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Right to amend?

How is the pharmaceutical industry reacting to the recent ammendment in the Drugs & Cosmetics Act? ***Suja Nair*** *gets the answers*

Old is no more gold, with changing times, outdated colonial laws are either scraped or ammended for good. One change that is surely going to alter the way the world looks at India is the amendment of 10th August 2009 relating to spurious drugs through the Drugs & Cosmetics Act. Sharing the industry's view, Daara B Patel, Secretary—General, Indian Drug Manufacturers' Association (IDMA) avers, "We welcome the recent amendments by Government to strengthen penalties for manufacture/sale of spurious drugs in India. The genuine licensed manufacturers in the Indian pharma industry have always followed the rules and regulations as laid down in the Drugs and Cosmetics Act, 1940 and Rules, 1945 there under."

The problem of spurious or fake drugs is not an issue pertaining to India alone it affects the humanity and such an action by the Indian government clearly indicates its serious intentions. It is in this accord that the government has decided to increase the fine and the period of imprisonment against the propagators of such crime.

Speaking on the recent amendment, Shirish Ghoge, Senior Director, Public Affairs and Communications, sanofi-aventis India shares, "The recent amendment is surely a positive step and it is comforting to know that the Ministry views these offences so stringently. A counterfeit does not only have financial repercussions but very importantly it causes havoc among the common people. Our company welcomes this amendment as it sends a strong signal to offenders to desist from such malpractices." However, adding a word of caution he says that industry apprehensions must also be given equal importance since genuine and law-abiding manufacturers could needlessly be trapped during inspections due to inadequate supply chain and testing facilities.

Reality check

Dr Surinder Singh, Drugs Controller General (India) (DCGI) had recently taken up a survey to check the extent of spurious drugs in India. Over 24,000 samples were collected, making it the largest ever study on spurious drugs undertaken in the world. The initial news reports indicates that only 10 were found to be spurious. The study covered 62 popular drug brands from nine therapeutic categories. Official tests held at Government laboratories during last five years put the quantum of counterfeits between 0.3 to 0.4 percent.

Such amendments to the Act from the Indian government will help in putting to rest a lot of speculation regarding the extent of fake drugs prevalent in the Indian market. Ghoge informs, "Estimates of the spurious drug market in India vary from as low as 0.4 percent to sometimes, as high as 25 percent. We have had some instances in the past where we discovered counterfeits of our products. In fact, we have taken steps to ensure that anti-counterfeiting measures are included in our packaging."

Imitation is, in a way, the best form of flattery but at times it can also act as an insult. The DCG(I) is very much aware of the situation and had stated that they want to put to rest all the speculation about the extent of fake drugs prevalent in the Indian market. Patel points out, "The recent reports of Chinese fake drugs with 'Made in India' labels or certain African countries faking Indian medicines as 'Made in India' show that the spurious drugs supposed to be of Indian origin are not made in India locally."

Dr Gopakumar G Nair, Patent Attorney and CEO, Gopakumar Nair Associates points out that the counterfeits being estimated, through synthesis of statistics is probably covering, also the potential or perceived losses incurred by MNCs where the innovator's innovator drug is not protected in India and the Indian generics are eroding or impacting MNC's profitability. He emphasises, "It is important to note that the DGGI's technical competency has substantially improved in recent times and it is virtually impossible for a spurious or counterfeit drug to cross the Indian borders."

Background check

"The recent reports of Chinese fake drugs with 'Made in India' labels or certain African countries faking Indian medicines as 'Made in India' show that the spurious drugs supposed to be of Indian origin are not made in India locally"

- Daara B Patel
Secretary-General
Indian Drug Manufacturers' Association (IDMA)

"Since India wants to be a major pharma hub of the world moves like this are needed to give confidence to the customers that the pharma products produced in India are safe and effective and meet the global standards"

- A S Krishna
Director-External Affairs
MSD Pharmaceuticals

In November 2003, the Expert Committee setup by the Ministry of Health and Family Welfare, Government of India under the chairmanship of Dr R A Mashelkar submitted the 'Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs'. The Report contained specific recommendations for amending the provisions of existing Drugs & Cosmetics Act, 1940 (existing Act), some of which have been given effect by way of the Drugs and Cosmetics (Amendment) Act, 2008 (amended Act). The amended Act has introduced many new provisions in the existing Act like introduction of a definition for 'adulterated cosmetics', which is similar to that of 'adulterated drugs' in the existing Act and corresponding prohibitions and offences provision; it has enhanced penalties for the offenders as given in the table. A unique feature of the amended Act is that the entire amount of fine that is realised from the person convicted for the offence of dealing with adulterated or spurious drug is payable, by way of compensation, to the person who has consumed the adulterated or spurious drug in question. If the victim has died due the effect of the adulterated or spurious drug, the relative of the victim is entitled to receive the same amount by way of compensation.

Among the other special features are trials for offences relating to trading in sub-standard drugs will now start at the level of the Sessions Court instead of the Metropolitan Magistrate/Judicial Magistrate of First Class, which is the lowest rung of criminal prosecution. Appeals from the Court of Session go to the High Court and then to the Supreme Court. This change is expected to accelerate the prosecution of these offences. Based on the report of the Expert Committee under the current legal system, most prosecution cases pertaining to offences related to spurious or adulterated drugs remain undecided for many years. To address this, a provision has now been inserted to ensure speedy trials of such offences. For trial of certain offences relating to adulterated drugs or spurious drugs, the Central Government, or the State Government, in consultation with the Chief Justice of the High Court, are required to designate one or more Courts of Session as Special Courts for such areas or for such class or group of classes, as shall be notified.

Elaborating on the provisions of the amended Act, Dr Milind Antani, Head, Pharma-Life Science Practice, Nishith Desai Associates informs that these Special Courts shall deal with only certain offences that are considered more serious in nature. These inter alia include importation of adulterated drugs, spurious drugs or spurious cosmetics, trading in drugs that fall under the definition of 'spurious drugs', trading in spurious or adulterated drugs which when used by any person for his treatment is likely cause his death or grievous hurt, non-disclosure of the name of the manufacturer by a person who is an agent of the manufacturer, willful obstruction of a Drug Inspector in the exercise of the powers conferred upon him by law, refusal to produce any documents relating to trade of a sub-standard drug in respect of the person who is believed to have committed an offence. Certain offences have been made cognizable and non-bailable. Antani informs, "Offences that relate to adulterated drugs and spurious drugs shall now be considered to be cognizable offences. (A cognizable offence, under the Code of Criminal Procedure, is an offence for which a police officer does not require a warrant (sanction of a Magistrate) to arrest the person believed to have committed the offence.) These offences are also non-bailable. Previously, most offences fell under the category of non-cognizable and bailable."

Excerpts from laws of certain developed and developing countries

UK: If an individual is convicted of offences under the Medicines Act 1968, they can be sentenced to a maximum of two years imprisonment and/or an unlimited fine. Where appropriate, the Medicines and Healthcare products Regulatory Agency (MHRA) uses the Proceeds of Crime Act 2002 to determine whether or not benefits were accrued through criminal activity and recoups illicit earnings if the individual is found guilty.
Source- http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON028412

USA: Federal Food, Drug, and Cosmetic Act (FD&C Act)
SEC. 301. [21 USC §331] Prohibited acts: The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded. (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce. (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
SEC. 303. [21 USC §333] Penalties: (1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.(For first time offence) (2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both. (For subsequent offence /intention to defraud.)
Source-http://www.fda.gov/RegulatoryInformation /Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCAc tChapterIIIProhibitedActsandPenalties/ucm086300.htm

Nigeria: From September 2009 onwards, lifetime jail term or death penalty would be pronounced on manufacturers and distributors of fake and substandard drugs where it is determined that such medicines has caused death or severe bodily injury to persons who had used them.
Source- http://www.vanguardngr.com/2009/09/07/fake-drugs-death-penalty-await-offenders-nafdac/

Philippines: Under the 'Special Law on Counterfeit Drugs' (Republic Act No. 8203)

- imprisonment of not less than six months and one day, but not more than six years for mere possession of counterfeit drugs
- imprisonment of six years and one day, but not more than ten years or a fine of not less than One hundred thousand pesos (P100,000) but not more than Five hundred thousand pesos (P500,000) or both such imprisonment and fine at the discretion of the court for manufacture, sale, offering for sale, donation, distribution, trafficking, brokering, or importation or possession of counterfeit drugs
- if, as a result of the use of the drugs found to be counterfeit, the illness sought to be cured is aggravated or physical injury or suffering results therefrom, a punishment of imprisonment from twelve years to fifteen years and a fine ranging from One hundred thousand pesos (P100,000) to Five hundred thousand pesos (P500,000) shall be meted out
- should a counterfeit drug be the proximate cause of death of a victim, who unknowingly purchased and took a counterfeit drug, the penalty of life imprisonment and a fine of Five hundred thousand pesos (P500,000) to Five million pesos (P5,000,000) shall be imposed.
  Source- http://www.chanrobles.com/republicactno8203.htm

Word of caution

Ghoge feels, "This Amendment will certainly send a strong warning signal to unscrupulous dealers of adulterated and spurious drugs. The inclusion of section 36-AC that makes offences cognizable, and non-bailable in some cases, would definitely help in curbing the menace. We hope that with the implementation of this Act, all those who are into manufacturing of spurious drugs will be cautioned and become aware that an appropriate legal process has been put into place." However he is quick to add "Though the enhanced penalties are definitely strong they need to be judiciously used to bring serious offenders to book. In that context, the guideline which is now available would be beneficial to prevent misuse of the strong provisions of the amendment."

"The enhanced penalties in the amended Act appear to be harsh enough to discourage dealing in spurious and adulterated drugs. However, when there delay in prosecuting culprits, the deterrent effect of the law gets diluted"

- Dr Milind Antani
Head

Antani informs that one scenario of concern is when labels of genuine

manufacturers are misused by spurious drug manufacturers, and second, when the quality of drugs deteriorates due to improper storage conditions. In both cases, genuine manufacturers are at a risk of being prosecuted. In order to prevent possible harassment of such manufacturers, especially in view of offences having become cognizable and non-bailable, the Ministry of Health and Family Welfare has issued certain guidelines that the Drugs Consultative Committee (DCC) of the Ministry has drafted. The guidelines divide Not of Standard Quality (NSQ) drugs into three categories: 'Spurious and Adulterated drugs', 'Grossly Sub-Standard drugs', and those having 'Minor Defects' and provides for the manner in which prosecution should be done for each category and also takes into account presence or absence of mens rea. The guidelines are however non-binding in nature and the industry hopes they will become binding on State Drug Licensing Authorities, which at present have mere persuasive value.

Pharma-Life Science Practice Nishith Desai Associates

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- Dr Gopakumar G Nair
Patent Attorney and CEO
Gopakumar Nair Associates

Antani opines, "The enhanced penalties in the amended Act appear to be harsh enough to discourage dealing in spurious and adulterated drugs. However, when there is delay in prosecuting culprits, the deterrent effect of the law gets diluted. The Special Courts set up in the Amended Act for prosecution of serious offences related to dealing in spurious and adulterated drugs have not been notified and it is yet to be seen how these courts function and if they are able to step up rate of prosecution in reality."

Nair feels that the recent amendment relating to spurious drugs is more likely to be misused for harassing the genuine licensed pharma manufacturers rather than for curbing the menace of decades—old problem of illicit, illegitimate unlicensed manufacturing of duplicate medicines." He suggests, "Such penalties should be accompanied by checks and balances to ensure that these are not misused against genuine generic manufacturers. mens rea or intentions (especially malintentions) of the officers must be diagnosed, if any, before coming to any conclusions on spurious or not."

ENHANCED PENALTIES IN INDIAN DRUGS & COSMETICS ACT

Type of drug	Period of imprisonment (minimum to maximum period prescribed)		Monetary Fine	
	Existing Act	Amended Act	Existing Act	Amended Act
Adulterated drug or spurious drug or a drug which when used by any person for his treatment is likely to cause his death or grievous hurt, solely on account of such drug being adulterated or spurious or not of standard quality.The amended Act changes this offence to 'adulterated drug or spurious drug and a drug which when used by any	5 years to Imprisonment for life	10 years to Imprisonment for life	Rs 10,000	Rs 1,000,000 or 3 times the value of the drug confiscated, whichever is higher

person for his treatment is likely to cause his death or grievous hurt'. Thus, both requirements need to be proved for conviction under this section now.				
A drug merely falling under the classification of 'adulterated drug'	1 to 3 years	3 to 5 years	Rs 5,000	Rs 100,000 or 3 times the value of the drug confiscated, whichever is higher
A drug merely falling under the classification of "spurious drug"	3 to 5 years	7 years to Imprisonment for life	Rs 5,000	Rs 300,000 or 3 times the value of the drug confiscated, whichever is higher
A drug that is manufactured or sold in contravention of the licence issued by the drug regulator authorities	1 to 3 years	3 to 5 years	Rs 5,000	Rs 100,000 or 3 times the value of the drug confiscated, whichever is higher
Any other offence, that would include misbranded drugs	1 to 2 years	1 to 2 years	No amount prescribed	Minimum of Rs 20,000

Actions speak louder than words

"Though the enhanced penalties are definitely strong they need to be judiciously used to bring serious offenders to book"

- Shirish Ghoge
Senior Director
Public Affairs and Communications
sanofi-aventis India

Since India is a leading generic manufacturer the problems faced by India are also unique. Many small or micro units may have lost or discontinued their drug registration and may have been continuing their activities through unlicensed, illegitimate, illegal operations and these need to be unearthed. Very often, such units find or obtain protection from the local governmental or FDA's lower level officers/employees and this is the area where attention is required. Nair states, "The distinction between substandard and quality-wise spurious products and the technically (for reasons other than quality and efficacy) spurious need to be appreciated. A willful copying of other reputed or well-known pharma manufacturers, well-known product amounting to passing off or riding on the other brand's reputation will surely need to be curbed and punished. For this, a genuine non-corrupt team of officials need to be in place. A perceived (one sided) infringement of a process or product patent by a SME manufacturer, who cannot afford to pay millions for an infringement suit, need to be not confused with a spurious drug."

A S Krishna, Director—External Affairs, MSD Pharmaceuticals opines that,"Since India wants to be a major pharma hub of the world, moves like this are needed to give confidence to customers that pharma products produced in India are safe and effective and meet global standards. The effectiveness of any law always lies in its implementation."

Antani observes, "In order to change the global perspective of India being the hub of the menace, there are two problems to be tackled. The first is to enforce the amended Act efficiently, honestly and transparently. The administrative mechanism envisaged by the lawmakers under the amended Act must be created without delay to bring the provisions into practice. The second is to control the problem of drugs manufactured outside India and marketed using 'Made in India' labels, which tarnishes the global image of Indian pharma industry. And as a matter of fact, the Government of India has started taking steps in this direction."

Agreeing on the same, Patel states that the findings of the DCG(I)'s survey must be studied and disseminated to the Indian public to put to rest all speculation on the extent of spurious drugs in India, and also improve our industry's standing and our nation's goodwill in the international markets. Simultaneously, he adds, "There must also be concerted efforts to erase the growing global menace of counterfeit and spurious medicines from whichever source they come from." To sum it up, the best way to deal with any problem is to find the root cause of it and treat it. Today, India is waking up to the call and taking stern decisions that would help in re-establishing the credibility and potentiality of our nation, provided, there is also proper implementation of the same.

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