugs for a plethora of minor ailments.

In such a situation, it is assumed that the law would be sufficiently effective to ensure that an appropriate number of standardised drugs, under various brandnames, are made available to the hapless consumer, already burdened by the distress of his illness.

The fact, however, is that the prevailing situation relating to substandard, hazardous and irrational drugs available on the Indian market is absolutely scandalous. The Journal of the Voluntary Health Association of India (VHAI) notes, "It is possible to go into your local chemists shop today, looking for something to treat a simple headache, a remedy for diarrohea, something for rheumatism, a tonic and a pregnancy test - and come out with one drug that can blind and paralyse you for life, another which can deform your baby still in the womb, one more which can make your young daughter grow a moustache, and another couple which can give you a serious and often fatal blood disease."

Today, it is officially acknowledged that one out of every five pharmaceutical products in the country are either sub-standard or spurious. Lest this create the impression that there is a vast sub-terrainian network of criminal drug manufacturers churning out these drugs, it is important to note that not all such sub-standard products come from indistinguishable back-room laboratories, or even from the small-scale sector. In what can only be described as acts of heartless negligence and profiteering, it has been found that some of the most reputed multinational companies are also actively palming

"It is possible to go into your local chemists shop today, looking for a remedy for diarrohea...and come out with a drug that can blind and paralyse you for life..."

off substandard drugs on the market. For instance, a survey conducted in 1981 revealed that out of a total of 218 samples collected, 135 sub-standard products were manufactured by multinational companies. Dr Mira Shiva of the Voluntary Health Association of India (VHAI) notes, "It is always alleged that the small scale sector does not have its own quality control. That the small scale sector is rubbish, and the large companies are good. But the large sector is extensively using the small sector through lease licensing agreements, and is merely packaging and marketing what the small sector produces."

"It is not only the small scale sector that is involved," adds Amit Sen Gupta of the Delhi Science Forum, "Most of the major companies have at some point or the other been indicted for using substandard drugs. There are reports, if you talk informally to the drug control authorities, that if a big company is caught, a lot of pressure is put on them. And by the time they can do anything about a particular case, a lot of those drugs have already been sold. They send an order saying that such and such batch should be withdrawn from the market, but it takes 3 months before the order actually reaches the market, and by that time most of the drugs have already been sold."

The problem, however, is not restricted to substandard and spurious drugs alone, but extends to a very large number of 'irrational' drug combinations which are quite legally available in the market. Irrational drug combinations are those that are known to be either quite useless for their declared purpose, or to have specific harmful effects that outweigh whatever limited benefits they may have. An estimate of the extent to which such 'irrational' drug combinations pervade the market is available from a very simple set of facts.

## Learning About The Dangers

* Public consciousness of the inherent dangers from drug use came into being dramatically with the Thalidomide disaster, the first major drug induced disaster in the world, which resulted in the birth of some forty thousand children with severe physical deformities. The case of Thalidomide induced teratogenesis is the classic example of how ingestion of a seemingly safe drug during a shor period of gestation can lead to sever structural defects in the offspring. Infants exposed *in utero* were born with phocomelia (total absence of limbs or the presence of flipperlike or shortened limbs) and other developmental abnormalities involving the face and ears.
* This was followed by the SMON disaster in Japan, where hydroxyquinoline drugs (such as Mexaform and Enterovioform) crippled, maimed and blinded over 11,000 victims, and are said to have affected over 30,000.
* Subsequently, the teratogenic effects (causing congenital malformations when taken during pregnancy) of DES (Diethylstilbaestrol), the negative effect of anabolic steroids on children, and the efect of amidopyrine on white cells and bone marrow, each, in turn, underlined the fact that drugs can be dangerous too.
* Unfortunately, a large number of drugs that have been widely demonstrated to be dangerous continue to be sold across the counter in India. For instance, over 130 brands of hydroxyquinoline deravitives, the drug responsible for the SMON disaster in Japan, are easily available, even in rural dispensaries with the most rudimentary facilities, in India.

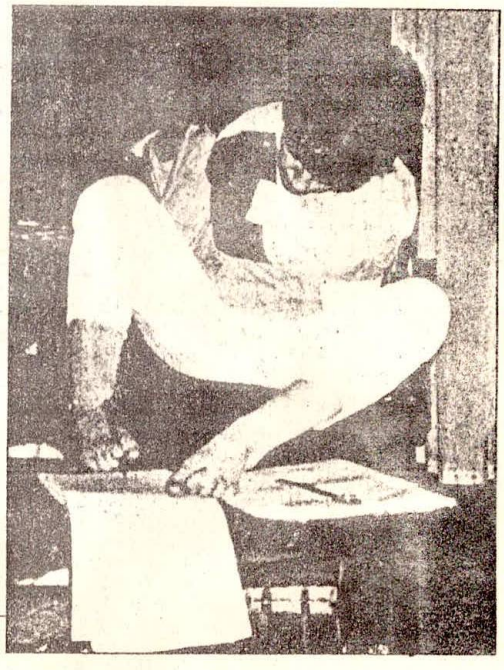
The World Health Organisation (WHO) List of Essential Drugs consists of 250 drugs and contains only seven combinations. In India there are presently over 20,000 pharmaceutical units producing between 60,000 and 75,000 drug formulations, many of them irrational, and some extremely toxic and hazardous. A large number among these are dumped in India, as in other Third World countries, by First World manufacturers who are not allowed to sell such combinations in thier own countries.

**The lack of unbiased drug information to doctors, health officiers and consumers precludes even the possibility of rational prescriptions**

The outcome is that, not only are dangerous and irrational formulations passed off as life-saving drugs, resulting in enormous loss of life, but the lack of unbiased drug information to doctors, health officiers and consumers precludes even the possibility of rational prescriptions. The only information available on some of the latest drugs and medical trends is from manufacturers and suppliers who exploit the situation to their own advantage, thriving on concealment and disinformation.

The department of health, however, is not particularly perturbed by the proliferation of brands. Dr Prem K Gupta, Drug Controller of India, responding to queries by SURYA observes, "Since India is self-sufficient in drug formulations and since there are many pharmaceutical units, there are bound to be a large number of formulations moving in

*A German victim of the Thalidomide Disaster*



# The Politics of Medicine

The overwhelming power of the vested interests in the drug industry, working constantly and surreptitiously, are seldom noticed in their operation. It is only when governments, or some enlightened members in government, seek to bring about rationalisation and change that they reveal themselves. It is only then that the world is witness to the level at which manipulation and pressures may be generated.

In Sri Lanka, Dr Senaka Bibile recognised the economic exploitation occurring in the name of medicine, and attempted to evolve a rational drug policy for his country in the 1970s by restricting the number of drugs to be imported, and calling for international tenders to prevent transfer pricing and channelising purchases. The policy, obviously, did not find favour with drug exporting countries. ***Sri Lanka was threatened with a stoppage of all food aid by the First World.*** The government buckled. The policy was subsequently completely watered down.

Dr Salvador Allende of Chile also sought to curb the control drug multinationals exercised over his country. He tried to rationalise drug policy during the short period he was President before his assassination. ***Among the first to be shot when the military junta took over after Dr Allende's death were the group of doctors who had assisted him in the formulation of a drug policy in the interest of his people and country.***

Dr Zafrullah Choudhury, the Director of the Gonosasthya Kendra, Bangladesh is the pioneer of his country's strict drug control policy, and was awarded the Magasaysay Award in 1986 for his work. Bangladesh is the first Third World country to evolve such a rigid code, with only 160 essential drugs available in its markets. This is largely a consequence of Dr Choudhury's vision and efforts. When Dr Choudhury sought to introduce the new drug policy into his country, powerful diplomatic pressures were exercised by various Western nations, including the USA which rushed a high power team to persuade General Ershad to reject or at least dilute the policy. The government resisted all these pressures, and the policy was adopted, making short shrift of the multinationals in the country. The Drug Policy was formally adopted on June 7, 1982, and the ordinance promulgated 5 days later.

Immediately, the US Government attacked the ordinance, and several drug multinationals expressed resentment and anger.

Within a week, the US Government sent an 'Expert Scientific Committee' to Bangladesh to discuss 'reconstruction' of the policy (an euphemism for diplomatic arm-twisting). The 'Expert Committee' members were found to be pharmaceutical industry representatives.

Simultaneously, the British, Dutch and German Embassies joined to exert pressure on the Government for fear of losing their markets if other third world countries followed suit.

Under severe pressure from the multinationals and foreign governments, the Bangladesh Government set up a review committee of 6 military doctors. Based on the Review Committee Report, a Drug Control Ordinance amendment was announced, permitting only *minor* changes.

Dr Hafden Mahler, Director General WHO, congratulated Bangladesh on "its courage in starting to put its drug house in order along the lines endorsed by the Wordl Health Assembly."

With Ershad's demission from the Presidentship, and the political turmoil in Bangladesh, the field is once again considered to be opening out for the multinationals.

***On October 27, 1990, the offices of the Gonosasthya Pharmaceutical Limited, the production wing of the Gonosasthya Kendra, were burnt down, resulting in a loss of 10 million takas. This was one among several attempts on Dr Zafrullah Choudhury's life. The Magasaysay Award winner has now been implicated in a case of murder and has been forced to flee underground.***

An estimate of the vested interests that arise in the entire drug trade can be had from the financial stakes of the top multinational companies whose turnovers often outstrip the Gross National Product (GNP) of many a Third World nation.

***The table below gives a comparison of growth of sales of 20 leading pharmaceutical companies with the growth in GNP of 25 countries whose GNP is close to the turnover of the companies (in $ million).***

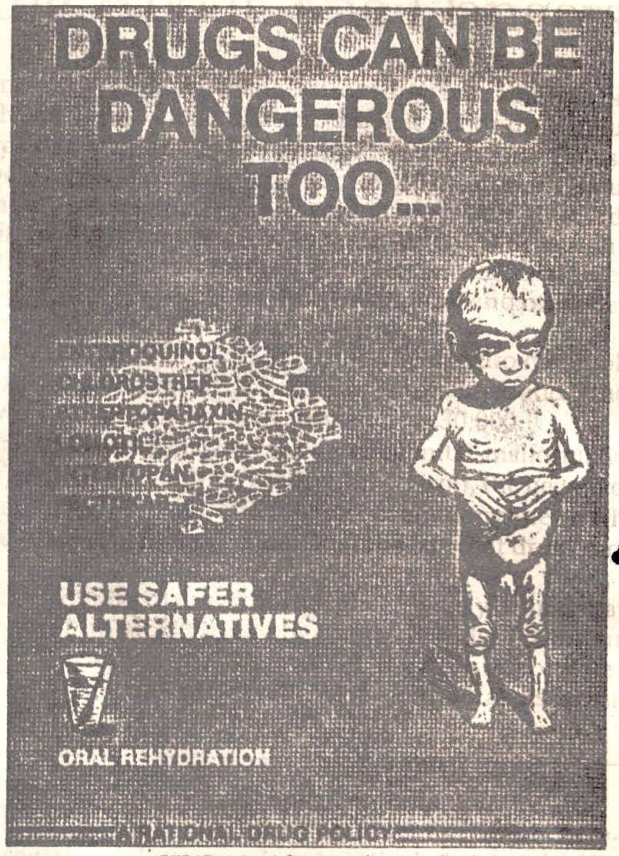
| Company or country | 1986 Turnover/GNP | Average yearly change(%)83-86 |
|---|---|---|
| Costa Rica | 3,996.0 | 13.9 |
| Bolivia | 3,900.0 | 6.7 |
| Yemen | 3,850.0 | 4.0 |
| Uganda | 3.680.0 | 4.4 |
| Merck Sharp & Dohme(USA) | 3,441.0 | 10.9 |
| Honduras | 3,330.0 | 6.2 |
| Cyprus | 3,052.0 | 5.3 |
| Hoechst (FRG) | 3,042.6 | 4.7 |
| Mozambique | 3,003.0 | -4.1 |
| Afghanistan (estimated 1984-6) | 2,924.0 | 6.2 |
| Lebanon (estimated 1984-6) | 2,889.0 | 1.2 |
| Ciba-Geigy (SWI) | 2,851.2 | 9.1 |
| Bayer (FRG) | 2,787.5 | 3.5 |
| Senegal | 2,772.0 | -0.2 |
| Nicaragua | 2,686.0 | -0.8 |
| Iceland | 2,682.0 | 8.1 |
| Albania (estimated 1984-6) | 2,604.0 | 2.2 |
| Papupa New Guinea | 2,592.0 | -1.1 |
| American Home Products (USA) | 2,560.4 | 3.0 |
| Nepal | 2,535.0 | 0.3 |
| Madagascar | 2,369.0 | -7.7 |
| Haiti | 2,244.0 | 5.4 |
| Pfizer (USA) | 2,203.0 | 5.3 |
| Sandoz (SWI) | 2,155.1 | 11.5 |
| Glaxo (UK) | 2,143.2 | 17.5 |
| Eli Lilly (USA) | 2,119.8 | 7.9 |
| Roche (SWI) | 2115.0 | 9.8 |
| Zambia | 2,070.0 | -20.3 |
| Abbott (USA) | 2,057.0 | 8.0 |
| Warner Lambert (USA) | 2,041.0 | 11.5 |
| Guinea (estimated 1986) | 1,984.0 | 7.4 |
| Bristol-Myers (USA) | 1,961.7 | 8.4 |
| Jamaica | 1,932.0 | -15.8 |
| Smith Kline (USA) | 1,896.0 | 8.2 |
| Upjohn (USA) | 1,863.0 | 10.7 |
| Rwanda | 1,827.0 | 5.5 |
| Congo | 1,782.0 | -5.5 |
| Johnson & Johnson (USA) | 1,731.7 | 12.0 |
| Takeda (Jpn) | 1,700.0 | 3.8 |
| Wellcome (UK) | 1,675.7 | 12.0 |
| Niger | 1,638.0 | 3,1 |
| Boehringer Ingelheim (FRG) | 1,616.9 | 8.2 |
| Mongolia (estimated 1984-6) | 1,560.0 | 3.4 |
| Schering-Plough (USA) | 1,557.6 | 12.0 |
| Barbados | 1,545.0 | 7.7 |
| Mali | 1,494.0 | 5.0 |

Table: Andrew Chetley, *A Healthy Business? World Health and the Pharmaceutical Industry.*

the market. For example, if 100 pharmaceutical units manufacture approximately 300 drugs given in the WHO essential list under different brand names, the total number of formulations would be 300x100=3,000. In India there are about 20,000 pharmaceutical units including about 200 big DGTD registered units." From this point of view, presumably, the Drug Controller would not be unduly agitated even if the number of formulations on the market went up to 20,000x300=6,000,000!

But the argument is *non sequiter*. It shifts imperceptibly from citing the WHO essential drug list to the innumerable brands of garbage available on the market. The fact, however, is that, despite the proliferation of brands, India has a chronic shortage of essential drugs. Says Sen Gupta, "We have about one-third of total leprosy patients in the world today. We have about 500,000 deaths due to Tuberculosis every year. And the production of anti-TB and anti-leprosy drugs is under 50 per cent of the target every year. The Government has consistently failed to compel the industry to produce essential drugs. The 1978 Drug Policy, based on the Hathi Commissions recommendations, had a stipulation that 20 per cent of turnover of any company was to be made up of essential drugs. This recommendation was never implemented, and finally, in the 1986 Policy, that clause was scrapped totally."

Another point, missed out quite completely by the Drug Controllers obtuse alibi, is that the formulations available on the market are largely irrational combinations (and occasionally hazardous combinations) of chemicals that find no place on the WHO list. What is more, with the total absence of reliable and easily accessible information, Doctors often fail to understand what they and their colleagues are prescribing, with possibly drastic results for their patients. "The number of combinations available on the market is so large," observes Dr Mira Shiva, "that neither Doctors nor Chemists can be completely familiar with them. There is compelte chaos. I don't know what your favurite drug is — and when the patient comes in half dead to the hospital, I can't make sense of your prescriptions. You just don't know the ingredient. Nobody *thinks* ingedient. They think brands."




*VHAI campaign against Quinol derivatives*

The situation, feels Dr Shiva, has arisen at least partially because of the pricing structure. Drugs needed for the National Health Programme, and other life saving and essential drugs are all listed by the Government as Category I and Category II drugs, and their prices are fixed by the Government. All other formulations are decontrolled. "So manufacturing units prefer to produce decontrolled drugs for which they can charge what they please."

At a 75 per cent markup for Category I drugs and a 100 per cent markup for Category II drugs, the drug industry claims that it is being driven to sickness due to low profits. The industry claims an overall profitability of barely 5 to 7 per cent (this

***Harrassed, Hounded, Driven out: Dr Zafrullah Chowdhury, the man behind drug policy rationalisation in Bangladesh.***

**Useless Drugs**

- Protein powders and liquids: an adult need 60 gm of Protein a day and a child 3-4 grams of protein/kg a day. If a child consumes protein from protinules, the cost would be Rs 10/day and if protone liquid, Rs 35/day. 100 grams of protein from wheat, gram, groundnut and jaggery would cost about Rs 4/- day.
- Glucose powder: e.g., Glucon D costs Rs 9.50 for 200 grams. 250 grams of sugar cost about Rs 1.25. You spend more only to inflate the industry.
- Red injections of Vitamen $B_1$, $B_6$, $B_{12}$. Anemia due to $B_{12}$ deficiency is very rare in India.
- Vitamin E preparations: the anxiety of infertile couples is being exploited by drug manufacturers.
- Placentrex (An extract from the placenta): is not mentioned in any standard medical textbook.
- Encephabol and Hydergine are expensive and cannot regenerate destroyed nerve cells.
- Stryptics (stypobion, styptochrome, styptindon, botrapase, etc.) have no proven efficacy in the treatment of bleeding.

includes profits from decontrolled drugs), and argues that many units are already on the verge of closure. They have consistently been producing much less than the requirement of essential and Categorised drugs, although the number of decontrolled brands is multiplying constantly on the market.

The industry's assertions on profitability are a little hard to swallow, though it is equally difficult to incontrovertibly prove the contrary in the absence of any data. The absence of data, however, is largely a consequence of the industry's unwillingness to provide reliable information, and this suggests that there is a great deal to hide. "It is almost impossible to find actual levels of profits in the industry," asserts Sen Gupta, "The Bureau of Industrial Cost Pricing (BICP) is supposed to determine costs and suggest suitable prices for all drugs. But BICP officials tell us that they have actually been physically assaulted when they have gone to the units for surveys. The industry just refuses to give data. However, the NCAER (National Council for Applied Economic Research) did a study to find the breakeven markups, and they came up with a figure of 53 per cent. This study was sponsored by the Organisation of Pharmaceutical Producers in India (OPPI), that's the multinational lobby in India. And inspite of the fact that it was an OPPI sponsored study, the NCAER, in its report, said that they had extreme difficulty in getting data, and in many cases it was simply refused by the companies.

*Illness becomes a dreaded nightmare, with the possibilities of contaminated drugs everpresent*

**The NCAER did a study to find the breakeven markups, and they came up with a figure of 53 per cent**

Nonetheless, if a markup of 53 per cent was evaluated as being remunerative in an industry sponsored study, it is hard to understand how it could be going sick at a markup of 75 per cent for Category I and 100 per cent for Category II drugs, especially when the combined production of all such listed drugs is barely 10 per cent

### Irrational Drugs

These are drugs that are either not proved to be therapeutically useful, or have harmful side effects which affect the benefit they render and for which better and cheaper substitutes are available. Examples are:

* Tonics which contian glycerophosphates, minerals like manganese or copper, additional components of unproved value, like choline, methionine, inositol.
* Cyproheptadine, which is prescribed as an appetite stimulant without the underlying cause being diagnosed. The effect is inconsistent and reversible.
* Cough expectorants containing guacolates, creosotes, etc. None of these is included in the WHO essential drugs list.
* Fixed dose combinations of:
  Tetracycline with analgin or Vitamin C
  Chloramphenicol with Streptomycin
  Penicillin and Streptomycin
  More than one anti-histamine
  Antihistamine with tranquillizer
  Analgesics and Vitamins.
  Pain killers like codein, caffeine and phenacctin.

### Hazardous Drugs

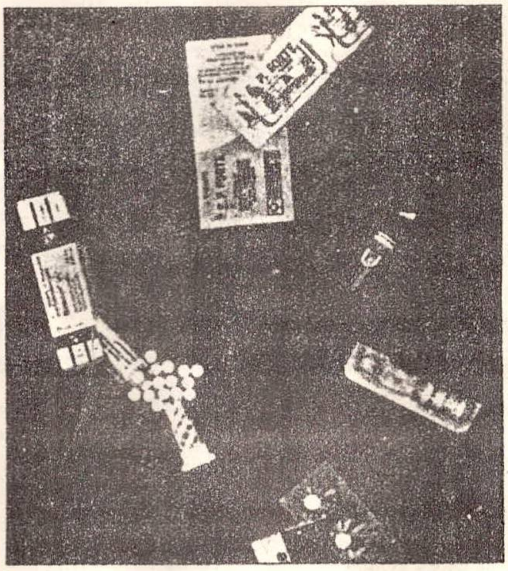
These are drugs with a clearly high and unfavourable benefit/risk ratio and which in the presence of safer alternatives should not be marketed at all. The tragedy of thalidomide and phocomelia is well known. Thalidomide, of course, was withdrawn from the world market after the scandal broke out. However, there are a large number of hazardous drugs still available on the market, especially in India and the Third World.

* Halogenated clioquinolines are neurogenic and can produce subacute myelo optic neuropathy (SMON). 130 brands are available on the Indian market.
* High dose estrogen progestrone combination drugs can lead to brith of deformed babies if taken during pregnancy. Brand names: Disecron forte, EP forte, Menstrogen, Orasecron forte, Orgaluton, Oestrone, etc.
* Anabolic steroids: in young children they can cause early closure of epiphyses, causing stunted growth. In boys they can cause precocious sexual development, and in girls, deformity of external genitals. They can also cause liver tumors and prostratic cancer.
  Brand names: Anabolex $B_{12}$, Durabolin, Evabolin, Neurobol H, Orabolin, Trinergic, Unabol, etc.
* Analgin: can cause fatal agranulocytosis (failure of certain types of white blood cells to form) and aggravate bleeding tendencies. Brand names: Analgic, Avafortan, Baralgan, Novalgin, Pamazine, Ultragin, Esgipyrine, Oralgin, Trinergin, Spazmizol, Spasmolysin, Zimalgin, etc.
* Phenylbutazone and Oxyphenbutazone: can cause fatal agranulocytosis, also liver and kidney damage. Brand names: Betaflam, Butaproxyvon, Flamar P, Jagril, Maxigesic, Suganril, Esgipyrine, Zolandin, etc.
* Paediatric tetracycline syrups: cause staining of deciduous (milk) and permanent teeth, as well as retardation of bone growth.

## Lying For Sales

The killing competition between the over 60,000 formulations in a small market of just 20 per cent of the population who can afford them results in a resort to a variety of unethical marketing practices. These could number in the thousand, but a few examples can suffice to indicate the extent to which pharmaceutical companies will go to fish into the pockets of hapless patients.

* Glaxo Laboratories cited the authority of the enormously respected medical journal *Lancet* to promote its sales of Ostocalcium B-12, even though there was no such endorsement of the product in the journal.
* Boehringer-Knoll quoted UNICEF and used their logo to promote the use of streptomycin-chloramphenicol combination for diarrhoea treatment, whereas UNICEF actually promotes simple oral re-hydration therapy for most common diarrhoeas.
* Franco-Indian Laboratories misquoted Goodman and Gilman (a standard pharmacology textbook) to promote their tonic as beneficial for anaemia, whereas Vitamen $B_{12}$ has no role in ordinary anaemia.
* SG Chemicals misquoted Goodman and Gilman, and Martinadale (a standard pharmacopia) to promote a combination of two dangerous drugs, analgin and oxyphenbutazone, whereas, in fact, the texts warn against the use of this dangerous combination.



***It required an eight year long legal battle, resisted all the way by the drug industry, to get the hazardous Estrogen Progesterone combinations banned***

of the industry's annual turnover of Rs 3,500 crores.

Experts, however, suggest that a few units may, in fact, be going through some difficulties, not as a result of price controls, but rather due to the absolutely distorted, indeed absurd, direction in which the industry is growing. "The industry is now caught in a loop," argues Sen Gupta, "They are targeting at a very middle class market which constitutes 10 to 15 per cent of the Indian population. That's the kind of people who can shell out the money to buy their drugs. To get to that market, the amount of promotional expense they are incurring, that is a spiralling expense for the industry. All this is their own fault. With certain essential drugs, they wouldn't even have to put up one chit of paper to sell. Advertising plays a very small role in essential drugs. You don't have to promote an anti-leprosy or anti-TB drug. It's only for irrational and useless products that you are incurring those expenses."

**"Advertising plays a very small role in essential drugs. It's only for irrational and useless products that you are incurring those expenses."**

Even so, the plea of sickness is somewhat incredible, particularly in an industry that has, on occassion, imposed a price markup of right upto 1000 per cent for some of its products (Baralgan Ketone, produced by Hoechst, for instance).

Whatever the case, the result is that the total growth in the drug market today is artificially pumped up with advertising hype, and far more money is going into advertising than into research and development, and none at all into clinical and confirmatory studies regarding the side effects of various (especially controversial) drugs. "The drug industry often claims it's doing a lot of innovation. But the maximum innovation it's doing is in the field of advertising. Finding out markets which have no use except for getting them higher revenues."

Whatever the case may be, the current situation is one of medical anarchy, with the hapless patient a vulnerable, and totally uninformed victim of an insensitive, profit oriented industry.

The comprehensive failure of the government to check this flagrant abuse of public trust, and the assault on the health and lives of the people that it constitutes, is, at least partly, a consequence of the information lacuna, on the

### Double Standards

Multinational companies do not promote many drugs in their own countries or in any developed country, but dump these drugs on India and other Third World nations. Some examples of such drugs, available in India, but banned in their country of origin, are;

| Name of Drug | Company | Country of Origin |
|---|---|---|
| Avil Expectorant | Hoechst | FRG |
| Soventol Expectorant | Boehirnger Knoll | FRG |
| Piriton Expectorant | Glaxo | UK |
| Periactin | Merind (MSD) | USA |
| Ostocalcium B12 | Glaxo | UK |
| Amebiotic | Pfizer | USA |
| Novalgin | Hoechst | FRG |
| Baralgan | Hoechst | FRG |
| Suganril | CIBA Giegy | Swiss |

# "Enormous Clout of the Drug Lobby"

—Dr Shakeel-ur-Rahman,
Minister for Health and Family Welfare

***In India there are over 20,000 pharmaceutical units producing approximately 63,000 drug formulations. The WHO List of Essential Drugs consists of 250 drugs and just seven combinations. What measures have your undertaken to bring the situation on standardisation of drugs in conformity with international norms of safety?***

I can only agree with you that the situation relating to the proliferation of brands is causing great concern. However, the interests in perpetuation of the system are entrenched. Over 15 years have elapsed since the recommendations of the Hathi Commission were accepted as the correct direction in which drug policy in the country must evolve, but none of the recommendations have actually been implemented.

The Health Ministry had, in the past, attempted to rationalise the situation at least in terms of bringing most essential drugs under price control after the drug policy was announced in 1986. We had suggested the inclusion of some 100 essential drugs in the list of Category I drugs. Eventually, however, only 27 were included.

The problems here are that the Ministry of Health alone is not involved. The Industries Ministry, the Ministry for Petroleum and Chemicals, they play the defining role in drug policy. This itself is an anomaly, and needs to be seriously looked into.

As Minister, I have been apprised of the immense problems relating to hazardous and irrational drugs, and I realise the necessity and urgency of drastic reform in this field. We are currently appraising the situation and seeking to coordinate action with the other ministries involved. I personally stand totally committed to a rationalisation of drug policy in India.

*It is an officially accepted fact that one out of every five pharmaceutical products are substandard or spurious, and that many of these are manufactured by large and multinational companies. What steps have been undertaken by you to attack this problem?*

The testing of standards is the responsibility of the States, and there is little we can do on a day to day basis. However, the Health Ministry monitors the activities of the various Drug Control Authorities in the States.

*The present machinery to monitor drug production and to test finished products is completely inadequate. What measures do you plan to improve the situation?*

It is proposed that both the monitoring and testing facilities should be expanded. The difficulties here are financial, as the burden of establishing testing facilities in the States where they are lacking or inadequate, would be enormous.

> **"I personally stand totally committed to a rationalisation of drug policy in India."**

At least for testing of drug standards, the existing infrastructure of various research and educational institutions may be utilised. We are working out the logistics of this at present.

*Formulations of traditional medical systems often make exaggerated and unsubstantiated claims of effectiveness for a variety of ills. What steps have you taken to standardize such medical formulations?*

The traditional medical and homeopathic systems are responding to the same market forces that are creating havoc in the allopathic drug market. Our policy of encouraging these systems has been wrongly taken advantage of by innumerable manufacturers, who are selling all sorts of formulations, many of which have no basis in the literature of traditional medicine, as *ayurvedic* or *unani* products. Unfortunately, in doing this they are not violating, but only skirting the law. Often, by adding or identifying a single herbal ingredient in their product, they seek to avoid pricing and other controls. There is an urgent need to review all such formulations, in fact, to review all drug formulations in the market, to correctly determine their efficacy, and to see that the consumer is not cheated through unethical advertising and marketing practices.

This is a tremendous exercise, and the resources required are not immediately available. However, we are certainly going to initiate a phased review in the immediate future. Also, I feel that a strong consumer movement, and efforts at consumer education can help counter the trends to mislead and cheat the consumer. The ministry is planning to coordinate its efforts with those of various NGOs and consumer groups active in this field.

*Why have the recommendations of the Hathi Committee not been implemented till now? What are the plans relating to their implementation?*

Successive Governments have failed to implement the Hathi Committee report, despite a theoretical acceptance of its findings. The only reason I can discover is an absence of the necessary political will, and the enormous clout the drug lobby exercises over the political executive.

Speaking for myself, I can say that the political will is now not lacking. We have not had sufficient time to take action, and the issue is complex, involving more than one ministry. Action has already been initiated, however, and we shall definitely show results soon.

# "Bungling and Corruption"

—Rasheed Masood, MP (JD),

***Despite a very brief tenure of five months as Minister of State for Health and Family Welfare, Rasheed Masood insists that he had already initiated moves for a overhaul of the Government's practices relating to substandard and spurious drugs, and had demanded the whole issue of drug policy be placed under the Ministry of Health. Excerpts from an interview:***

* In my opinion, not only drug policy, but the entire Health Ministry is very wrongly placed. The responsibility for implementation is cent per cent that of the State Governments, but the Central Government is answerable for what they do. The result is that, in most matters we find it impossible to defend our failures in the House. We keep writing to the States, but no one pays any attention.
* There must be a single cell involving both Central and State representatives, to monitor the entire drug scenario.
* Interestingly, the Health Ministry has nothing to do with the drug policy. It comes under the Ministry of Chemicals. But we are answerable again. Quality Control is our problem. Production is under them. I had written during my tenure that the entire drug policy formulation and implementation must be brought under one ministry.
* There is enormous bungling and corruption in the listing of Category I and Category II drugs. They are no experts on the Committee that draws up these lists. In fact, let me tell you something amazing that happened while was in charge. I directed the Secretary Health to give me details of the nominees of the Committee of experts for deciding Category I and II drugs. I was away for a few days, and when I returned, I asked the Secretary what had happened in that matter. He told me he had already finalised the list of 150 drugs and sent it to the Ministry of Chemicals. He completely bypassed me. I sent for the file again, but it wasn't brought back while I was there. Of course, our ministry fell a little later.
* I feel that all manufacturers of substandard drugs should be blacklisted in perpetuity. And not only should the companies be blacklisted, their owners should also be balcklisted, so that they can't set up a new company and restart manufacture.
* I agree that our drug policy is irrational...
* There is no sentiment of service in the industry. It's just a question of making profits - that is the one point programme of the manufacturers. And that is precisely why these fellows under us, these bureaucrats, *yeh kahte hain aur gadbad hoti chali jaati hai* (they take bribes and this hanky panky continues).
* I think there should be a review of our drug policy in its entirety. A central committee should be formed and should also go into the question of hazardous and irrational drugs. We can reduce the total number of formulations to 200 or 250. We intended doing this. Unfortunately, the very little time our Government had made this impossible.
* Even if you don't go so far as to remove the multinationals, you will definitely have to place restrictions on them. They are blocking indigenous development.

### Tonics - A Waste Of Money

Common Brands: Bayer's, BG PHos,Neogadine Elixer, Orheptal, Ranbaxy's, Santevini, Dexorange, toniazol, Hepatoglotin, etc.
Used and Propagated for: Debility, Chronic diseases, loss of appetite, restorative, weight loss, fatigue, etc.
Why Irrational: What is needed in the above cases is an adequate mixed diet and not tonics which are mixtures of B-complex vitamins in solutions of sugar and alcohol. None of the above cases can be cured by vitamins. Morever, if vitamin deficiency occurs, it is to be treated by supplying the specific vitamin which is deficient, and should be taken in dry tablet form. No medical textbook recommends the use of tonics.
Why Irrational: Consumption of B-Complex vitamins as tonics may not be hazardous as such, but other substances like caffeine, strychnine, Leptazol, etc, present along with it are potentially harmful. Regular intoke of excess of vitamin A and D are hazardous.
Tonics and health restoratives are banned in Bangladesh.

**The plea of sickness is somewhat incredible, particularly in an industry that has, on occassion, imposed a price markup of right upto 1000 per cent for some of its products (Baralgan Ketone, produced by Hoechst, for instance)**

one hand, and the absence of adequate facilities to gather required information, on the other. Various health activists representing voluntary agencies insist that government follow WHO guidelines and international standards, banning all drugs that are currently banned in the Western nations. There is, however, a certain degree of conflict on this count as well, as no universal norms are followed throughout Europe and America. Furthermore, official experts insist that local conditions vary, and so do the effects of the drugs. Thus, speaking of entroquinol, a drug banned in many Western countries, the Health Minister, replying to questions raised in the Parliamentary Consultative Committee Meeting held on 26.7.90, stated that, "The drug entroquinol, a hydroxyquinoline derivative, is not banned all over the world. It is marketed in many countries, particularly where Amoebic diarrohoea is very prevalent. The drug is marketed in 34 countries including Austria, Canada, France, Germany and Mexico. The drug was banned in Japan due to a topical adverse reaction seen in Japanese population suspected due to administration of the drug. Adverse reaction started with skin reaction, peripheral neuritis and finaly leading to a syndrome of eye disease called SMON. The Opthalmologists and expert bodies like ICMR were consulted and commented that drugs like entroquinol is cheap and essential for the treatment of Amoebic diarrohoea and they have not come across such adverse reaction in Indian population (sic)." The result is that the drug is freely available for use in India as an across the counter remedy.

However, the 'expert opinion' expressed in this case, as in other cases, goes little beyond intelligent guesswork. There are few, if any field studies, virtually no research or data collection, and no clearly directed effort to confirming or disproving the allegations relating to a particular drug. It is only when a major tragedy draws media attention to a particular formulation that some action is taken. More often than not, the drug soon reappears on the market, with some minor changes, under a different brand name.

There is, however, a major flaw in the offical argument. "In many cases," observes Sen Gupta, "there is evidence of unacceptable risks associated with particular drugs. Mainly, these are reported from outside India because we have a very weak surveillance system, and there is no monitoring of adverse drug reactions. In

**"You cannot have these double standards: you introduce a drug based on studies in the West, but ae not prepared to ban a drug on similar studies"**

### Peddling Placebos
### Cough Syrups/Expectorants

Common Brands: Avil, Benadryl, Cadistin, Cheston, Corex, Coseopn, Cosome, Deacos, Dilosyn, Driostan, Grilincutus, Kanaka, Phensedyl, Piriton, Tixylix, Zeet, etc.

Used and propogated for: All sorts of Coughs.

Why Irrational: These cough syrups are mixtures of drugs which stimulate coughing (Ammonium chloride, Ipecac, Etc), as well as those that suppress coughing (codeine, noscapine, etc.) and antihistamines that dry the secretions (Benadryl, Piritone, Avil, etc). Coexistence of such drugs in a syrup is abslolutely unscientific and irrational. Coughing is a protective activity of the body. It should not be suppressed except in certain conditions. In these cases, single ingredient cough suppressants (codeine, dextromethorphan, etc.) should be used.

Why Hazardous: Prolonged use of cough syrups is habit forming; may cause stomach upsets; reduce food intake; cause drowsiness. Chloroform preset in many of these cough syrups may damage the liver and may even cause cancer. Bangladesh has banned all cough syrups and combinations. No cough syrup or cough lozenge has been included in the WHO essential drug list.

*Living as they do, at the very edge of despair, a vast majority of our population lacks access to even the most essential and life saving drugs, while the markets are flooded with expensive garbage.*

the West, they have fairly elaborate systems of monitoring drug reactions. Whenever the question arises of banning a drug in India because of reports outside India regarding the hazards of its use, the official plea given for continuing these drugs is that these reports are not Indian reports. The point is that, one, there *are* no Indian reports. And, secondly, when these drugs are introduced in India, the studies quoted are Western studies. You cannot have these double standards: you introduce a drug based on studies in the West, but are not prepared to ban a drug on similar studies."

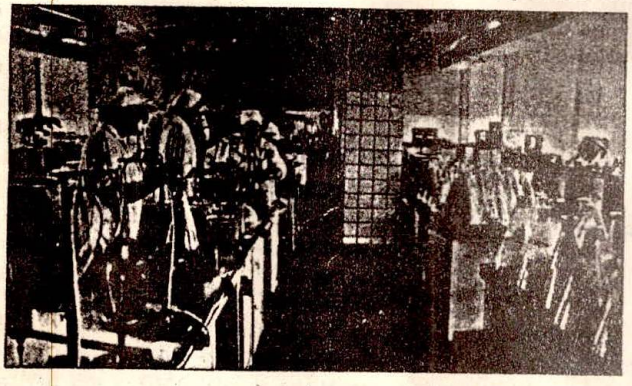
This widespread availability of hazardous drugs is thus largely consequent upon the absence of an adequate mechanism to monitor drug quality and reaction. The possibility of effective preventive measures by Government is completely precluded by the fact that there is, relative to the need, almost a total absence of testing facilties. Only four States in the country have full-fledged drug quality testing laboratories, and 10 states have facilities to test only non-biloogical drugs; most of these laboratories have inadequate equipment and manpower to perform their tasks satisfactorily. With over 60,000 combinations, it is obvious that this situation is unacceptable. Barely 26,000 samples are tested every year as against millions of batches of drugs turned out by thousands of geographically dispersed manufacturing units. Worse still, facilities to test adverse drug reactions are virtually non-existant.

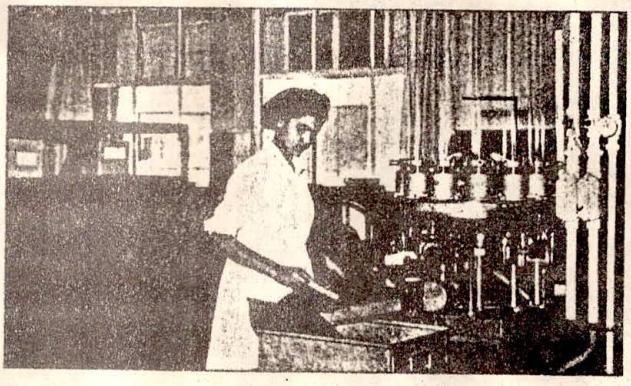
The situation relating to field inspection of drug units and retail outlets is similarly abysmal. Ther are just about 800 drug inspectors, as against 2,689 recommended by the Health Ministery Task Force.

The result is that a large number of hazardous drugs continue to be marketed in the country, and the colection of evidence is virtually impossible. Less than 10 per cent of prosecutions against manufacturers of spurious and sub-standard drugs result in convictions.

### Cures or Trips?

A staggering 62 formulations have Alcohol listed as one of their major ingredients. These include a vast array of combinations ranging over:
Tonics (BGPhos)
Mouthwashes (Dettolin)
Expectorants (Eskold)
Nasal Drops (Dristan)
Sedative Syrups for babies (Vallergan Forte Syrup)
Remedies for toothaches (Gelosa)
There is no rationale to this, except that the effects of alcohol as a depressant of the Central Nervous System are evidenced. This is completely unrelated to the symptoms or disease these 'tonics' and formulations are supposed to cure.





*Quality testing facilities (above) are severely inadequate, as both large and small manufacturers (below) produce substandard drugs.*

| Name of Co. | Country | No. of substandard Samples |
|---|---|---|
| BAYER | FRG | 13 |
| BOOTS | UK | 9 |
| BURROUHS WELLCOME | UK | 8 |
| CIBA GEIGY | SWITZERLAND | 4 |
| MERCK | FRG | 2 |
| UPJOHN | UK | 10 |
| WASCHST | FRG | 7 |
| MERIND (MSD) | USA | 11 |
| PFIZER | USA | 9 |
| ROCHE | SWITZERLAND | 5 |

'81 survey showed 135 substandard products out of 218 samples collected, ufactured by 23 multinational companies. This table lists the major ders.

## Do Doctors Know?

- That only 20 per cent of our people have access to modern medicine.
- That 50 per cent of drugs are sold over the counter without prescription?
- That medical students are taught about drugs, but not the economics behind drugs?
- That after the medical student graduates all his subsequent education is taken over by the drug representatives?
- That generic names are taught in medical colleges but the prescriptions are all in trade names?
- Out of 218 cases of substandard production of drugs, 135 were from 23 multinational companies?
- That vitamen A is in short supply while 40,000 children in India go blind each year?
- That the bulk of the drugs produced and sold are tonics, cough syrups and pain killers, while drugs for leprosy, tuberculosis and malaria are in short supply?
- The 60 million people in India suffer from endemic goitre for want of iodized salt?
- The drug policy is formulated by the Ministry of Chemicals rather than the Ministry of Health?

Source: VHAI

The existing legislation on the subject, furthermore, presents a scenario of contradictions and inadequacy. Currently, drug quality control comes under the Drugs Cosmetics Act of 1940 (Amended in 1955, 1960, 1962, 1964, 1972, 1984); The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1955; the Dangerous Drugs Act, 1930; and the Poisons Act, 1919. These Acts give apparently sweeping powers to the Central government for the control of drug quality and marketing, as well as to ban import and manufacture for sale of such drugs as are therapeutically irrational or which involve risk to human beings and animals. Rules framed under these Acts also provide for the banning of drugs, the manufacture, sale or distribution of which is prohibited in the coutry of origin.

Despite these laws, a wide range of drugs banned in the country of origin are being dumped in India, and the manufacture, import and sale fo therapeutically irrational and hazardous drugs continues unabated.

The impotence of these legal provisions is evident in the case of the attempts to ban amidopyrine. The Drug Controller of India directed the State Drug Controllers to ban the fixed dose combinations of amidopyrine with effect from February 1982. When the Maharashtra Drug Controller issued orders for the ban, several multinational drug companies obtained a stay order from the Bombay High Court on the ground that these drugs were allowed to be sold in other states.

Conversely, through another order, the Drug controller directed the State Drug Controllers to ban the manufacture of high dose estrogen and progesterone combinations from March 31, 1983, and their sales from 30 June 1983. Three drug companies obtained stay orders from the High Courts of Calcutta and Bombay on the grounds that the Central Government has no powers to ban the manufacture and sale of drugs. Another fact that emerged from these cases is that one of the multinational companies Ms Organon [known in India as Infar (India) Ltd] is prohibited from manufacturing and selling the product in its parent country, Netherlands.

Thus, through various court orders, it appears that neither the State Governments nor the Central Government is *de facto* empowered to ban dangerous or irrational drugs. It was only after an eight-year legal battle that the Hydroestrogen-Progesterone combinations were banned. And these were extremely hazardous drugs. "These were being marketed as pregnancy test kits without a warning to the mother that they could cause severe congenital abnormalities," points out Dr Shiva, recalling the protracted legal battle in this case, "In the West, women were using these drugs to find out at the earliest if they were pregnant, in ordrer to terminate pregnancy. In India, however, women who wanted to have a baby were using these kits to confirm pregnancy. It was really criminal. Especially since we found that Organon wasn't allowed to sell the drug in the Netherlands. Yet, only after a great hue and cry, was the drug eventually withdrawn from the market in 1988."

The fight ban a single drug, on which an elaborate data base of clinical

it appears that neither the State Governments nor the Central Government is *de facto* empowered to ban dangerous or irrational drugs

*If Health for All is to be taken as a serious programme, manufacturers must be compelled to produce adequate supplies of essential drugs.*

trials already exists, can thus be totally exhausting. Where such completely incontrovertible evidence is not in existence, or where there is even a little controversy in medical circles regarding the possibility of its efficacy, all the efforts of government and voluntary agencies would prove worthless against the legal quibblings of industry lawyers. The result is that the Drug Controller of India and the State Drug Controllers are rendered totally ineffective, and drug manufacturers continue to produce these harmful drugs with impunity.

Interestingly, the Government's initiatives to promote traditional medeicine systems (such as Ayurveda and Unani) and homeopathy has had its own unfortunate fallout, adding to the already chaotic medical remedies scenario. These systems do, of course, offer cheap, and perhaps safe, alternatives to the allopathic system in many cases. Unfortunately, the trade in these medeicines is almost completely out of the Government's control, concentrated as it is in the hands of unregistered practitioners, and often of quacks, who are marketing untested and substandard combinations with claims of miraculous cures for a wide range of ailments from the common cold to cancer.

Some of the larger producers, such as Dabur and Maharishi Ayurveda are now aggressively marketing brands of specific combinations for a range of ailments, including paracetamols, antacids, asthama cures, and liver treatments. Virtually nothing is known about the composition of these formulations, and there is, of course, no available data on clinical trials.

"Take, for instance, Liv 52, a Hamdard product," observes Sen Gupta, "For years it has consistently been one of the top ten selling brands. It has a total turnover of something like Rs 15 crores annually. Uptil now, I have yet to see a study where it has been conclusively shown that Liv 52 acts in *any* condition. Yet, if you have jaundice, and go to a Doctor, nine times out of ten doctors will prescribe Liv 52. I can challenge you that none of the Doctors know what the ingredients of Liv 52 are, what their actions are, what their side effects are. That's the kind of thing advertising builds up."

*Anti Drug-price rise rally at Calicut*

The unregulated administration of such 'treatment' has a double danger: in the first place, these 'cures' may actually be harmful; secondly, even where they are no more than ineffective, they cause undue delay in the administration of scientifically tested therapy, often taking the gullible patient over the brink before he is taken to a recognised hospital or medical practitioner.

The gravity of the situation relating to the unregulated traditional medicines bazaar can be estimated by the fact that almost 70 per cent of the population (primarily the poor) is still dependent on locally available traditional skills. The market induced distortions, consequent upon the 'herbal remedies fad' have further magnified the problem, unloading hundreds of brands, most of them

**"None of the Doctors know what the ingredients of Liv 52 are, what their actions are, what their side effects are. That's the kind of thing advertising builds up"**

The Hathi Committee

Main Recommendations:

* Nationalisation of Multinatinal Drug Companies.
* Establishment of a National Drug Authority.
* Priority Production of 116 Essential Drugs.
* Abolition of Brand Names and Introduction of Generic names.
* Revision and updating of the Indian National Formulary.
* Strengthening of quality control.
* Elimination of irrational drug combinations.

The Committee on Drugs and Pharmaceuticals (commonly known as the Hathi Committee), appointed by the Ministry of Petroleum and Chemicals, submitted its report in April 1975.

The Report provided the inspiration for the formulation of Bangladesh's National Drug Policy, the most radical policy in the Third World.

***Not a single recommendation of the Hathi Committee has been implemented in India.***

Source: AIDAN/VHAI

garbage, of 'authentic and safe herbal remedies' for just about everything. Their range varies from toffees with high sugar content, labelled 'Ayurvedic digestive drops' (e.g. Swad, which is 97 per cent sugar), to high alcohol-content preparations (medicines which contain more than 24 per cent alcohol, e.g. Mrit-sanjeevani sura) which are commonly sold as liquour substitutes in dry areas.

Dr Unnikrishnan of the VHAI writes, "From a study of the range of ayurvedic products sold, it emerges that the main emphasis is on the production of cosmetics and tonics which have nothing to do with the basic needs of the people. Of the Rs 150 crore annual sales of Dabur India Ltd, 80 per cent is from just 24 of its products, most of which are non-essential. Yet this company has a burgeoning growth rate of 25 per cent every year, its turnover doubling every three years."

**Comparison Of Expenditures on R&D and Marketing by 52 Multinational Companies**

| Year | R&D | Marketing |
|---|---|---|
| 1975-76 | 107 | 1317 |
| 1976-77 | 136 | 1462 |
| 1978-79 | 156 | 1534 |

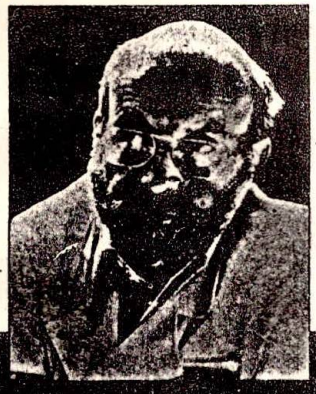
In Lakhs of Rs. Source: M Bhagat, Aspects of Drug Industry in India

Another reason for the explosive growth of the herbal remedies market is that they are completley outside price control. The result is that, even traditionally allopathic drug producing companies are jumping onto the ayurvedic/ unani bandwagon. "You can charge just anything," notes Sen Gupta, "as soon as you *call* your medicine an Ayurveic product. Take an interesting example, the case of Vicks Vaporub. Vaporub contains Menthol, and the 1986 drug policy brought Menthol under price control. Overnight, Vicks Vaporub began to call Menthol by its Ayurvedic name, and started claiming to be an Ayurvedic product. So overnight they came out of price control." He adds, "With Ayurvedic drugs, like 30 Plus and other tonics, you can get to the consumer diretly. You don't have to go to the Doctor."

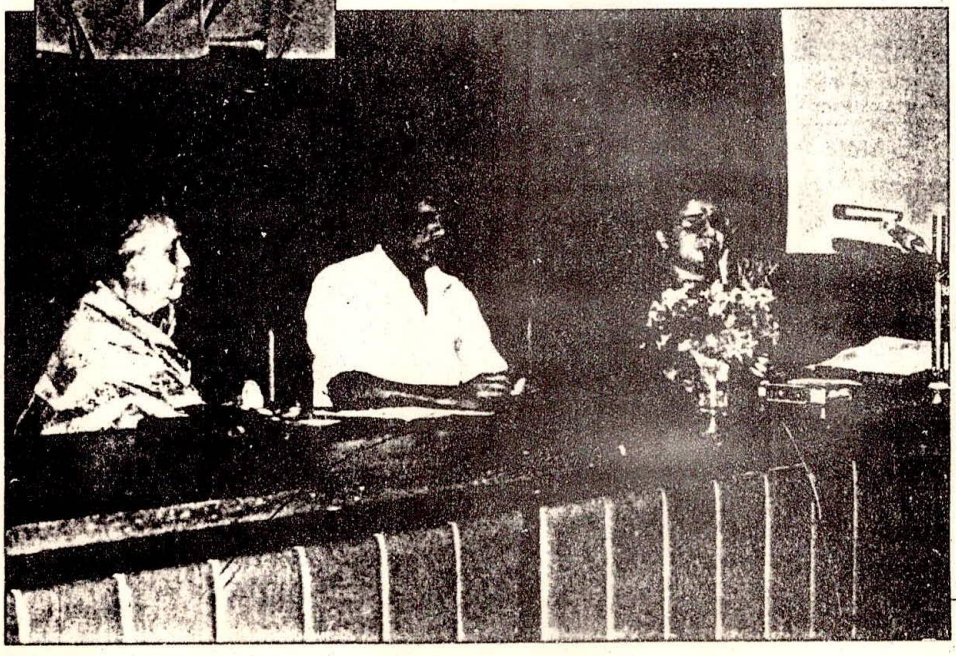
**Vicks Vaporub contains Menthol. The 1986 drug policy brought Menthol under price control. Overnight, Vicks Vaporub began to call Menthol by its Ayurvedic name and became a herbal remedy**

The most significant problem in this scenario of chaos is the lack of coherence in the overall policy perspective. Perhaps the most significant reason for this is the Ministerial breakup of responsibility, with the entire drug policy being determined by the Ministry of Industries and Chemicals, while the Ministry of Health is supposed to be responsible for implementation, and has nothing to do with policy formulation. As a matter of fact, as must be clear by now, the Health Ministry can do little by way even of implementation, except in the Union Territories and in the CGHS schemes, since, once again, implementation of drug quality control norms is a State subject, and the States have been notorious for thier unwillingness to take a hard line against the drug lobby.

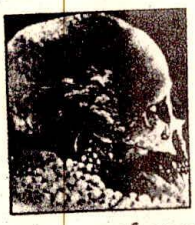
One of the critical reccommendations of the Hathi Committee, and one that has been repeated at every Parliamentary consultative committee meeting, seminar and discussion, is for the formation of a centrally controlled National Drug Authority, responsible for all aspects of policy formulation and



*Dr Olle Hansson, one of the pioneers in the struggle to protect the consumer from hazardous drugs, who died recently of cancer.*



***Dr Zafrullah Chowdhury (centre), Dr Mira Shiva (Right), and the late Mrs Tara Ali Baig at a rational drug policy meet.***



implementation in connection with drugs. The constitution of such a body would have gone a long way towards bringing order to the reigning madness of the market. Despite the passage of over 15 years, however, such an Authority is nowhere nearer constitution.

The absence of the necessary political will to implement this decision in the face of opposition from the drug lobby is largely responsible for this failure. The drug industry has been the single largest beneficiary of the of the confusion that prevails, and feels it has a vested interest in sustaining current levels of disinformation, and in resisting all efforts at a rationalisation. It has fought tooth and nail against every effort to impose controls of any kind. Indeed, the limited efforts by government to control at least the price of essential and life saving drugs have been resented by the industry to such an extent that, in August last year, the entire industry threatened a two day strike, perhaps the first such incident in the industrial history of the country. The strike, eventually, failed to materialise, but certain concessions were announced by Government a little later suggesting that a 'deal' had been worked out.

To the extent that the drug industry has adopted this attitude, it appears that it isa victim of its own insecurities. The impact of a rationalisation of drug policy does not necessarily imply declining revenues. Indeed, when Bangladesh drastically cut down its drug list to a bare 160 essential drugs, the revenues of the major companies, far from shrinking, continued to grow. It would, therefore, not be to the detriment of the drug industry if it abandoned the route to chaos that it is currently pursuing, and ceased to be an obstacle to public health.

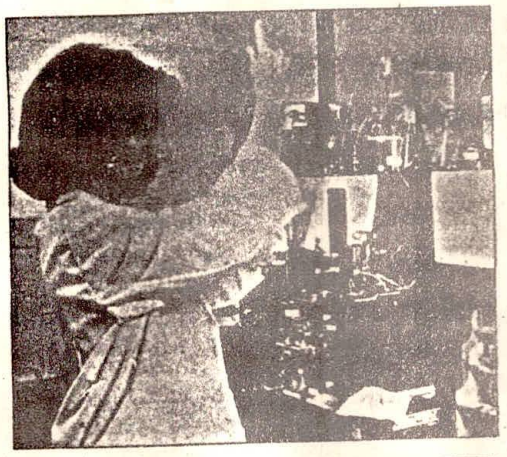
Given the complex situation, furthermore, it is evident that the current drug policy requires more than a marginal reform; it requires an overhaul. Comprehensive screening of all drugs and remedies on the market, stringent penalties for substandard and spurious drugs, adequate testing and evaluation facilities, and a National Drugs Control Authority (as recommended as far back as 1975 by the Hathi Committee), and tighter legislation can only be a beginning in what promises to be an ardous journey towards public safety in medical treatment. The responsibility for initiating these reforms rests with whatever government that presently holds power at the Centre, irrespective of the political imperatives it may face. Government and Industry must unequivocally accept that slogans of liberalisation cannot be permitted to become excuses for exploitation. The liberalisation of drug policy is inextricably linked to its rationalisation.

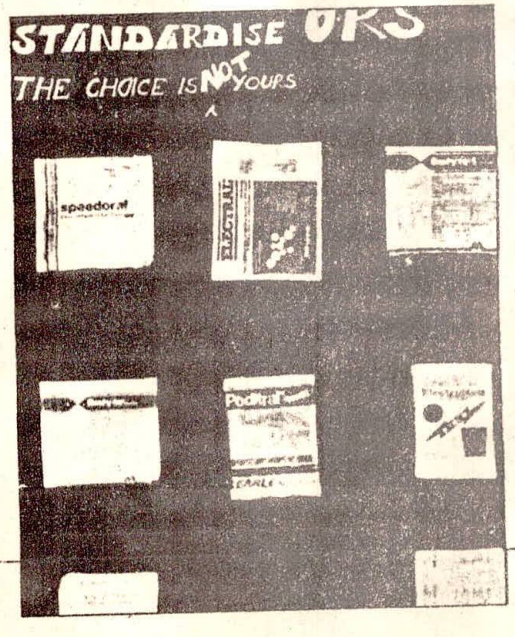
**Ajai Sahni**

**Government Action On Hazardous and Substandard Drugs**

| Year | No. Of Samples Tested | No. Found Substandard | No. Found Spurious | Prosecutions Launched | Convictions Obtained |
|---|---|---|---|---|---|
| 1987-88 | 26,545 | 3,687 | 31 | 639 | 265 |
| 1988-89 | 27,696 | 3,987 | 56 | 611 | 281 |
| 1989-90 | 26787 | 3,539 | 35 | 541 | 174 |

Source: Drug Controller (India)






*Increasing testing facilities is a first imperative (above left); and VHAI campaign for standardisation of Oral Rehydration Therapy Sachets (left)*

It would not be to the detriment of the drug industry if it abandoned the route to chaos that it is pursuing, and ceased to be an obstacle to public health.

Drug Policy

# Speculation rife on US hand in drug policy

Shyam Kumar

BOMBAY 12 MARCH

IS THERE an American hand behind the government's policy of disallowing remunerative prices to the pharmaceutical industry, forcing many units to stop manufacture and diversify into unrelated areas?

A wild conjecture? But one that is increasingly being talked about in the industry. There is no shred of evidence to back the allegation. At the same time, many in the industry say that a "deliberate, systematic undermining" of the industry by successive governments cannot be a mere coincidence.

This argument is also supported by the fact that very few American companies have a significant presence in the Indian drugs industry — an undermining of the Indian industry's profitability, therefore, will not hurt the Americans much, say industry sources.

India has become a name to reckon with in global market for many drugs, affecting the market share of leading western companies. Ethyl Corporation of United States has been lobbying against imports of cheap but high quality Indian ibuprofen for the past few years. US firms have been very critical about Indian patent rules and were among those instrumental in placing India under Super 301 clause. Many Indian firms have been penetrating the US generic market for drugs which are off patent.

Recent decisions of the department of chemicals and petrochemicals smack of a conspiracy against the industry, according to some industry leaders here. A temporary fall in the open market price of a bulk drug on a particular day is immediately monitored and followed up by a cut in its notified price, they said. Some units which have received claims under Drug Price Equalisation Account (DPEA) in recent months say there are horrendous miscalculations some of which appear deliberate rather than accidental.

Till recently, the department has been reducing prices as recommended by BICP, but ignoring its recommendations for price increases based on its own cost audits. In a recent instance, it went one step further by proferring information on an imported drug and requesting for a recommendation for price cut. BICP declined to do so on the basis of the information offered. The government can, of course, cut the price suo moto as it has been doing.

New price cuts are in the offing. A notification announcing reduction in the price of sulphamethaxazole is being issued shortly. The current price is around Rs. 325 per kg.

This is a leading item in India's export basket. As in the case of some other drugs, good price realisation abroad and competition in the home market has at times led to market prices falling below the notified price.

Ibuprofen, metronidazole and amoxycillin have been other drugs whose prices were similarly cut in recent months. The first two are again among top export earners. At least in the case of ibuprofen, a reduction in the domestic price will benefit American drug companies, which are major players in this drug in the world markets. This is particularly so because importers of drugs from India normally negotiate prices using the domestic price as a benchmark.

DR 22.11

ANNEXURE-II

Drugs and Pharmaceuticals (Monitored Bulk Drugs) Prduction Targets and Achievements (Organised Sector)

| Name of the Drug | A/c Unit | Production | | | |
|---|---|---|---|---|---|
| | | 1987-88 (Actual) | 1988-89 Target | 1988-89 Actual | 1989-90 Target |
| 1 | 2 | 3 | 4 | 5 | 6 |
| **I. ANTIBIOTICS** | | | | | |
| 1. Penicillin (excluding 1st crystal) | MMU | 304.83 | 500 | 330.47 | 520.00 |
| 2. Streptomycin | T | 248.32 | 270 | 243.79 | 270.00 |
| 3. Chloramphenicol Powder** | T | 94.64 | 300.00 | 92.84 | 300.00 |
| 4. Chloramphenicol Palmitate** | T | 1.93 | | 14.50 | |
| 5. Tetracycline | T | 210.22 | 400.00 | 184.33 | 420.00 |
| 6. Oxytetracycline | T | 120.62 | 190.00 | 164.49 | 200.00 |
| 7. Ampicillin* | T | 235.19 | 500.00 | 272.34 | 580.00 |
| 8. Erythromycin | T | 41.50 | 80.00 | 40.72 | 90.00 |
| 9. Amoxicillin | T | 48.67 | 130.00 | 53.68 | 145.00 |
| 10. Doxycycline | T | 17.94 | 10.00 | 9.25 | 11.00 |
| 11. Gentamycin | Kg. | 345.00 | 2310.00 | 884.00 | 2660.00 |
| 12. Framycetin | Kg. | * | 3890.00 | 4400.00 | 4000.00 |
| 13. Rifampicin** | T | * | 80.96 | 73.67 | 93.10 |
| 14. Ampicillin Sodium | T | * | n.a. | — | n.a. |
| 15. Cloxacillin | T | * | n.a. | 10.72 | n.a. |
| 16. Cephalexin | T | * | 15.95 | 45.84 | 17.54 |
| 17. Phenoxymethylpenicillin | MMU | * | n.a. | — | n.a. |
| 18. Griseofulvin | T | * | 26.65 | — | 29.20 |
| **II. SULPHA DRUGS** | | | | | |
| 1. Sulphamethoxazole** | T | 688.00 | 620.00 | 1445.56 | 720.00 |
| 2. Sulphadimidine | T | 475.36 | 800.00 | 465.72 | 850.00 |
| 3. Sulphacetamide | T | 49.50 | 85.00 | 48.09 | 90.00 |
| 4. Phthalyl Sulphathiazole | T | — | 305.00 | 13.57 | 320.00 |
| 5. Sulphadiazine | T | 78.99 | 135.00 | 10.05 | 140.00 |

* It was not monitored during 1987-88.

** Substantial production from small scale units also

n.a. Not Available

| | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| 6. Sulphamoxole | T | 42.39 | 135.00 | 92.90 | 140.00 |
| 7. Sulphaphenazole | T | 25.60 | 90.00 | 2.49 | 90.00 |
| 8. Sulphaguanidine | T | 183.04 | 285.00 | 219.56 | 285.00 |
| 9. Sulphasomidine | T | 24.61 | 80.00 | 45.74 | 85.00 |
| 10. Sulphanilamide | T | 10.24 | 30.00 | 12.57 | 30.00 |
| 11. Sulphamethizole | T | — | 4.00 | — | 4.00 |
| 12. Sulphadoxine | T | * | n.a. | | n.a. |
| **III. VITAMINS** | | | | | |
| 1. Vitamin A | MMU | 76.10 | 185.00 | 74.24 | 210.00 |
| 2. Vitamin B1 | T | 64.35 | 180.00 | 75.25 | 190.00 |
| 3. Vitamin B2 | T | 21.52 | 7.00 | 25.74 | 80.00 |
| 4. Vitamin B12 | Kg. | — | 53.00 | 101.63 | 580.00 |
| 5. Vitamin C | T | 831.26 | 115.00 | 868.77 | 1210.00 |
| 6. Vitamin D3 | Kg. | 404.00 | 530.00 | 249.00 | 580.00 |
| 7. Vitamin E | T | 72.83 | 20.00 | 101.59 | 20.00 |
| 8. Vitamin K | T | — | 2.68 | — | 2.81 |
| 9. Vitamin P | T | 2.47 | 4.50 | 1.84 | 4.50 |
| 10. Folic Acid | T | 7.55 | 13.00 | 9.26 | 15.00 |
| 11. Nicotinic Acid** | T | 0.48 | 420.00 | 8.74 | 470.00 |
| 12. Nicotinamide** | T | 89.14 | | 115.95 | — |
| 13. Vitamin B6 | T | * | 70.00 | 27.32 | 80.00 |
| 14. Calcium Pantothenate | T | * | 35.00 | — | 40.00 |
| **IV. ANALGESICS & ANTIPYRETICS ETC.** | | | | | |
| 1. Analgin** | T | 274.90 | 1000.00 | 271.80 | 1000.00 |
| 2. Aspirin | T | 1512.49 | 2490.00 | 1582.50 | 2740.00 |
| 3. Oxyphenbutazone** | T | 5.11 | 190.00 | 0.19 | 220.00 |
| 4. Phenyl Butazone** | T | 40.21 | 100.00 | 30.04 | 100.00 |
| 5. Paracetamol** | T | — | 5780.00 | 2.39 | 6650.00 |
| 6. Pethidine | Kg. | 478.00 | 1600.00 | 515.00 | 1760.00 |

* It was not monitored during 1987-88.

** Substantial production from small scale units also

n.a. Not Available

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| 7. Ibuprofen | T | 91.66 | 120.00 | 125.35 | 140.00 |
| 8. Probenecid | T | * | n.a. | 6.80 | n.a. |
| 9. Baralgan Ketone | T | * | n.a. | 2.82 | n.a. |
| 10. Dextropropoxyphene HCl | T | * | 17.00 | — | 19.00 |
| 11. Methyl Salicylate | T | * | n.a. | 410.51 | n.a. |
| 12. Piroxicam | T | * | n.a. | — | n.a. |
| **V. CORTICOSTEROIDS** | | | | | |
| 1. Dexamethasone | Kg. | 228.00 | 1390.00 | 343.00 | 1600.00 |
| 2. Betamethasone | Kg. | 858.00 | 1620.00 | 932.00 | 1600.00 |
| 3. Prednisolone | Kg. | 2157.00 | 5010.00 | 1923.00 | 6390.00 |
| 4. Hydrocortisone | Kg. | * | n.a. | 11.00 | n.a. |
| **VI. ANTI T.B. DRUGS** | | | | | |
| 1. PAS & Its Salts | T | 68.77 | 250.00 | 74.48 | 250.00 |
| 2. INH | T | 57.84 | 400.00 | 140.29 | 450.00 |
| 3. Thiacetazone | T | 39.58 | 80.00 | 24.69 | 85.00 |
| 4. Ethambutol | T | 345.31 | 370.00 | 407.99 | 450.00 |
| 5. Pyrazinamide* | T | 27.71 | 32.50 | 3.87 | 35.00 |
| **VII. ANTI MALARIALS** | | | | | |
| 1. Chloroquin | T | 140.10 | 450.00 | 141.16 | 470.00 |
| 2. Amodiaquin | T | 19.81 | 44.00 | 20.16 | 47.00 |
| 3. Pyrimethamine | T | * | n.a. | — | n.a. |
| **VIII. ANTIDYSENTERY DRUGS** | | | | | |
| 1. Metronidazole** | T | 444.93 | 480.00 | 436.27 | 572.00 |
| 2. Tinidazole | T | 37.98 | 73.00 | 44.20 | 84.00 |
| 3. Diloxanide Furoate | T | 5.95 | 48.00 | 15.06 | 53.00 |
| 4. Iodochlorohydroxyquinoline | T | 197.12 | 416.00 | 204.87 | 460.00 |
| 5. Di-iodochlorohydroxyquinoline | T | 4.89 | 145.00 | 6.08 | 160.00 |

* It was not monitored during 1987-88.

** Substantial production from small scale units also

n.a. Not Available

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| 6. Triamterene | T | * | 205 | — | 225.00 |
| 7. Leperamide | T | * | n.a. | — | n.a. |
| **IX. ANTI DIABETICS** | | | | | |
| 1. Chlorpropamide | T | 54.50 | 44.00 | 50.09 | 49.00 |
| 2. Tolbutamide | T | 36.86 | 40.00 | 132.88 | 40.00 |
| 3. Glybenclamide | T | 2.05 | 1.42 | 1.43 | 1.56 |
| 4. Insulin | MU | 3148.00 | 4080.00 | 2846.00 | 4480.00 |
| **X. CNS STIMULANTS** | | | | | |
| 1. Caffeine** | T | 7.36 | 135.00 | 27.32 | 140.00 |
| 2. Nikethamide | T | 0.07 | 6.00 | 0.42 | 7.00 |
| **XI. DIURETICS** | | | | | |
| 1. Frusemide | T | 6.89 | 14.00 | 10.25 | 16.00 |
| 2. Acetazolamide | T | * | n.a. | 1.79 | n.a. |
| 3. Hydrochlorothiazide | T | * | 7.09 | 22.16 | 7.80 |
| 4. Spironolactone | T | * | n.a. | 0.48 | n.a. |
| 5. Amiloride | T | * | n.a. | — | n.a. |
| 6. Triamterene | T | * | n.a. | — | n.a. |
| **XII. ANTI ASTHAMATICS** | | | | | |
| 1. Ephedrine | T | 28.68 | 70.00 | 35.50 | 77.00 |
| 2. Salbutamol | Kg. | 4158.00 | 2660.00 | 2736.00 | 2930.00 |
| 3. Terbutaline | Kg. | 448.00 | 390.00 | 362.00 | 430.00 |
| **XIII. CARDIOVASCULAR DRUGS** | | | | | |
| 1. Propranolol | T | 10.70 | 13.80 | 1.10 | 15.96 |
| 2. Xanthinol Nicotinate | T | 11.26 | 19.00 | 15.83 | 20.00 |
| 3. Digoxin | Kg. | 11.32 | 35.00 | 6.97 | 39.00 |
| 4. Methyl Dopa | T | 75.07 | 59.00 | 60.49 | 68.00 |
| 5. Dihydralazine | T | * | n.a. | 15.20 | n.a. |

* It was not monitored during 1987-88.

** Substantial production from small scale units also

n.a. Not Available

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| 6. Glyceryl Trinitrate | T | * | 6.94 | — | 7.98 |
| 7. Isosorbide Dinitrate | T | * | | — | |
| 8. Isoprenaline | T | * | n.a. | — | n.a. |
| 9. Quinidine | T | * | n.a. | — | n.a. |
| 10. Reserpine | T | * | n.a. | — | n.a. |
| 11. Verpamil | T | * | n.a. | — | n.a. |
| 12. Dipyridamile | T | * | 6.47 | — | 7.44 |
| **XIV. ANAESTHETICS** | | | | | |
| 1. Lignocaine/Xylocaine | T | 8.14 | 70.00 | 7.52 | 80.00 |
| 2. Procaine | T | 42.25 | 94.00 | 54.35 | 98.00 |
| **XV. ANTI HISTAMINES** | | | | | |
| 1. Cyproheptadine | T | * | n.a. | — | n.a. |
| 2. Pheniramine Maleate | T | 21.75 | 28.00 | 24.48 | 31.00 |
| 3. Chlorpheniramine Maleate | Kg. | — | 1900.00 | — | 2100.00 |
| 4. Diphenhydramine | T | 15.57 | 35.00 | 7.90 | 39.00 |
| 5. Mebhydroline | T | * | n.a. | 19.15 | n.a. |
| **XVI. ANTI HELMINTICS** | | | | | |
| 1. Piperazine and Salts** | T | 3.85 | 270.00 | 11.10 | 280.00 |
| 2. Mebendazole** | T | 42.03 | 57.00 | 18.11 | 63.00 |
| 3. Bephenium Hydroxy Napthoate | T | * | 16.00 | — | 17.00 |
| 4. Tetramisole | T | * | — | 13.11 | 35.00 |
| 5. Pyrantel | T | * | n.a. | 31.33 | n.a. |
| 6. Levamisole | T | * | n.a. | — | n.a. |
| **XVII. TRANQUILIZERS & SEDATIVES** | | | | | |
| 1. Phenobarbitone | T | 10.76 | 47.00 | 5.12 | 49.00 |
| 2. Diazepam | T | 10.33 | 5.00 | 7.22 | 5.00 |
| 3. Trifluperazine | T | * | 3.54 | — | 3.90 |
| 4. Imipramine | T | * | 3.51 | 0.41 | 3.87 |

* It was not monitored during 1987-88.

** Substantial production from small scale units also

n.a. Not Available

| 1 | 2 | 3 | 4 | 5 | 6 |
|---|---|---|---|---|---|
| 5. Lorazepan | T | * | n.a. | — | n.a. |
| 6. Nitrazepan | Kg. | * | n.a. | 90.00 | n.a. |
| 7. Prochlorperazine | T | * | n.a. | 0.28 | n.a. |
| **XVIII. ANTI FILARIALS** | | | | | |
| 1. Diethyl Carbamazine** (D.E.C. Citrate) | T | 7.15 | 81.00 | 17.17 | 89.00 |
| **XIX. ANTI LEPROTICS** | | | | | |
| 1. Dapsone | T | 23.54 | 40.00 | 23.55 | 80.00 |
| 2. Clofazamine | Kg. | 2.07 | 4000.00 | 1.45 | 3000.00 |
| **XX. IMMUNOLOGICAL AGENTS** | | | | | |
| 1. Triple Vaccine | KL | 13.04 | 32.2 | 10.40 | 33.3 |
| 2. Tetanus Anti Toxin | MU | 7071.00 | 13000.00 | 7700.00 | 13000.00 |
| 3. Diphtheria Anti Toxin | MU | 136.00 | 800.00 | 219.00 | 800.00 |
| 4. Hepatitis B Vaccine | MU | * | n.a. | | |
| **XXI. OTHER ANTI BACTERIAL** | | | | | |
| 1. Trimethoprim** | T | 84.72 | 160.00 | 99.56 | 190.00 |
| 2. Nalidixic Acid | T | * | n.a. | 20.40 | n.a. |
| 3. Nitrofurantoin | T | * | 5.00 | 3.25 | 5.00 |
| **XXII. ANTI CONVULSANT** | | | | | |
| 1. Carbamazopine | T | * | n.a. | 0.24 | n.a. |
| 2. Phenytoin | T | * | n.a. | — | n.a. |
| 3. Valproic Acid | T | * | n.a. | 3.36 | n.a. |
| **XXIII. GASTRO INTESTINAL** | | | | | |
| 1. Ranitidine | T | * | n.a. | 24.96 | n.a. |
| 2. Aluminium Hydroxide | T | * | n.a. | 1360.30 | n.a. |
| **XXIV. OTHER DRUGS** | | | | | |
| 1. Hydralazine | Kg. | * | n.a. | 224.00 | n.a. |
| 2. Heparin | MU | * | n.a. | 9186.00 | n.a. |
| 3. Chlorpromazine | T | * | n.a. | 2.66 | n.a. |
| 4. Atropine | T | * | n.a. | 1.72 | n.a. |
| 5. Iron Dextran | KL | * | n.a. | 29.16 | n.a. |
| 6. Menthol | T | * | n.a. | 17.62 | n.a. |
| 7. Silver Nitrate | T | * | n.a. | — | n.a. |
| 8. Warfarin | T | * | n.a. | — | n.a. |
| 9. Oxytocin | T | * | n.a. | — | n.a. |
| 10. Metoclopramide | T | * | n.a. | — | n.a. |

* It was not monitored during 1987-88.
** Substantial production from small scale units also n.a. Not Available.

POLITIKEN SOENDAG, Sunday 5 March 1989

DR 22 - IR

Developing Countries Victims in Power Struggle

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# The Pharmaceutical Industry Governs WHO

by Niels Stensgaard

Authority and responsibilities were cut bit by bit from Ernst Lauridsen's job. An effective, bureaucratic "salami technique" which finally made it impossible for him to continue as director at the WHO. Under a new leadership, deceit and sabotage became the norm. As head of the World Health Organisation's global campaign against unnecessary and expensive drugs he had long been unpopular in pharmaceutical industry circles. "I submitted my letter of resignation, and nobody urged me to withdraw it."

The 51-year old physician returned to Denmark this week to a job as consultant to DANIDA after six years as director of the WHO's Essential Drugs Programme (DAP). Ernst Lauridsen reveals for the first time how he was forced from the extensive, but controversial Programme.

## The Industry Man

The campaign was launched in 1982 after the WHO resolution on health for all and provision of essential drugs. Halfdan Mahler, Director General at the time, was the architect. During the term of this highly respected Dane, no-one dared touch the Programme, which was considered to be close to his heart. But no sooner that Mahler announced his departure last year, than the noose began to tighten around Ernst Lauridsen. It is common knowledge in the WHO that Mahler was very skeptical about his successor, the Japanese Hiroshi Nakajima. In addition to his career with the WHO, Nakajima has a past in a multinational pharmaceutical concern, and his candidacy was strongly supported by Japan, the second largest producer of pharmaceutical products.

Nakajima's name was first mentioned in January 1988 and we in the Programme became aware that his possible election would entail considerable changes in the pharmaceutical area (of the organisation's activities). He is known as a conservative who has always been "in" with the industry. After his election last May, I knew that my days were counted, because even before the election, Nakajima had offered my post to someone else. This despite the fact that I still had three years left on my contract and our Programme was reaffirmed every year by the General Assembly. Nakajima clearly favoured a candidate with a different outlook and conviction than mine. The candidate was American, and he confirmed to me that he had been asked if he would come to Geneva to assume my post. Nothing ever came of it, maybe because the new Director General got cold feet when several of the progressive countries declared that they thought it unwise to have a director from the USA, a country which has always been critical of the P programme.

The above is a very crucial bit of information about the Drug Action Program & it is v. imp for all of us to know its fate

## Pensioner In Seat Of Power

A few days after Nakajima,'s arrival, I requested a meeting with him in writing with a view to discussing the future of the Programme and my own role in it. To my great surprise he refused to see me. An unheard of situation in the UN system: that a director is denied access to upper management. A few days later I was informed that DAP was to be "reorganised". After five year's directorship, I was to be moved down two steps in the hierarchy--in addition to which an "advisor" was named and inserted between upper management and myself. An interesting phenomenon: one of Nakajima's old friends and confidant, a conservative pensioner of almost 70, was to review all my decisions . This "advisor" was in fact a controller whose mandate was to make my life so difficult that I would either go mad or disappear. As a former WHO director he was all too familiar with the bureaucratic game, and he was now to attempt to satisfy the pharmaceutical industry and the critics of the Programme.

I do not know if I might have been able to accept the situation. But I was really shaken when this retired gentleman denied me permission to travel to the Philippines, whose Minister of Health had specifically requested my presence for the purpose of developing a new drugs policy. And the justification...that this policy was controversial. It is indeed true that the industry had distanced itself from the new government's wishes--but we are talking about a policy developed in accordance with the guidelines and drug programme of the WHO. I pursued the matter and was told that the WHO should refrain from taking sides. My argument, that by doing nothing we would be adopting a position, was met with the incredible reply: "That is not so, because if we do not go there, nobody will know which side we might have chosen"...The perspective is frightening: by attempting to avoid conflict, the WHO may be subjected to coersion.

## No Support to Developing Countries

Towards autumn it became increasingly clear that we were no longer able to continue the previous technical and moral support to the drug action programmes of the developing countries. This was emphasized one day when I was summoned by the advisor who just wanted to inform me that, my contract not withstanding, I should feel no obligation to continue working at the WHO. That was strong stuff for a United Nations director with a clean record, so I complained internally. The reply was that our conversation had been off the record and that nothing concrete had been said. As if anyone is summoned to a private conversation during working hours...

I had no further doubts: I was through if I intended to do any meaningful work. My authority was gradually undermined to the point where I could no longer maintain an illusion of leadership. I was stripped of everyday executive functions, such as decisions on budgetary and mission matters, which now had to be approved by other authorities. Every bureaucrat knows how to cow others. The only thing left was for me to write my own resignation, which I did in November. Nobody urged me to reconsider, and no sooner had I left to spend my accumulated leave than the retired advisor was installed in my chair with the title of interim director.

Regression

When the Director General had addressed the World Association of Pharmaceutical Companies the previous month, I was only able to interpret his statements to mean that the organisation was to regress ten years. The advances accomplished by Programme with the blessing of the WHO General Assembly now has to be brought down to the level of the 1970s. During the development of the Drug Action Programme,we have been threathened repeatedly. The international pharmaceutical industry had protested vehemently in defence of a market with an annual wholesale turnover of about US$100 billion, presumably US$200-300 billion retail value. The (drug action) campaign has resulted in numerous legal processes and threats to curtail (industry) investments. We (DAP) maintained our position that unbelievable quantities of superfluous, useless, and even hazardous drugs were introduced onto the market. This is why we were never accepted by the multinationals. DAP's philosophy has been to suggest a selection of drugs carefully adapted to the need, enabling reduction in prices and wider drug distribution. We have been able to depress the prices of the most essential drugs. We have elaborated lists of about 250 drugs which cover the needs of developing countries, many of which were formerly flooded with up to 40,000 different drugs. The decisive question now is: who will be molding the future drug policy of the third world? Will it conform to WHO guidelines or to industry's wishes? WHO has promoted the goal of health for all by the year 2000. What I have experienced close up during the past year is possibly the last ideological struggle within the health care system before the turn of this century.

DR 22.13

DRUG ACTION FORUM-KARNATAKA

Workshop : Rational Drug Policy and Rational Therapy

- Understanding issues and evolving perspectives.

Dates : 8-10th June 1989

Venue : Vidyadeep, 128/1, Ulsoor Road, Bangalore 560042

Time : The Workshop will be a residential one and the timings of session will be evolved through a participatory discussion with the participants on the 8th morning.

(Tentatively there are possibilities for a short post breakfast session, a longer forenoon session, a post lunch till tea session, two short pre-supper and post-supper sessions. Adequate time will be available both in the sessions and after the sessions for small group interactions)

OBJECTIVES

The Workshop has arisen out of a felt need by DAF-K contacts to explore all aspects of the 'Drug Issue' so that they are better informed for project level/local/regional action.

The specific objectives of the Workshop will be:

WHAT IS THE PROBLEM

1. To understand 'Drugs' in their overall context

   a. Health situation in India
   b. Role of drugs in health care
   c. Pattern of drug production in India vis-a-vis health needs
   d. Dynamics of drug industry
   e. Patterns of drug distribution/availability
   f. National drug policies and laws.

2. To understand the irrational/overuse/misuse of drugs by

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health personnel focussing particularly on banned/bannable and hazardous drugs.

3. To try and understand the role and problem of drugs from the peoples point of view.

HOW/WHY THE PROBLEM

4. At a broader level to discover the Social/Economic/Political/ Cultural factors responsible for this problem.

5. At a micro level to discover the factors responsible for actual overuse/misuse by health teams and the people.

WHAT TO DO TO TACKLE THE PROBLEM

6. To consider the various responses to the problem at local/regional/national/international level by various groups/projects/institutions/government in the areas of :

   a. Consumer awareness and movements
   b. Updating/informing health personnel
   c. Pressure group on policy makers
   d. Search for low cost alternatives
   e. Individual/group action
   f. Project policy changes.

7. To explore ways and means by which the workshop participants can respond to this problem at individual/project level.

METHODOLOGY

The workshop will explore the above issues in a variety of ways using more participatory and group learning experiences keeping 'didactic input' sessions to a minimum

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A tentative list of possible components to the programme are as follows.

1. Getting to know each other sessions
   (pulling in information on both individual and project experiences)
2. 'Expectations from Workshop' and 'Participatory Planning' session.
3. Exploring all aspects of the Drug issue using **Tonics** as a case study
4. Two sessions on Banned, Bannable and Hazardous drugs.
5. Screening of videos, produced by:
   a. Voluntary Health Association of India, New Delhi
   b. Institute For Cultural Research and Action, Bangalore
   c. International Organisation of Consumer Union, Malaysia
6. Slide shows:
   a. Drug Policy in India - Ramakka's Story (CNFCE/CHAI)
   b. Tonics and Health (DAF-K)
   c. The Bangladesh experience (CDC)
7. Exploring issues and perspectives through a poster/chart exhibition.
8. Interviews/meetings with:
   a. Drug Controller
   b. Representatives of Drug Industry
   c. Doctors
   d. Medical Representatives
   e. Pharmacists
   f. Consumers

- understanding the issue from the point of view of each group

9. Reviewing actions/initiatives by members of All India Drug Action Network.

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10. A Cultural programme on Drug issues

    a. Drug issues through art
    b. A street theatre

11. Question-Answers sessions

12. A planning Future Action session.

## Participants

The workshop will be for a small group not exceeding 15 apart from a few resource persons. As of 1st April we have received confirmation from participants in KRVP, Srujana, DEED, DAKSHETHE, IDS, People's Trust, Grahaka Jagruti, Samagra Vikas, Ashwini Hospital, SNEHAKUNJA and CHC.

The above objectives and outline have arisen out of a questionnaire sent to participants as well as a core-group interaction in Bangalore on 27th March 1989. Participants are welcome to send any more suggestions to modify/improve the programme after perusing this note.

Some reading materials will be sent to all the participants in early May. More will be distributed at the time of the meeting. If participants/organisations would like to distribute some materials of their own, they are requested to bring 20 copies of each.

DR 22.13

# 'If there are no side effects, this must be Argentina

## DRUG COMPANY SPONSORED MISINFORMATION OF DOCTORS

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

with less contra-indications
less side effects

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

The following comparison of promotional literature for three drugs bears this out only too well.

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

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

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

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

(*Contd. to page 30*)

(*Contd. from page 22*)

| | | |
|---|---|---|
| Argentina | If patient has tendency to blood clot. | None |

Drug : **Imipramine** (Anti-depressant, Ciba Geigy) In U.S. used for depression only. In some Latin American countries, Ciba Geigy recommends it also for senility, pain and alcoholism

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

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

DR 2-2-15

# Medication as a Substitute for Caring

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

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

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

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

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

—Helping Health Workers Learn
David Werner and Bill Bower.

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"The physician who sets about to treat a disease without knowing anything about it is to be punished even if he is a qualified physician; if he does not give proper treatment, he is to be punished more severely, and if by his treatment the vital functions of the patient are impaired, he must be punished most severely."

—Koutilya Arthashastra

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# The Crazy World of Tonics

Mukarram Bhagat

'Health' tonics are a craze with the affluent in the cities with their supposedly hectic, energy-consuming life-styles. Feeling tired? Pop a pill or gulp down a spoonful and it will keep you going (nobody knows where!)

The most commonly used tonics are multi-vitamin preparations with highly excessive quantities of vitamins.

*Incremin C*, the famous growth tonic with the Giraffe logo, contains an important amino acid lysine which the human body cannot synthesise by itself. However, a teaspoon of Incremin contains only about 300 milligrams of lysine when just a handful of peas contains about 1800 milligrams of lysine. The advertising slogan that Incremin turns "extra eating into extra growth" is medically unsubstantiated and at best a half-truth. The quantities of vitamin constituents of Incremen are absurd: 10 times more vitamin B1, 25 times more vitamin B12, 2 times more vitamin B6 than required by the body daily. (1)

The daily requirement of the human body of vitamin C is about 50 milligrams, of vitamin B1 one milligram and some others in minute quantities of a few micrograms. Against these well established norms, most tonic preparations contain between 10 to 50 times the minimum requirements (2) which are simply excreted away by the body--a colossal waste of valuable nutrients in a poor country. Further, most vitamins are needed in small amounts to stimulate the processes of normal metabolism, they are not energy-giving in themselves.

It is almost certain that the high-potency multivitamin formulations consumed by the well-fed are almost wholly rejected by the body. For example, the daily requirements of vitamin C can be obtained from a single fruit or a salad helping. Vitamin A, supplied by green, leafy vegetables, is stored in large amounts by the body for proper vision. Vitamin D is naturally synthesised by the skin from daily sunlight. Despite all these simple facts, the craze for 'health' tonics continue unabated. (2).

Why ? Manohar S Kamath in his article in THE DAILY MAGAZINE provide the answers :

> "The real culprits behind the 'tonic craze' are the manufacturers of such formulations. The principal reason for their hard selling of such products that the tonics and vitamins fell in 'category four' of the Drugs Price Control Act, which means that there is no limit on profits made on these preparations. With easy pickings and a readymade market, no wonder then that every new company entering the pharmaceutical world wants to market its own brand of tonic rather than any life-saving drug;" (2)

Explaining how the 'tonic craze' is the result of systematic campaigns of the large companies, he says :

> "The first part of the plan was the mounting of an intensive sales campaign to influence doctors on the need for tonics in their day to day practice. This was followed by free sampling" (2)

"The other part of the marketing gimmickry in selling tonics was by directly advertising in the mass media, to catch the public eye. Slogans like "Do you feel tired at the end of the day? You need..." or "A woman needs iron every day" gradually made a deep impact on the people until many were psyched into believing that they could not do without a tonic."(2)

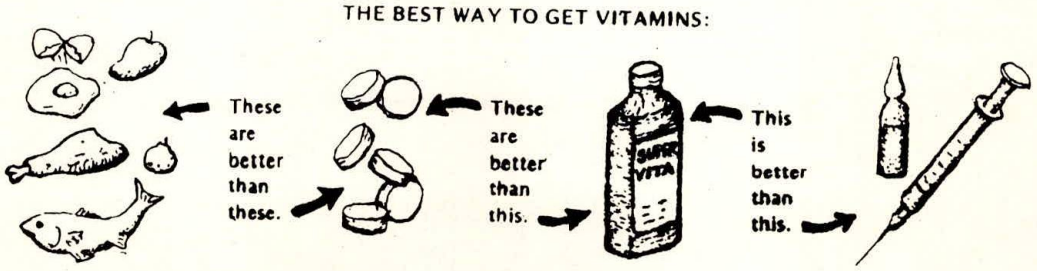

*Waterbury's Yellow Label Tonic*, a brand leader in the Indian tonics markets, contains only 3 milligrams of iron per teaspoon just 1/10 of which may be absorbed by the body. The Indian Council of Medical Research (ICMR) recommends at least 10 milligrams for women. The producer claims that this tonic stimulates appetites and builds bodies. But chemical analysis has revealed that it has 10% alcohol content which is the real appetite-stimulant : (1),

We have noted that these tonics are not consumed by the poor but mainly by the relatively rich whose ordinary diet adequately meets their vitamin and other requirements. In recent years, evidence has grown that the excessive vitamins may not simply be discharged by the body but may even cause severe disorders. Prolonged consumption of excessive viramin C may form kidney stones, excessive vitamin A may cause diseases of the hair, skin and liver and vitamin D in excess may cause disorders of the kindneys and bones. (2)

Take this further example from South East Asia. In the U K., Sanatogen is marketed as a 'nerve tonic' for old women who believe in its doubtful ability to tranquilise. But Sanatogen Powder is marketed to students in Malaysia who believe in its ability to stimulate their minds. "Worried about exams?" says the advertisement. Sanatogen will give you "Greater energy and concentration". Can a drug both stimulate and sedate? (3)

**A person who eats well does not need extra vitamins.**

THE BEST WAY TO GET VITAMINS:



Thus, the sheer irrationality and deliberate exploitation of consumers through this sinister "tonic racket" is obvious. The fact that many such, rackets' continue unabated is a measure of the enormous influence and power of the large pharmaceutical corporations not only in India but in many other countries, particularly the developing ones.

More than 20 years ago, the following words were spoken before the Kefauver Committee hearings on drugs in the U.S.A.:

"The incidence of disease cannot be manipulated and so increased sales volume must depend atleast 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 any one who wishes to increase profits. The enormous sales of so-called tranquillisers are only a small part of the crop reaped from this ground. The pharmaceutical industry is unique in that it can make exploitation appear a noble purpose." (4)

*Source*: Aspects of the Drug Industry in India C E D.

References:


1. Health for the Millions, VHAI, April-June 1981
2. "Some Boost, and at what price?", The Daily Magazine, 7 May 1981.
3. The Impact of multinational corporations on Health in Developing Countries, by Charles Medawar, Seminar on Health, Food and Nutrition, Consumers Association of Penang, Malaysia, 15-20 Sept 1977.
4. Drugs and the Common Man, Science Today, November 1970.

DR22.17

Drug Utilisation Survey Report

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

Some of the findings of the survey are as follows:

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

Analgesics, antipyretics and anti-inflammatory drugs:

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

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drug poisoning per month.

Vitamins and Tonics:

- only 31% persons surveyed had a correct concept regarding nutritional supplements. The majority held the erroneous view that daily consumption of tonics was essential for health. The credit for this false belief goes to advertising pressure as well as doctors' prescription practices.

- 16% of the doctors had prescribed simultaneously more than one vitamin preparation having the same ingredientsin various dosage forms.

- iron deficiency anemia, B2 deficiency, were the commonest deficiencies in the population but sales of B Complex (B1, B2, B6 B12) combinations and other vitamins topped the list of sales figures.

Antibiotics:

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

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

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

# Prescribing Drugs

Questions to ask yourself before writing a prescription.

| | |
|---|---|
| 1. Need | Is this drug really necessary ?<br>Is it being given to make the patient feel that something is being done ? |
| 2. Aim | What aim is to be achieved by this drug ?<br>What disorder of function is to be corrected ?<br>What symptom/s have to be relieved ? |
| 3. Knowledge | What is the approved or generic name ?<br>What class does it belong to ?<br>What are its characteristics ?<br>Do I have the requisite experience or knowledge to use it ?<br>Have I weighed the potential toxic effects against the benefit ? |
| 4. Route and Dosage | By what route, in what dose and at what intervals is the drug to be given and why ? In what form/s does the drug come ? |
| 5. Alternatives | Have I selected the best agent available for this particular purpose ?<br>What other remedies might have been chosen ?<br>How do these compare in efficacy, safety, cost ? |
| 6. Duration | For what period of time, days, weeks or months will it be advisable to continue therapy ?<br>When and how could a decision be made to stop ? |
| 7. Observations | What observations can be made to judge whether the aim has been achieved ?<br>When should they be made and by whom ?<br>What laboratory investigation if any would help in this assessment ? |
| 8. Elimination | How is the drug eliminated ?<br>Will the patients illness change the usual pattern of distribution, effects or elimination of the drug ? |
| 9. Unwanted effects | What are the side effects or toxic effects of the drug ?<br>Are they acceptable ?<br>How frequent are they ?<br>How can they be modified/managed ? |

10. Precautions — Have I checked for the following :

a. possible allergic risks

b. possible idiosyncratic reactions

c. patients drug diet which may interfere with the drug

What precautions can I take to ensure continuation of therapy.

11. Contraindications — Are there any conditions in which this drug is contraindicated ?
Are these 'absolute' or 'relative' ?
Are there any drugs which should be avoided when the patient takes this treatment ?
Which and why ?

12. Patients point of view — What does the patient believe about the drug ?
What has he been told about it ?
And what has he remembered ?
Does he need additional information ?

13. Patient reliability — Does his relative need additional information ?
Is the patient reliable for this type of therapy ?
Will he need/get proper supervision by relatives or attendants ?

14. Cost — Is the drug the cheapest drug of that type ?
If not could a cheaper drug do the job as well ?

15. Finally is there anything else I need to know about this drug ?

Adapted from :


i. A Herxheimer : The Lancet II 1186-1187, 27th Nov 1976

ii. Formulary and Therapeutic guide—Kurji Holy Family Hospital

iii. Prescribing drugs — MNAMS Handout, Dept of Pharmacology, St John's Medical College, Bangalore

# What Can We Do ?

| | |
|---|---|
| 1. Educate ourselves | We should make an effort to avail ourselves of all the available materials on drugs.<br>We should purchase some of the books and subscribe to some of the journals and bulletins mentioned in 'widening horizons' to keep ourselves upto date. |
| 2. Share and Disseminate information | We should circulate all the information and resources to all our staff and to other colleagues and centres through all possible channels of communication. We could share our own initiatives and experiences. |
| 3. Adopt essential drug list | We should draw up an essential list for our institution in which cost, efficacy, safety and quality will be important criteria (refer to WHO's suggested list)<br>We could purchase and stock drugs in accordance with this list. |
| 4. Adopt generic | We could use/adopt the generic drug concept during purchasing, prescribing or dispensing drugs. |
| 5. Stop Irrational prescribing | Could stop prescribing drugs whose only advertised values are :—<br>a. cosmetic embellishments<br>b. elegant packing<br>c. irrational combinations<br>d. imitative drugs<br>e. inadequate evidence of greater value<br>We could weed out 'banned drugs' as well as restricted drugs.<br>We could stop 'injection and tonic' practice. |
| 6. Avoid Drug Industry Linkages | We could refuse to take gifs and physician samples<br>We could avoid allowing drug companies to sponsor events/meetings<br>We could beware of unethical trade discounts or other forms of inducement |
| 7. Adopt Rational : Drug Purchase | We could adopt bulk purchasing<br>Support cooperative purchasing or production endeavours<br>Produce drugs in your hospitals/dispensaries. |

| | | |
|---|---|---|
| 8. | Adopt open policy to non-allopathic systems and non-drug therapies | We should be open to other forms of treatment. Seek information and be willing to incorporate it in our work<br><br>Share our experience with others<br>Send our staff for training in these forms of treatment if necessary. |
| 9. | Support networks/ organization/ consumer movements taking up drug issues. | Find out about all such groups at local, regional, state level or national level<br>Support and participate in their activities. |
| 10. | Promote 'Health for all' priorities. | We should actively promote the following in our work :<br>a. simple home remedies<br>b. herbal remedies and herbal gardens<br>c. health education and patient awareness<br>d. training of village level workers<br>e. community health initiatives<br>f. development programmes<br>g. awareness building. |

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Reporting in 1956 on the excessive amount of space taken up by advertisements in Indian newspapers, the Indian Press Commission commented :

"The largest field of..... objectionable advertising which we feel should be put down by law is of drugs and proprietary medicines.....The volume of advertising of such commodities ranks next only to the volume of advertising of cosmetics.

—Use and Misuse of the Media
Sumanta Banerjee, World Health, Feb-March 1983

# Misuse and overuse of medicines—Why ?

**Some Reasons**

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

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

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

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

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

6. **Sale of prescription medicines without prescriptions** This is common in many countries (partly because poor people cannot afford doctors' fees). Most people who 'self-medicate' try to use the medi-

cines well, so they follow the patterns set by doctors. Unfortunately, this often leads to incorrect use. For example, in Latin America atleast 95% of doctors, prescriptions for Vitamin $B_{12}$ injections are among the most widely used self-prescribed medicines in Latin America—at a cost of millions to a people too poor to eat well!

7. **People not adequately informed.** Neither doctors nor the people are adequately informed about the correct use of medicines. Most doctors rely on the information given in misleading 'blurbs' supplied with sample medicines, while villagers who self-prescribe often receive no information at all. In Mexico, for example, upto 70% of prescription drugs are sold without prescription. Yet the packaging of these medicines generally contains no information about use, dosage, or risks.

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

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

From Helping Health Workers Learn
—David werner and Bill Bower

This rare Himalayan herb will cure your headache. If it doesn't I'll give you a pill prepared by a famous multinational drug house.

# The Drug Industry in India—

What our experts say

## The Industry

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

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

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

## Pattern of Drug Production

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

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

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*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).