The Drug Industry in India 9/1 1994 MS

What our experts say. RF_DR_5_SUDHA To end of article

ICMR/ICSSR

HEALTH FOR ALL - AN ALTERNATIVE STRATEGY

report of a study group set up jointly by the
INDIAN COUNCIL OF SOCIAL SCIENCE RESEARCH (ICSSR)
and the
INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)
1981

findings on drugs and pharmaceuticals

THE INDUSTRY

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

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

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

(11.03)

PATTERN OF DRUG PRODUCTION

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

(11.05)

...2

OUT OF a total production of Rs.700 crores in 1976, 25 percent is taken away by vitamins, tonics, health restoratives and enzyme digestants, mostly consumed by the relatively well-fed urban population. Twenty percent is covered by antibiotics, only 1.3 percent by sulphonamides (a very cheap and useful anti-infective) and 1.4 percent by anti-tuberculosis drugs.....

(11.07).

PATTERN OF PRESCRIBING

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

STRUCTURE OF THE INDUSTRY

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

(11.14)

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

(11.15)

PRICE CONTROL

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

(11.18)

.....3

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

(11.19)

THERE MAY indeed be a glut of applications for the introduction of 'Me-Too Drugs' which will not attract new legislation for another five years in regard to price control...

(11.19)

GENUINE 'BREAKTHROUGH' research has declined in recent times.

(11.19)

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

(11.19)

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

(11.19)

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

(11.19)

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

....4

QUALITY CONTROL

THE STANDARDS prescribed are unrealistic.. are mechanically copied from books. ....and not unformly enforced in all parts of the country.

CONSUMPTION OF DRUGS

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

(11.22)

.....

An Overview (Refer p185)

we

ill health

(11.24)

— From _____

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3

6 On a world-wide scale, an estimated $2 billion are spent annually on Research and Development in drugs Of this, less than $70 million or 3.5% is spent on tropical diseases. At the same time, over 1 billion poor people or about 30% of the world's population are extremely vulnerable to these diseases.

-- Drugs and the Thirld World, Anil Agarwal

7 In India, at present, some 20,000 branded medicines are on the market, a large number of which are considered irrational. The basic bulk drugs used for their formulation number only 400. The Hathi Committee considered just 117 generic drugs (0.6% of the number of drugs currently marketed) sufficient for satisfying the basic requirements of the country.

-- Aspects of the Drug Industry in India, Mukarram Bhagat

8 The Lavraj Kumar Committee, which investigated the profitability of multinational drug firms during the 1970's found that their research and development outlays accounted for only 0.83% of their total costs, with the exception of only 2 companies, against this, sales promotion, administrative overhead expenses accounted for 33% of their total costs.

--Foreign Drug Firms Spend Too little on R & D, The Hindu, 12 March 1980.

.....4

9 A peculiar feature of the drug industry is that the consumer is 'captive'. He normally does not possess sufficient knowledge to make his choice from a bewildering array of branded products available on the market. It is his physician who makes this choice for him. However, the confusion is no less for the prescribing physician too: it isvirtually impossible for him to make a rational evaluation of the thousands of price and quality alternatives the market is flooded with.

Further, most doctors can hardly find enough time to keep abreast of all the latest pharmacological developments in their respective fields through the scientific journals. Thus the doctors mainly depend on information provided by the large manufacturers as part of their promotional campaign. As one would expect, much of this information transmitted through beautiful pamphlets and company medical representatives (the ubiquitous salesman of the drug industry), is of doubtful objectivity. In the enthusiasm to promote their products, many 'ifs' and 'buts' of vital importance are simply left out in the promotional literature.

-- Aspects of the Drug Industry in India,
Mukarram Bhagat.

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

-- WHO Technical Report Series No.615
Criteria for selection of essential drugs.

ESSENTIAL DRUGS NEEDED AT THE COMMUNITY LEVEL

ASPIRIN	MEBENDAZOLE
CHLOROQUIN	DI-IODOHYDROXYQUINOLINE
SULPHONAMIDES	METRONIDAZOLE
STREPTOMYCIN	FERROUS SULPHATE
PENICILLIN	VITAMIN - A
ISONIAZID	VITAMIN B COMPLEX
THIACETAZONE	THIOCARBAMAZINE
PIPERAZINE	ORAL REHYDRATION SALT

- ICMR/ICSSR STUDY

91.4

THE PHILOSOPHY OF VHAI

" WE BEGIN WITH THE COMMUNITY.
OUR GOAL IS A HEALTHY COMMUNITY.
OUR AIM IS TO MAINTAIN THE HEALTH OF THE COMMUNITY.....

WE PROMOTE SOCIAL JUSTICE IN THE PROVISION AND DISTRIBUTION OF HEALTH CARE .....

WE KNOW ENOUGH ALREADY TO PROVIDE ALL CITIZENS WITH SIMPLE HEALTH CARE.....

IF THE POOR DO NOT HAVE HEALTH, IT IS NOT BECAUSE WE DO NOT HAVE SUFFICIENT KNOWLEDGE IT IS BECAUSE WE AS THE ORGANISED PEOPLE OF INDIA LACK THE WILL.

OUR OLD HEALTH SERVICES HAVE BEEN BUILT TO FAVOUR THE EDUCATED, THE PRIVILEGED AND THE POWERFUL.

WE WISH ALL GOODS AND SERVICES TO BE MORE EQUALLY SHARED WITH THE WHOLE COMMUNITY.

THE WORLD COMMUNITY JOINS US TO PROCLAIM

HEALTH CARE FOR ALL BY THE

YEAR 2000 A.D.

THE SPIRITUAL TESTAMENT OF
V H A I

" FROM THE BEGINNING OUR PRINCIPLE HAS BEEN
TO EMPHASIZE AREAS OF AGREEMENT AND
DE-EMPHASIZE AREAS OF CONTROVERSY.
PEOPLE ARE NOT MERELY INDIVIDUALS.
ALL OF US ARE ALSO SOCIAL, POLITICAL,
ECONOMIC AND RELIGIOUS ....."

DRUG POLICY OF GOVERNMENT OF INDIA (1978)

BROAD OBJECTIVES

a) TO DEVELOP SELF RELIANCE IN DRUG TECHNOLOGY,

b) TO PROVIDE A LEADERSHIP ROLE TO THE PUBLIC SECTOR,

c) TO AIM AT QUICK SELF SUFFICIENCY IN THE OUTPUT OF DRUGS AND TO REDUCE THE QUANTUM OF IMPORTS,

d) TO FOSTER AND ENCOURAGE THE GROWTH OF THE INDIAN SECTOR,

e) TO ENSURE THAT DRUGS ARE AVAILABLE IN ABUNDANCE IN THE COUNTRY TO MEET THE HEALTH NEEDS OF OUR PEOPLE,

f) TO KEEP A CAREFUL WATCH ON THE QUALITY OF PRODUCTION AND PREVENT ADULTERATION AND MALPRACTICE.

R E S E A R C H ; BUT WHAT ABOUT TROPICAL DISEASES

- THE DISEASES THAT AFFECT DEVELOPING COUNTRIES ARE MAINLY INFECTIOUS OR COMMUNICABLE.
- ONE BILLION PEOPLE, MOST OF THEM AMONGST THE POOREST IN THE WORLD, ARE EXPOSED TO THESE DISEASES.
- UNTIL THE MID-1970s THE TOTAL WORLDWIDE ANNUAL RESEARCH EXPENDITURE ON THESE TROPICAL DISEASES AMOUNTED TO ABOUT $30 MILLION. - "EQUIVALENT TO THE COST OF BUILDING A FEW MILES OF MOTORWAY" SAYS W H O.
- $30 MILLION IS LESS THAN ONE FIFTIETH OF THE ANNUAL EXPENDITURE ON CANCER RESEARCH.

One of the most distressing aspects of the present health situation in India is the habit of doctors to over prescribe or to 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 ....If the medical profession could be made more discriminating in its prescribing habits, there would be no market for irrational and unnecessary medicines.

--ICMR/ICSSR 'Health for All' Report

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

Physicians prescribe medicine of which they know little, to cure diseases of which they know less, in human beings of which they know nothing.

--Voltaire, 18th century

There are two types of physicians:

Those who promote life and attack diseases

Those who promote diseases and attack life.

--Charaka Samhita

4. As far as sub-standard drugs are concerned, there is an urgent need to tighten up the drug control machinery of the states. This will require larger resources in the form of trained personnel and fully equipped testing laboratories being made available to the states. The Food and Drug administration of the states need to be made more effective. It is well known that sub-standard and spurious drugs originate largely in those states where the drug control administration is ineffective.

-- Aspects of the Drug Industry in India
Mukaram Bhagat, 1982.

5 According to some estimates upto 80% of the present output of many foreign drug companies comprises of simple household remedies and inessential formulations. Essential drugs like insulin, anti-leprosy drugs, anti-TB drugs, vaccines etc., account for only 30% of the value of formulations sold by many large firms.

-- Drugs on the Market by Jug Suraiya
The Statesman, 8 December 1980.

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

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

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

DRUG ALERT!

DRUGS FOR ARTHRITIS IN THE DOCK

On 17th May 1984, local newspapers announced that two popular drugs used for arthritis (Tanderil and Tendacot) — both oxyphenbutazone derivatives — were ordered to be immediately withdrawn, from the market in UK by a government order[1]. The action was taken on the recommendations of the Committee on Safety of Medicines (CSM). Though the manufacturer Ciba Geigy had exercised its right of appeal under the Medicines Act to stall the government's decision, which actually had been taken sometime ago, the Medicines commission had upheld the decision to revoke the licence.

400 deaths are reported to have taken place in Britain in the last two years due to these drugs[2]. The committee found them twice as dangerous as three other drugs belonging to the phenylbutazone group (Butazone, Butacodine and Butacote) which were withdrawn in March this year. The CSM had continued to receive reports of adverse reactions including fatal ones due to blood disorders, gastro-intestinal intolerance and bleeding[3].

Sidney Wolfe, Director of the Health Research group (sponsored by Ralph Nader) has estimated that world wide probably more than 10,000 patients had died as a result of taking these drugs. In his letter to the Department of Health and Human Services, he gave anaemia, agranulocytosis, leukemia, gastro-intestinal bleeding and peptic ulcerations as the leading causes of drug induced deaths. Other deaths were also attributed to hepatitis, thrombocytopenia and renal failure[4].

Interestingly in the last two years, three other non-steroidal anti-inflammatory drugs benoxaprofen, indoprofen and zomepirac and a formulation of indomethacin (osmosin) were also withdrawn. A review of current CIMS[5] shows 20 formulations of oxyphenbutazone (Algesin-O, Aristopyrin cream, Butacortindon, Butadex, Butaproxyvon, Disiflam, Flamar-P., Ganrilon, Inflavan, Kilpane, Maxigesic, Oxalgin, Oxyrin, Oxytriactin, Reducin-A, Reparil, Rumatin, Suganril, Tendon, Tromagesic) and 8 formulations of phenylbutazone (Actimol, Algesin, Aristopyrin, Butapred, Ebeflam, Parazolandin, Zolandin, Zolandin-Alka) recommended for use by doctors in India. How many patients must die before something is done about this in India as well?

An mfc annual meet background paper in 1982 concluded that the ideal anti-inflammatory drug was yet to be discovered and Aspirin remained the agent of choice when cost-factor and benefit to risk consideration were taken into account[6]. Have events in UK endorsed this?

With such a large number of anti-inflammatory drugs in the docks, will homeopathy[7], ayurveda and non-drug therapies have a role to play in the treatment of arthritis?

— Community Health Cell, Bangalore

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Editorial - Towards an "Eternal Vigilance" movement.

THE ICMR/ICSSR report on 'Health for All' has 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 drugs does not become a vested interest in ill-health[1]". The Drug Action Network which has come together in the last two years is symbolic of this vigilance, which is growing in India. The memorandum drawn up by the participating organisations, which is featured in this issue highlights the diverse aspects of drug policy towards which this vigilance has to be directed.

THE banning of a wide range of commonly used drugs for arthritis in U.K., in recent weeks (article on Drugs alert) raises questions about the complexities of this vigilance. In countries like U. K. and U.S.A. in spite of drug safety committees, comprehensive drug laws, efficient drug control authorities, active consumer groups and socially sensitive elements in the profession — drugs continue to slip through and get used for years before their dangers get known and bans are instituted.[2] How much more difficult will it be in our country where all these elements of 'vigilance' are still only in the process of evolving?

William Osler's exhortation that one of the first duties of the physician is to educate the masses not to take medicine[3] is particulaly relevant in today's drug situation. The role of doctors in acting as watchdogs is primary — laws, controls and authorities notwithstanding. Are doctors prepared adequately for this role in India? Medical education stresses the minutiae in pharmacology and medicine without stressing the factors of cost, safety and social relevance. It also does not consciously immunize the doctors against the half-truths of persuasive medical advertising[4]. In the absence of programmes of continuing education in the country, practicing doctors continue to be informed only by the profit oriented pharmaceutical industry, thus worsening the situation.

UNLESS there is a growing realisation among medical students, young doctors, teachers, health workers, professional associations, consumer education groups and science movements that this problem needs to be tackled in the form of an organized movement very little change can be expected in the present situation. Satchidanandan's critique presents an analytical framework and background against which such a movement would have to evolve. H[illegible] suggestions for a multi-dimensional campaign — demystification, conscientization, study, curriculum change and deprofessionalization could well be initiated taking drug issues as the focal point. It would, however, be important to keep in mind that over seventy five percent of the people in India have little or no access to health care. Hence an action programme only on drug matters would be cut off from the needs and aspirations of the majority[5]. However, if this became part of a wider people's movement for socio-political change, the drugs problem would be tackled at its very roots.

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