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The authors examine the relationship between the pharmaceutical industry, pharmacists, medical practitioners, users and abusers of pharmaceutical drugs. The role of social action through law in establishing an equitable framework is also considered.

The term 'drug' brings to mind the image of heroin, cocaine and other narcotic drugs with dangerous effects. However, the dangerous effect of 'healing medicines' i.e. pharmaceutical drugs has not been in the limelight. The emphasis has been on the dangers of addiction and not on the harmful consequences or side effects that swallowing an ordinary pill or taking drugs prescribed by the doctor could have.

A drug in the medical sense is labelled a 'medicine', with stress on its healing effects. A medicine is amplified as "a substance which influences the bodily tissues and is destroyed or eliminated without being incorporated with them." This includes within its scope everything except food substances.

'Drugs' According to the Law are-

1. All medicines for internal or external use of human beings or animals and all substances intended to be used in diagnosis, treatment, mitigation or prevention of any disease, or
2. Substances that affect the structure and function of the body, or
3. Devices used for internal or external use in diagnosis, prevention of disease or disorder.[1]

Drugs are classified as essential and inessential drugs. The emphasis is on the prevention and mitigation of diseases rather than on its effect upon the human body.[2]

Every drug has both therapeutic and toxic properties. The production of drugs without toxic properties remains a dream, so one must accept the fact that every drug is to some extent a poison. The efficacy and speed of the modern drug is accompanied by a narrow margin between the effective and toxic dose. It is to be noted that variable factors such as the extent of dosage and the individual concerned, the effect of each drug on each individual varies.[3]

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1 *See* Section 3b, Drugs and Cosmetics Act, 1940

2 It classifies drugs into four categories- 1) Life saving drugs 2) Other essential drugs 3)& 4) non-essential drugs; cited in S.V. Joga Rao "Legal Dimensions of Drug Consumption vis a vis Consumer Justice -Thrusts and Contradictions", AIR 1993 Jour.161

3 Ethel Browning, *Modern Drugs* (Further information not available)

What can be said to be a safe drug? The therapeutic value of the drug can be qualified at three different levels - 1) Probable effectiveness, 2) Possible effectiveness 3) Ineffectiveness.[4] Thus a safe drug must pass the test of efficacy in order to be used for human consumption.[5]

Self Medication

Where pharmaceutical drugs are concerned, "use", "abuse", and "risk" are emotionally charged terms that are generally ill-defined. Drug abuse in some form is common to humankind in many acceptable ways, under medical supervision, as part of home remedies, self medication, social use (alcohol etc.), and private use (cigarettes). In fact, the rarest and most 'abnormal' form of behaviour is not to take drugs at all.[6]

The identification of 'abuse' depends on relevant questions such as: How much of the drug is taken and how the intake is distributed? Does a person take disapproved drugs (heroin instead of alcohol, marijuana instead of tranquilizers)? Does he take drugs in unapproved settings (e.g. an adolescent drinking wine with a gang rather than at the family dinner table)? Does his behaviour under the influence of drugs offer some real risk (e.g. crime, accidents)[7]?

It is appalling to note that the health of the person concerned is not a criterion.

'Self Medication' may seem a misnomer as in many cases it turns out to be self poisoning. The problem has grown with the development of medicine, chemistry and pharmacology. Modern means of manufacturing and marketing have caused modern societies to become enormous consumers of drugs which are presumably taken as health measures.[8]

The drugs that enter the channel of 'Self Medication' mostly fall into the category of 'inessential drugs' and are purchased without a doctor's prescription. More often, the drugs serve a situtational purpose like the use of pain killers for headaches, the student who uses amphetamine to keep awake at exam times, and the housewife who takes anti-obesity pills.[9]

While self medication need not lead to addiction, physical or psychological dependency cannot be ruled out, neither can the process of tolerance which causes the human system to demand an increased dosage over time.[10]

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4 *See*, Dominga Aviato, *Krantz & Caer's Pharmacological Principles of Medical Health*, 8th ed. (Baltimore: William & Wilkings Co., 1977).

5 *Ibid*

6 Richard H., Blum, "Summary of Current Knowledge about mind-altering drugs," cited in "Mind-Altering Drugs", Task force Report: Narcotics abuse (Washington DC: The President's Commission of Law Enforcement & Administration of Justice, 1967), Appendix A-1.

7 Adapted from *supra* n. 6.

8 Walter C. Reckless, *The Crime Problem*, 5th ed. (New Jersey: Prentice-Hall Inc.,)

9 Fact Sheet 4. The Drug Abuser (Washington D.C: Bureau of Narcotics & Dangerous Drugs, US Dept., of Justice) cited in *ibid.*

10 *See, supra* n. 4.

In the Indian context, the problem of self medication has facets not common to the Western world. Lack of access to doctors, stupendous medical fees, the prevalence of quacks, availability of most medicines (albeit illegally) over the counter and the affordability of inessential drugs are some of them.

Schedule H of the Drugs and Cosmetics Rules, 1945 has attempted to prevent self medication by stipulating certain drugs which can be sold only on the prescription of a registered medical practitioner. However, many such drugs are available freely over the counter. 'Analgin' is a classic example.

Liabilities of Doctors & Chemists

The pharmaceutical industry has become so specialised that the consumer cannot be expected to know the utility, effect or toxicity of the innumerable samples in a constantly changing drug market.

Doctors and chemists are the intermediaries between manufacturer and consumer and come into direct contact with the consumer. It is their duty therefore, to act in the best interests of the affected person, and to impart awareness of the prescribed drug. However, the current state of affairs is appalling.

Doctors relying on the advice of pharmaceutical companies prescribe drugs of whose effect they may not be aware of; it is also a known fact that pharmaceutical houses funding professional association conferences are common. The Indian Academy of Paediatrics is probably the only Indian professional medical society that does not take donations from drug companies for its annual conferences.[11]

The lack of the habit of generic prescription[12] and the invariable use of brand names by doctors and chemists lends weight to the fact that they wish to promote a particular company rather than a particular drug.

The absence of continuing education for doctors is a serious handicap as they are forced to rely on the pharmaceutical houses for information about the drug. Many medical practitioners prescribe very strong drugs with little concern for the side-effects theymay cause. Continuing education is imperative if the medical community wishes to safeguard the health of the public. It must be realised that wanton prescription is fraught with danger and only essential drugs must be used. It is interesting to know that an ordinary drugstore in the neighbourhood is a storehouse of strong, powerful drugs which possess the potential to destroy the health of the person who want only takes them. On a cursory look at the drugs in the market, what is striking is the number of powerful drugs available illegally over the chemist's counter, without a doctor's prescription. In the Indian context, where there is widespread ignorance regarding the use and abuse of drugs, this has proved fatal, the only beneficiaries being the doctors, chemists and pharmaceutical companies.

11 S. Srinivasan, "The Drugs Charade," *EPW* 18 Jan. 1986.

12 i.e. Prescribing by using the chemical or technical name instead of the brand name.

A dangerous trend has begun wherein chemists have started denying liability for the drugs they are selling despite its inclusion in Schedule H of the Drugs and Cosmetics Act. Many such drugs are freely available and chemists seemed apathetic to the legal ban, suggesting deregulation to legalise a practice which will go on anyway!

Consumer Protection: The apathy of doctors *et al* may be countered by consumer law. Consumers of pharmaceutical drugs may avail of remedies against the following parties under the Consumer Protection Act, 1986:

1 Remedy against manufacturer for producing harmful drugs,

2 Remedy against chemist for issuing Schedule H drugs without a doctor's prescription and otherwise violating the law, and

3 Remedy against doctors for medical negligence as has been suggested in recent times.

However, the Consumer Protection Act seeks to remedy the damage already done and does not seek to prevent occurrence of damage.

Since the price of essential drugs is controlled,[13] there has been a shift in the manufacturing pattern. The production of inessential drugs has gone up, while the output of essential drugs has decreased.[14] Therefore profit-making and not national health becomes the consideration.

It was due to these factors that the Hathi Commission[15] recommended the nationalisation of the sector of pharmaceutical drugs industry relating to essential drugs. Priority should be given the production of the hundred and sixteen essential drugs.

Effect of the Dunkel Draft

Now with the signing of the Dunkel Draft, brief mention about the plight of consumers in this scenario serves in context. The position of consumers has clearly further weakened. However, multinational drug companies have come up with ridiculous arguments to allay their fears. They pointed out that most patents are not patents in the strict sense as they are not revolutionary products, but mere improvements on existing ones.[16] They have ignored the creation of artifical differences and the fact that the Indian consumer cannot make an 'educated choice' due to lack of specialised knowledge of drugs.

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13 Drug Price Control Order, 1979.

14 Percentage of Total Drug Production

Category	1978	1980	Result
I	4.5%	3.6%	(decrease)
III	67.1%	68.6%	(increase)

cited in *supra* n. 3.

15 Hathi Commission, 1974 under the chairmanship of Jaisukhalal Hathi c.f. "In defence of a National Drug Industry", EPW March 27, 1976 pp. 496-501.

16 Thomas T, "Foreign Investment And Technology Transfer - The Role of Intellectual Property Rights." World Symposium on Intellectual Property Rights, INTERPAT ITF, Bombay.

Another contention raised by these companies is that though drug prices are low because of artificial price administration, they will continue to remain low on amending the Patents Act due to healthy competition.[17] Chemists have however predicted a doubling in prices as companies will try to maximise profits. The cost of public health will invariably be pushed up.

Conclusion

While considering any aspect of pharmaceutical drugs, it must be kept in mind that the situation in each nation must be seen *sui generis*. For instance, the health standards in India cannot be compared with that of the United States. At the same time, India should not become a dumping ground for the medicines which cannot be sold abroad by foreign multinationals.

This leads us to the question of trade off between affordability and injury. Many third generation drugs are out of the reach of the common man, whereas a banned drug like Lomotil is easily affordable.[18] Having a drug policy placing restrictions on the sale of commonly used drugs would be farcical without equally affordable, safer drugs and health awareness.

It is shocking that we do not have a clearcut drug policy today. The policy as such is prepared by the Ministry of Petroleum and Chemicals and the Health Ministry is in no way involved. The policy announced on 3rd January 1986, made a brief mention about banned drugs, but no thought was given to the loopholes in the ban orders.[19]

Suggestions

The following measures are suggested to improve the situation-

First, compulsory use of generic terms rather than brand names;

Secondly, price control of essential drugs to continue and the nationalisation option to be left open for consideration:

Thirdly review of restrictions and removal of restrictions on some commonly used drugs, or alternatively, if safer drugs are readily available, implementing restrictions more effectively than at present;

Fourthly, continuing education of doctors and chemists, and

Lastly, modifying the Consumer Protection Act to cover pharmaceutical disasters and also to prevent such disasters.

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17 *Ibid.*

18 Daksha Hathi, "Drugs you can do without," *Deccan Herald*, 28 October 1993.

19 *See, supra* n. 3.