Drugs and Cosmetics Amendment Bill, 2008

Exercising an iron fist...

India has emerged as the fourth-largest producer of pharmaceuticals and is growing at a rate of 10 per cent and above annually. However, its integrity is threatened, since there has been an unprecedented rise in the number of spurious drugs, and even worse, there are no stringent regulations for combating the same. The government has recently introduced the Drugs and Cosmetics Amendment Bill, 2008, which declares that stringent punishment should be given to those involved in manufacture, sale or distribution of an adulterated and spurious drug likely to cause death and grievous hurt. A few industry experts share their views on this new amendment and the impact it would have on the pharma industry with Richy D Alexander.

Daara B Patel
secretary-general, Indian Drug Manufacturers' Association

We welcome the government's initiative of providing stringent punishment to the offenders involved in manufacture, sale & distribution of adulterated and spurious drugs & cosmetics. However, we find that some of the provisions in the bill are likely to pose serious problems even to the bonafide, honest and law-abiding manufacturers of drugs and cosmetics. In fact, some of our members are already facing problems due to the misinterpretation of certain provisions, especially with respect to the definition of adulterated and spurious drugs. For instance, some of the field officers have classified 'drug declared as not of standard quality on account of presence of particulate matter or fungus growth' as an adulterated drug and have classified 'not of standard quality drug failing in assay of active ingredients' as spurious drug taking recourse to the definition of adulterated and spurious drugs under Section 17A and 17B of the Act respectively.

Some of the more serious provisions that could impact genuine manufacturers are Sections 36AC(a) and 36AC(b) of the amended Act. In Section 36AC(a), offences under Section 27(a) and 27(c) are made cognisable, which means that any manufacturer can be arrested by the police in case of even wrong interpretation of Government Analyst Report classifying a substandard drug failing only to assay as spurious drug under Section 17B(d) of the Act. Again, by applying Section 17-A to a substandard drug, even in isolated cases of particulate matter, under Section 27(a) of the Act, charges that this is likely to cause grievous hurt may be imposed.

The most worrying provision is that of Section 36AC (b), which severely restricts grant of bail. This provision is taken straight from the Narcotic Drugs and Psychotropic Substances Act, but unlike the NDPS Act, no safeguards are provided. This means that any drug inspector investigating a case, need not go to the police, but can directly file a case in court after completion of investigation and the accused manufacturer will not get bail as, in the opinion of the court, there is prima-facie a case. Also, in view of the missing words offences related to adulterated and spurious drug in Section 36AC (b), for all offences under Section 22(3), 28 and 28A – the person will not get bail. One solution will be to redefine 'adulterated drugs' in D&C Act by incorporating a proviso after Clause (f) of Section 17A – 'provided that a drug shall not be deemed to be adulterated only on account of being declared as not of standard quality drug due to presence of particulate matter or foreign particle or fungus growth.'

Dr K G Revikumar
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This is one of the best initiatives since the early 1960s, when cosmetics were brought into the Drugs Act 1940 and made it Drugs and Cosmetics Act. However, we still have miles to go. The present move will provide more strength and willpower to our legislature to take further harsh steps in other related areas of the Act. The Bill makes reasonably good recommendations with respect to cosmetics (S17) and the punishment for manufacturing and selling of spurious & adulterated drugs (S 27) and the establishment of special courts for dealing with the drug related crimes.

The Drugs and Cosmetics Act clearly defines adulterated, misbranded and spurious drugs, but fails to have a specific definition for counterfeit medicines, a widely and popularly used term throughout the world. Section 27 of the Act deals with the punishment and penalty for manufacture or sale or distribution or other activities in that line with the objective of marketing of spurious or adulterated drugs violating the provisions of the Act. The increase in the fine amount from Rs 10,000 to 10 lakh or three times the value of the drugs confiscated (whichever is more) is a wise decision. Though, one can demand for capitation punishment, there is provision for life imprisonment in the bill as passed by the Rajya Sabha.

Again, the provision to compensate the victim of adulterated and spurious drug is also a good initiative, particularly from the societal perspective. The issue of counterfeit, fake and spurious medicines that are harmful & injurious to health and life of the society has developed as one of the most serious threats to the Indian pharma as well as healthcare industry. These medicines fail to meet the prescribed standards of safety, quality and efficacy. They are produced and marketed violating national as well as international regulations and the trade practices of pharma products. They may or may not have a therapeutic benefit, can cause serious health hazards and even threaten the life of the user.

One has to take strong actions in order to make the medicine supply chain simple, straightforward and transparent. Avoiding traders and promoting professionals is necessary to make the Indian medicine distribution system scientific and effective. Traders should not be permitted to dictate the norms for a profession or its activities. Soon, serious steps will have to be taken to make prescription writing and dispensing activities more professional and evidence-based with the support of compulsory documentation, authentication and filing systems.

Tapan Ray
director general, Organisation of Pharmaceutical Producers of India (OPPI)

The growing menace of counterfeit drugs has remained a serious threat to the Indian healthcare sector. To bring into effect stricter penalties for those involved in counterfeit drugs, the process of amendment of the Drugs and Cosmetics Act, 1940 was initiated by the Ministry of Health in 2006. These amendments are expected to make the drug-related offences, cognisable as well as non-bailable. India, being a part of International Medical Products Anti-Counterfeiting Taskforce (IMPACT) established under the World Health Organization in 2006, resolved to work together to combat the growing menace of counterfeit medicines. The Drugs Controller General of India (DCGI) had several discussions with the convenor of the IMPACT to effectively address such serious threats to the patients at large. Many people believe that China and India are the main sources of counterfeit drugs in the world.

The latest amendment to the Drugs and Cosmetics Act, 1940, became a law in 2008. The punishment for selling or distributing spurious drugs that are likely to cause death and grievous hurt to the patients is now imprisonment for a term not less than 10 years and fine not less than Rs 10 lakh or three times the value of drugs confiscated, whichever is more. Although, the Indian pharma industry welcomed this strict law, it expressed its apprehensions due to the lack of clear demarcation in the definition between spurious drugs and those that can lose their original potency because of improper transportation and storage. If the law-enforcing authorities pick up such medicines from retail outlets, they can easily get categorised as spurious drugs under Section 17A and 17B of the Drugs and Cosmetics Act, 1940. Consequently, the concerned manufacturers could be put behind bars with no fault at their end.

While stringent punishment is essential for those involved in such a heinous crime, the government should take enough measures to ensure that the genuine drug manufacturers are not harassed by the law enforcing authorities, as the courts will have no judicial discretion to award less than minimum punishment, as prescribed under this Act. To allay the major apprehensions of the industry regarding possible misuse of some provisions of the Act, the Ministry of Health is expected to work out clear guidelines for implementation of the act.

T S Jaishankar
managing director, Quest Life Sciences (P) Ltd

Amendment to Rule 51 and 52 of the Drugs and Cosmetics Rules was undertaken in 1945 to make a provision that no prosecution shall be filed without written consent from the controlling authority. Insertion of new Rule 50B stated that duties and procedures should be followed by the controlling authority. Framing of rules to provide for the authority empowered to exercise powers to issue directions under Section 33-P of the Act, the procedure and the manner in which such powers can be exercised.

The Drugs Controller General of India may be empowered under these rules to issue directions in consultation with the Drugs Consultative Committee. The central government may issue written guidelines for drugs control officers to provide elaborate procedures & guidelines for effective and uniform implementation of the Drugs and Cosmetics Act, 1940, and Rules, 1945 and to provide safeguards for bonafide, licensed manufacturers. The Manual should include the procedure to be followed by the controlling authorities while scrutinising the proposal seeking consent to file prosecution under the Act and Rules. The Manual should also include elaborate guidelines for taking action on not of standard quality reports and other violations of conditions of licences and various provisions of Act and Rules with emphasis on administrative action. The guidelines should also include instances that should be regularised instead of taking legal actions like failure to obtain license for additional premises, failure to submit renewal application within stipulated period, failure to obtain fresh licences in view of change in the constitution, within stipulated period, etc.

It is necessary to act judiciously in accordance with the written guidelines issued by the central and state government. Also, there should be clarity in the circumstances and manner in which the stock of drugs and cosmetics should be seized. The guidelines may also include a directive that the action should be finalised within specified time from the date of issue of prohibitory order in Form 15. The drugs inspector should record storage conditions of the drugs and cosmetics while drawing the sample. The inspector should carry out enquiries to ascertain the actual manufacturer and give the counterpart of the sample to the manufacturer of such drug. He should also provide a copy of the Government Analyst Report to the manufacturer of drug.