

Pharma & Healthcare Update

August 27, 2009

THE NOOSE TIGHTENS AROUND ADULTERATED AND SPURIOUS DRUGS PLAYERS

The Ministry of Health and Family Welfare, Government of India ("**Ministry**") has recently notified an amendment to the Drugs and Cosmetics Act, 1940¹ that attempts to strengthen the existing law against the menace of adulterated and spurious drugs. The amendment has been made by the passage of the Drugs and Cosmetics (Amendment) Bill, 2008.

This amendment has changed certain provisions of the Drugs and Cosmetics Act, 1940 ("**Existing Act**") that specifically relate to the offences of manufacture and trade of adulterated and spurious drugs. Significantly, the amendment has enhanced penalties for such offences, and brought them under the classification of serious offences. The amendment introduces "special courts" for prosecution of such offences, as well as provides for compensation to the victim of adulterated and spurious drugs.

The amendment incorporates most recommendations of the "*Report of the Expert Committee² on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs*" to examine *inter alia* the problem of sub-standard drugs in the country ("**Expert Committee Report**").

The Ministry also has a "whistle blower" policy on its cards that aims to reward citizens, who provide information on the trade and source of spurious drugs. While this next phase in strengthening the laws is yet awaited, the pharmaceutical industry and consumers hope to see positive results of the Drugs and Cosmetics (Amendment) Act, 2008 ("**Amended Act**").

SOME OF THE SALIENT FEATURES OF THE AMENDED ACT ARE AS FOLLOWS:

(I) INTRODUCTION OF THE DEFINITION OF "ADULTERATED COSMETIC" AND PROHIBITION IN RELATION THERETO

The Existing Act contains certain prohibitions and offences listed in relation to "misbranded³", "spurious⁴" and "adulterated⁵" drugs. However, in relation to cosmetics, prohibitions and offences were provided only for "misbranded" and "spurious" cosmetics. The Amended Act introduces a definition for adulterated cosmetics, which is similar to that of adulterated drugs in the Existing Act⁶.

(II) ENHANCED PENALTIES

The penalties under the Existing Act were found to be inadequate to act as a deterrent for persons involved in drug offences. The enhanced penalties in the Amended Act for manufacture, sale, distribution, stocking or exhibiting or offering for sale or distribution of the various classes of substandard drugs are summarized below:

| 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 ⁷ , 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 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. | 5 years to Imprisonment for life | 10 years to Imprisonment for life | INR 10,000 | INR 1,000,000 or 3 times the value of the drug confiscated, whichever is higher |
| A drug merely falling under the classification of "adulterated drug" | 1 to 3 years | 3 to 5 years | INR 5,000 | INR 100,000 or 3 times the value of the |

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| | | | | 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 | INR 5,000 | INR 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 | INR 5,000 | INR 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 INR 20,000 |

Similarly, penalties for trading in sub-standard cosmetics, as well as penalties for subsequent offences have been substantially enhanced. Penalty for trading in sub-standard Unani, Ayurvedic and Siddha drugs has been raised to an amount which is 3 times the value of the confiscated drug, if this amount exceeds INR 20,000.

(III) COMPENSATION TO VICTIM OF ADULTERATED OR SPURIOUS DRUG

A unique feature of the Amended Act is the provision for the entire amount of fine that is realized from the person convicted for the offence of being dealing with adulterated or spurious drug being payable, by way of compensation, to the person who consumes 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

(IV) FORUM OF TRIAL

Another significant change in the Amended Act is that trials for offences relating to trading in sub-standard drugs now start at the level of the Court of Session⁸. The appeals from the Court of Session lie to the High Court and then to the Supreme Court. This change is expected to accelerate the prosecution of these offences.

(V) SETTING UP OF A SPECIAL COURT

The Expert Committee Report had noted that under the current legal system, most prosecution cases pertaining to offences related to spurious 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.

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 drug 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

(vi) Certain offences have been made cognizable and non-bailable

Offences that relate to adulterated drugs and spurious drugs are now considered to be cognizable offences⁹. 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 one who is believed to have committed the offence. These offences are also non-bailable. Previously, most offences fell under the category of non-cognizable and bailable.

OBSERVATIONS ON THE AMENDED ACT

Offences that relate to adulteration of food and drugs are strict liability offences, which means that *mens rea* or intention to commit offence is not required to be proved in order to prosecute an accused under adulteration laws. Adulteration is also an offence under Section 274, 275 and 276 of the Indian Penal Code, 1100% under which the offence is non-cognizable and non-bailable. The Expert Committee Report had recommended the deletion of this provision in view of its inconsistency with the Drugs and Cosmetics Act, 1940. However, the Amended Act makes no mention of such deletion.

The Amended Act attempts to deter dealings in sub-standard drugs by stepping up the rate of conviction by means of the Special Courts and enhanced penalties. The “whistle blower” policy on the anvil would boost this mechanism.

Quality of drugs can also degrade due to improper storage or transport. In order that genuine and innocent manufacturers or sellers of drugs found to be not of standard quality (“**NSQ drugs**”) due to reasons out of their control are not unduly harassed by Drug Inspectors conducting inspections and raids, the Drugs Consultative Committee (DCC) of the Ministry has drafted a set of model guidelines. The guidelines divide NSQ drugs into 3 categories: ‘*Spurious and Adulterated drugs*’, ‘*Grossly Sub-Standard drugs*’, and those having ‘*Minor Defects*’. The guidelines are however non-binding in nature and the industry hopes they will become binding on Drug Inspectors, which at present have mere persuasive value.

The Amended Act is a welcome move for the industry as the menace of spurious and adulterated drugs has been posing serious threats to genuine manufacturers and consumers. It is anticipated that speedier trials and harsh penalties would ultimately lead to the availability of safe drugs in India.

- **Aditi Nadkarri & Gowree Gokhale**

¹ The Bill that sets out this amendment had been first introduced in the Lower House of the Parliament in December 2003. It finally received approval from both the Houses of the Parliament in October 2008 and then Presidential assent in December 2008. The Act has come into force on August 10, 2009, vide Central Government notification no. S.O.2076(E).

² The Expert Committee was constituted by the Government of India in November 2003, under the chairmanship of Dr. R.A. Mashelkar.

³ Misbranded drugs are incorrectly labeled drugs or those bearing false or misleading claims on their labels.

⁴ Spurious drugs are imitations or attempts to pass off genuine drugs or are sold with the incorrect or fictitious name of manufacturer or product.

⁵ Adulterated drugs contain harmful or toxic or decomposed substances, or are packed in containers that render the contents injurious to health, or have substances mixed that reduce the potency or quality of the drug in question.

⁶ Section 17E “*Adulterated Cosmetics*” has been inserted in the Amended Act.

⁷ “Grievous hurt” as defined in Section 320 of the Indian Penal Code, 1100%

⁸ Under the Existing Act, it starts at the level of Metropolitan Magistrate (MM) or Judicial Magistrate of the first class (JMFC) which is the lower most rung of the criminal court system in India.

⁹ The categorization of these offences overrides the provisions of the Code of Criminal Procedure that categorises offences.

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