Pharma & Healthcare Update

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GUIDELINES FOR MEDICAL DEVICES NOTIFIED AS "DRUGS"

The Ministry of Health and Family Welfare ("**Ministry**") has now provided the guidelines ("**Guidelines**") for the licensing, registration and manufacture of specified medical devices, which were notified as "drugs" by Notification dated October 6, 2005. The following devices have been declared as "drugs" under Section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 ("**Act**").

1. Cardiac Stents
2. Drug-Eluting Stents
3. Catheters
4. Intra Ocular Lenses
5. I.V. Cannulae
6. Bone Cements
7. Heart Valves
8. Scalp Vein Set
9. Orthopedic Implants
10. Internal Prosthetic replacements.

These Guidelines are effective from March 1, 2006.

IMPORT OF MEDICAL DEVICES

For the purpose of import of the devices specified above, the procedure for registration and import licence as prescribed under the Drugs and Cosmetics Rules, 1945 ("Rules") are to be followed. The Guidelines provide that the application for the import and registration should be made within 60 days after the publication of the Guidelines. However, in respect of the devices, which were not imported into India prior to March 1,2006, the import would be permitted only with the approval of the competent authority.

The specified devices, which are currently in use, will be permitted to be sold for six months from March 1, 2006 or until an application for import is approved or rejected, whichever is earlier. However, this provision will not be applicable to stents or drug eluting stents if the applicant has not sold at least one thousand (1000) stents of the particular specification prior to the date of issue of Guidelines.

It is also suggested in the Guidelines that separate committees consisting of subject experts and representatives of the office of the Drug Controller General of India ("DCGI") would be set up for their expert advice on the evaluation of specific categories of devices. Such expert committees would formulate their own benchmarks and procedures for evaluation and determination of the standards to which such devices should conform.

The Guidelines have also prescribed norms regarding the documents and information to be submitted along with the application for import and registration of medical devices.

MANUFACTURE OF MEDICAL DEVICES IN THE COUNTRY

For manufacture of notified devices in India, an application for the grant of licence is required to be made in a stipulated form to the State Licensing Authority, accompanied by the requisite fee in the form and manner as prescribed in the Rules, along with a copy marked to the office of the DCGI. If the devices mentioned in any specified category have not been manufactured in the country before the date of notification, no manufacture would henceforth be permitted without the approval of the competent authority as per the norms prescribed.

SALE OF MEDICAL DEVICES IN THE COUNTRY

The importers, stockists and retail sellers of the specified devices will be required to obtain appropriate sale licences from the State Licensing Authorities within a period of three months from the date of issue of these Guidelines.

The amendments to the Act and subsequent Guidelines are an outcome of litigation in the Bombay High Court. Till recently, there was no specific provision in the Act or any other statue by which the manufacture, sale, distribution or importation of medical devices was regulated. While hearing a writ petition challenging the Maharashtra Foods & Drugs Authority order for regulating the sale of some of the devices, the Bombay High Court expressed astonishment with regard to the lack of such regulation involving medical devices and directed the DCGI to enact a specific legislation pertaining to such devices at the earliest.

The amendment and the Guidelines are however silent in respect of the clinical trials of such devices in India and it

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remains to be seen how the government reacts to applications for clinical trials of medical devices in India.

- Gowree Gokhale & Dr. Milind Antani

Source: Central Drugs Standard Control Organization

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