**A NOTE ON SALIENT PROVISIONS UNDER THE DRUGS AND COSMETICS ACT, 1940 TO CHECK THE PRODUCTIONS AND EXPORT OF SPURIOUS AND SUBSTANDARD MEDICINE AND MEDICAL DEVICES.**

The manufacture and sale of drugs is a licensed activity under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. The licensees are required to comply with the provisions of the Act, Rules and the condition of the licence granted to them by the licensing authorities for manufacture and sale of drugs.

The Drugs and Cosmetics Act, 1940 have elaborate provisions to check the production of spurious and substandard drugs in the country. The Act provides elaborate definitions of the terms spurious, adulterated and misbranded drugs for the purpose of taking penal actions against the offenders. The terms have been defined as under.

'**Spurious drugs -** For the purposes of this Chapter, a drug shall be deemed to be spurious,-

(a) if it is manufactured under a name which belongs to another drug; or

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

(d) if it has been substituted wholly or in part by another drug or substance; or

*(e)* if it purpose to be the product of a manufacturer of whom it is not truly a product.'

'**Adulterated drugs -** For the purposes of this Chapter, a drug shall be deemed to be adulterated,-

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.'

**'Misbranded drugs -** For the purposes of this Chapter, a drug shall be deemed to be misbranded,-

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.'

**Drugs and Cosmetics (Amendment) Act, 2008**

The Drugs and Cosmetics Act, 1940, has been recently amended under the Drugs and Cosmetics (Amendment) Act, 2008 providing very strict penalties for manufacture of spurious and adulterated drugs.

It is provided that any drug deemed to be adulterated or spurious when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more. The fines realized in such cases will be paid to the relative of the deceased or the aggrieved person.

Any drug deemed to be spurious but not being a drug referred to above shall be punishable with imprisonment of a term which shall not be less than 7 years but which may extend to imprisonment for life and with fine which shall not be less than 3 lakh rupees or three times the value of the drugs confiscated, which ever is more.

Offences relating to sale and manufacture of spurious and adulterated drugs have now been made cognizable and non bailable.

It has been provided that besides an Inspector appointed under the Act, the person aggrieved or consumer associations, a gazetted officer authorised by the Government have also been authorised to launched prosecution under the Act.

A provision has been made for especially designated courts for trial of offences under the act.

A provision for compounding of minor offences has also been introduced.

**Regulatory control over the manufacture and sale of drugs**

Regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments which are responsible for monitoring the quality

of drugs moving in the market. As a part of their function, the Inspectors appointed by the State carry out market surveillance by drawing samples from the sales establishments, hospitals and manufacturers and get them tested at governments' laboratories. Wherever a drug is declared as spurious or adulterated or not of standard quality, prosecutions are launched against offenders in the court of law by the concerned regulatory authorities depending upon the merits of the case. Being an undercover activity, it is difficult to detect the manufacture or movement of spurious drugs except by continuous surveillance by the State Drug Control Organization and active cooperation from the law and order Enforcement machinery in the State and other stakeholders like drug manufacturers associations and voluntary associations.

A Drug Inspector appointed by the respective Governments is required to inspect not less than once a year all establishment licensed for manufacture or sale within the area assigned to him and to satisfy himself that the conditions of license are being observed. He may draw samples of a drugs or cosmetics from the manufacturing or sale premises, where he has reason to doubt the quality of drug, in a prescribed manner and send them for test and analysis to the Government analyst to check the quality.

The manufacturer is also required to allow an inspector to inspect all registers and records maintained by him and to take samples of manufactured products, if required, and provides such information as required for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed. The inspection may be conducted by one or more inspectors to examine the premises, plant, appliances and process of manufacture, professional qualifications of technical staff and capability of the manufacturer to comply with the requirements of Good Manufacturing Practices and requirements of plant and equipment before a license is granted.

**Quality controls at manufacturers level**

The manufacturer is required to ensure that the drugs manufactured and marketed by him are of standard quality and tested before release. The provisions of the Drugs and Cosmetics Rules provides for in process controls over the quality of drugs manufactured by the licensed manufacturers.

Schedule M to the Drugs and Cosmetics Rules provides requirements for Good Manufacturing Practices and requirements of plant and equipment for manufacture of drugs. It specify in detail the requirements of premises, surroundings, personnel, sanitation, storage of raw materials, documentation and records, self inspections and quality control systems and site master files etc. The manufacturer is required to comply with the requirements of Schedule M under the conditions of the license.

The manufacturer is required to provide and maintain adequate staff, premises, plant and machinery for manufacture of drugs under the conditions of license for manufacture of drugs. He is also required to maintain records of manufacture including the testing of raw material and finished products. Each batch of the product is required to be tested by the manufacturer either in his own laboratory or any laboratory approved by the Licensing Authority before releasing the product into market.

**Media reports about spurious drugs**

The prevalence of spurious drugs is a public health concern and an emotive issue. Unverified and unsupported figures are being reported in the media regarding large-scale production and trading of spurious drugs in India. The media had been projecting problem of spurious drugs in the country in a manner which does not provide a balanced perspectives and has, therefore,

caused serious apprehensions. The figures quoted by media range from 10% to 25% of drugs in the country being spurious drugs. These are totally unsubstantiated reports. For example, on the basis of an alleged WHO report, the media frequently reports that 35% of fake drugs produced in the world come from India. However, when enquired, the WHO has categorically denied its authenticity. Further 80% of total production of drugs in the country is by the large and medium units in the organized sector which strictly follow GMPs, in process controls etc. The figures quoted by the media therefore, looked more on the basis of hearsay. Similarly certain figures were published by ASSOCHEM about spurious drug in the year 2009. On enquiry it was revealed that the report was based on the fall in sale of specific drugs and not on the basis of any survey conducted on the availability of spurious drugs.

**Extent of Spurious Drugs**

It has been observed from the reports of the drug samples tested all over the country in last three years as received from State Drug Controllers, that about 0.3% to 0.4% of around 40,000 samples per annum fall within the category of spurious drugs.

**Country wide survey on Spurious Drugs**

A survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health, through CDSCO. Statistical principles were provided by Indian Statistical Institute (ISI), Hyderabad. Under this survey 24,136 samples of 61 brands of drugs belonging to 9 therapeutic categories of 29 manufacturers from over 100 different Pharmacy outlets in different regions of the country and located in each stratum viz. metros, big cities, district, towns and villages were collected. The survey has revealed that the extent of drugs found spurious was 0.045% only.

**Initiative taken by the Government to Enforce Drugs And Cosmetics Act More Effectively**

**i. Whistle blower scheme**

Whistle Blower Scheme has been announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities.

**ii. Guidelines for taking action on test reports in the light of enhanced penalties**

In the 40th meeting of Drugs Consultative Committee (DCC) consisting of the DCGI and all State Drug Controllers held on 29.6.2009, guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were adopted for the purpose of uniform implementation of the Drugs and Cosmetic Act in the country. The guidelines with approval of the Ministry of Health were forwarded to the State Drugs Controllers for information and compliance. The guidelines have also been placed on the web site of CDSCO (www.cdsco.nic.in).

**iii. Strengthening of drug testing laboratories**

Under a Capacity Building Project through World Bank, assistance was provided to upgrade testing facilities and to establish new drug testing laboratories in the country so as to enhance the capacity of the laboratories to test large number of samples. Under this project 23 States and 6 Central Drug laboratories have been strengthened through renovations, extensions and equipments.

It is expected to increase the number of samples tested in the country from about 36,000 samples to 1,00,000 samples per year and to reduce the reporting time to less than a month as against the present period from 3 to 6 months.

**iv. Good manufacturing practices**

Schedule M to the Drugs and Cosmetics Rules, 1945, pertaining to Good Manufacturing+ Practices was amended to make it at par with the international standards and it is mandatory for the manufacturers of drugs to comply with the requirements of this Schedule for quality control of the drugs manufactured by them.

v. **Other Measures**

a. To take care of the quality of import/export consignments of drugs which are presently kept along with food stuff, meat and other general cargo, it has been decided to set up exclusive pharmaceutical zones with dedicated area for storage of drugs meant for export/import at Delhi, Hyderabad and Mumbai Airport.' CDSCO is involved in negotiation/consultation with the port authorities in the matter.

b. To take care of increased traffic of import and export of drugs, two SubZonal offices at Hyderabad and Ahmadabad airport have been converted into Zonal offices. A new Sub-Zonal office at Bangalore airport has also been set up to cope up the situation of increased traffic of import and export of drugs in that region. It has also been decided to set up a sub zonal office at Chandigarh as northern India has become a major Pharma hub due to setting up of large no. of drug manufacturing units in the excise free zones.

c. Detailed guidelines have been issued to the State Govts. to undertake focused surveillance over possible movement of spurious drugs.

d. Training programme for regulatory officials of State Govts. on logistics of intelligence, surveillance, prosecutions, etc. has been conducted with the assistance of FDA, Maharashtra.

e. Pharma industry and traders has been motivated to fight menace of spurious drugs as a

shared responsibility. No. Of cases could be successfully detected through the initiative taken by Pharma industry involving hiring of retired intelligence officers.

**Medical Devices**

Only a limited number of notified medical devices (14 in number) are being regulated under the said Act at present. These devices are regulated under the provisions applicable for drugs. The proposal to regulate quality of medical devices in general is under consideration of the Government of India.