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Brief Review

Drugs, Law and Society

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ABSTRACT

Drugs inevitably produce unwanted effects. Legally, there exist various provisions and acts to regulate the manufacturing, prescription, administration and dispensing of drugs. Hence, consistent care is needed at every stage, from drug manufacture to administration, to avoid legal consequences. The present article is an overview of these regulations and usage of drugs.

Keywords: Drug, Law, Prescription, Medico-legal liabilities, Legal consequences

INTRODUCTION

Drugs inevitably produce unwanted effects. If legal consequences of adverse reactions are to be avoided, consistent care is needed at every stage, from drug manufacture to administration. Different regulations apply to different drugs. Some drugs are available only by prescription, while others can be bought and sold at convenience stores. A handful of drugs are widely used for recreational purposes, owing to their psychoactive effects, which many users find to be pleasurable. These drugs are also put through different kinds of controls.

Legal Definition of Drugs

The most widely cited legal definition basically contains three disjunctive clauses. It identifies drugs as 'substances recognised in the official United States Pharmacopeia' or 'substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals', or 'substances (other than food) intended to affect the structure or any function of the body of man or other animals'[1].

Legal Regulations

The Drug and Cosmetic Act, 1940

It regulates the import, manufacture, distribution and sale of drugs and cosmetics. It has two schedules. The first schedule deals with the Ayurvedic and Unani drugs and the second schedule deals with import of drugs and drugs manufactured, stocked and exhibited for sale or distribution. It also provides punishment for contravention of the provisions of the act and rules. The Ministry of Health and Family Welfare notified and implemented, on 10 August 2008, the Drugs and Cosmetics (Amendment) Act, 2008, significantly increasing the penalty for manufacture of spurious or adulterated drug. The amended act enhances the penalty for manufacture of spurious drugs to a minimum imprisonment of 10 years, which may extend to a life term, and a minimum fine of Rs 10 lakhs or three times the value of the drugs confiscated, whichever is higher. It can also classify the offence as non-bailable in some cases. Self-medication has grown with the development of medicine and pharmacology. Schedule H of the Drugs and Cosmetics Rules, 1945, prevents self-medication by stipulating certain drugs,

which can only be sold when prescribed by a registered medical practitioner[2].

The Drug Control Act, 1950

It provides the control of sale, supply and distribution of drug along with limitation on quantitythat may be possessed at one time. Contravention of provisions of this act shall be punishable by rigorous imprisonment for a term that may extend up to 3 years or fine, or both[2].

Drug Price Control Order, 1979

The price of essential drugs is controlled, which in turn led to increased production of inessential drugs and decrease of essential drugs[3]. The Hathi commission, 1974, recommended the nationalisation of the pharmaceutical drug industry related to essential drugs along with priority for the production of 116 essential drugs[4].

Consumer Protection Act, 1986

It gives remedies against the following parties to the consumers of pharmaceutical drugs[5]:

(a) Manufacturer for producing harmful drugs.

(b) Chemist for giving Schedule H drugs without a doctor's prescription.

(c) Doctor for medical negligence.

Indian Penal Code

The Indian Penal Code (IPC) has sections 274, 275, 276, 284 and 328 to deal with offences related to drugs:

(a) Sec. 274 IPC– The punishment for adulteration of drugs in any form with any change in its effect, knowing that it will be sold and used as an unadulterated drug, is imprisonment of either description for a period of 6 months and/or fine.

(b) Sec. 275 IPC– The punishment for knowingly selling adulterated drugs with reduced efficacy or altered action, serving it for use as unadulterated drug, is imprisonment of either description for a period of 6 months and/or fine.

(c) Sec. 276 IPC– The punishment for selling a drug as a different drug is imprisonment of either description for a period of 6 months and/or fine.

(d) Sec. 284 IPC– The punishment for negligent conduct with respect to poisonous substance is imprisonment of either description for a period of 6 months/or fine upto 1000/- rupees.

(e) Sec. 328 IPC– The punishment for causing hurt by means of poison or any stupefying, intoxicating or unwholesome drugs or any other things with the intent to commit an offence is imprisonment of either description for a term, which may extend up to 10 years, with or without fine.

Medico-Legal Liabilities

Essential care is required at every stage from drug manufacturing till administration. In order to avoid legal consequences, proper care and duty should be performed by the manufacturer, the licensing authority, the medical practitioner as well as the pharmacist[6].

Duties of the manufacturer

Every drug has both therapeutic and toxic effects. Before a drug can be used on the patients, it must pass the efficacy test for use in human consumption. Adequate knowledge about the adverse effects in humans may be very less at this step; so, research using human subjects should be carried out according to the protocol approved by the ethical committee, in accordance with the Declaration of Helsinki. The volunteers must be informed of the risks foreseen in order to take properly informed consent.

The pharmaceutical company is bound by the Doctrine of Products Liability. They have the duty to be honest, legal and truthful when advertising a drug. They can be convicted for false and misleading advertisements. A manufacturer has to warn about the risks associated with the use of drugs via patient information leaflet or datasheet for medical practitioners.

Duties of the licensing authority

The licensing authority has to monitor and ensure that the testing procedures and trials for the drugs have been satisfactorily devised, implemented and completed. The result should reach an accepted level prior to granting the license.

Duties of the medical practitioner

The medical practitioners should judge cautiously the need of a drug for a particular patient. They must compare the benefits with adverse effects, alternative methods of getting the same benefits or any likelihood of harm from drug interactions or contraindications. A doctor must caution the patient about the adverse effects of the drugs so that he/she can decide about them. The doctor prescriptions must be decipherable. Any damage to the patient due to misinterpretation of writing on the prescription is considered as a liability of the doctor, the nurse as well as the pharmacist.

Duties of the pharmacist

The pharmacist has duty to administer the sale of the over-the-counter (OTC) drugs, which are available only in pharmacies, and to dispense the drugs cautiously and appropriately, as prescribed by the doctor. He/she has to get in touch with the prescriber in case of any query regarding the prescription.

Duties in administering the drugs

Utmost care is considered to be necessary during the administration of drugs. Knowledge of the site of injection in order to avoid damage to the nerves or underlying structures is expected of a practitioner; so, the mistake itself accounts for a negligent act. Fundamental procedures for checking the labels, dose, route of administration, etc., carry enormous importance, particularly with injectables and filled syringes.

DISCUSSION

The OTC preparations are not legal terms and are better referred as 'non-prescription drugs' or 'household remedies'. The OTC drugs have to be identified by the reduction and absurdum logic. Current drug laws specify prohibitions - drugs which must not be given without a valid prescription. Thus, all the drugs that are not specified in the list of 'prescription drugs' must be considered as non-prescription drugs (or the OTC drugs). Prescription drugs fall under two schedules of the Drug Rules, 1945 - Schedule H and Schedule X. The latter consists of habit-forming, abusable drugs requiring double prescription. The preparations containing Schedule H or Schedule X drugs must conspicuously display on the label the following warning -'To be sold by retail on the prescription of a Registered Medical Practitioner only'. The left top corner of the container is marked by any one of the symbols given in Table 1.

Table 1:

(a)	'R_X' for preparations containing Schedule H drugs.
(b)	'NR_X' (in red colour) for preparations containing Schedule H drugs that also come within the purview of the 'Dangerous Drugs Act'.
(c)	'XR_X' (in red colour) for preparations containing Schedule X substances.[7]

Forget heroin and cocaine, the dangerous drugs claiming the lives of many people are prescription painkillers, a new class of happy pills that doctors are recommending. There are lakhs of nervous types of people in the country who have become accidentally addicted to benzodiazepines, a family of tranquillisers, while many take them knowingly, for fun. Upon addiction to benzodiazepines, they are now taken illicitly in high doses by majority of drug abusers worldwide. They are part of the drug scene. More worrying in a way are the habit-forming drugs that can be bought without prescription at high street pharmacies. If we check the symptoms of anybody asking for OTCs, it can be found that they would have taken these drugs with something other than pain relief in mind.

A lot of us are developing a dependency to analgesics, anti-inflammatories, antihistamines or other popular remedies. Drugs that carry a risk of addiction do so because they alter the binding of neurotransmitters to the receptors in the brain. In short, they are, in different ways, mood enhancers. The prescription drugs causing most concern are antidepressants-selective serotonin and nor-adrenaline reuptake inhibitorsor SSNRIs. By increasing the levels of serotonin, these drugs make us feel more sociable and relaxed. They also boost adrenaline, making us more energetic and sometimes slightly manic. This has caused a rapid rise in the problem of 'prescription drug addiction', the chief of these being antidepressants. There are complaints that doctors had given no indication

or flatly denied that the drug carried any significant side effects or risk of dependency. The opioids were developed as a means of longer and more effective pain relief for cancer sufferers, but for an abuser, it means a longer, more consistent high, with a reduced risk of an overdose.

'Pharming' refers to consuming a cocktail of prescription drugs. 'Doctor shopping'means visiting several physicians to fulfil a medicine wish list, and if that does not pan out, there are always 'pill ladies', elderly prescription holders who take advantage of the difficulties experienced by the young in obtaining heavy-duty drugs created to ease chronic back pain or the suffering of cancer patients. For the truly desperate, the practice of robbery has acquired a new subdivision -the 'prescription theft'. The dubious online pharmacy will always be just a click and a credit-card payment away. The internet supplies drugs if doctors do not or if the patients do not want their doctors to know what they are up to. Anything is available on the internet and there is little control of internet pharmacies or wholesale suppliers.

When predicting the future for prescription drug abuse, all eyes are on India, where the situation has been barrelling out of control for decades. Tranquillisers abused by recreational users enjoy a high profile position. Today, the misuse of prescription drugs is 'not about getting out of it, but they keep you going'.

CONCLUSION

The need to protect a human being against abuses towards his/her dignity is worrying the society. It has become a part of an ongoing explosive debate. In fact, sometimes, it might be more appealing to proceed with a strict regulation, evaluating the current drug policies along with strict compliance to them. This is a complex issue because the main problem is to find a balance in order to build the general guidelines. Concerted efforts have been made by the Government in this path. Now, the responsibility lies with the drug industry, manufacturers, national and international organisations, etc., to work in line with the Government's policy for sustainable development in the right direction. In conclusion, healthcare organisations and system administrators should ensure that the clinicians and their supporting staff receive ongoing legal instructions as well as newly formulated rules and amendments in the previous ones.

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