Pharma & Healthcare Update

October 10, 2014

MEDICAL DEVICES REGULATORY FRAMEWORK GETTING STREAMLINED

- Whole-time manufacturing supervisor now required to have significant experience.
- Foreign qualification of whole-time manufacturing supervisor now acceptable.
- New labeling requirements prescribed.
- Maximum shelf-life of 60 months notified.
- Import and manufacture of custom made medical devices recognized and exempted from regulatory framework.
- Standards of medical devices clarified.
- By a separate office order, DCGI clarifies that regulatory framework for medical devices will not to apply to non-notified medical devices.

The manufacturers of medical devices listed in Schedule C and C1 of the Drugs and Cosmetics Rules, 1945 ("**D&C Rules**"), namely sterilized surgical ligature, sterilized surgical suture, sterile disposable devices for single use only and in-vitro diagnostic devices for HIV, HbsAg and HCV, and those notified by Ministry of Health and Family Welfare (See **Annexure-A**) are now set to face stricter regulations. Through the Drugs and Cosmetics (Fourth Amendment) Rules, 2014 notified on September 24, 2014, the Ministry of Health has introduced certain changes to the existing regulatory framework applicable to medical devices under the D&C Rules. We have summarized the major changes below:

1. WHOLE-TIME EMPLOYEE TO SUPERVISE MANUFACTURE IS NOW REQUIRED TO HAVE SIGNIFICANT EXPERIENCE:

The Health Ministry has made it mandatory for the manufacturers of medical devices listed in Schedule C and C1 to employ only those manufacturing supervisors who have considerable experience. Under the old rule, there was no minimum experience prescribed. The below table provides for the new minimum experience requirements.

Sr. No.	Qualification	Minimum experience requirement
1.	Graduate in Pharmacy or Engineering (in appropriate branch)	At least eighteen months practical experience in the manufacturing or testing of devices to which this licence applies after his or her graduation.
2.	Graduate in science, with Physics or Chemistry or Microbiology as one of the subject	At least three years practical experience in the manufacturing or testing of devices to which this licence applies after his or her graduation.
3.	Diploma in Pharmacy or Engineering (in appropriate branch)	At least four years practical experience in the manufacturing or testing of devices to which this licence applies after his or her diploma.

2. MANUFACTURING SUPERVISORS MAY NOW HAVE FOREIGN QUALIFICATION:

The Health Ministry has relaxed the requirement under the D&C Rules to hire manufacturing supervisors with only domestic qualifications for manufacture of medical devices listed in Schedule C and C1. A person with foreign qualification, the quality and content of training of which are comparable with those specified in Table under Sr. No. (1), clause (2) and (3) above and who is permitted to work as competent technical staff by the Central Government, may be hired as a manufacturing supervisor. The D&C Rules make it mandatory to manufacture under the active direction and personal supervision of a competent technical staff who is a whole-time employee.

3. NEW LABELING REQUIREMENTS:

Under the old rule, the manufacturers of medical devices were required to comply mainly with the labeling specifications laid down by the Bureau of Indian Standards (BIS), in addition to any other requirement prescribed under the D&C Rules. The BIS notified a few domestic standards but relied majorly on International Standard Organization (ISO) standards and European Standards (EN). BIS was also not able to keep pace with the developments under the international standards. The Health Ministry has now decided to completely move away from reliance on BIS and has notified an exhaustive list of labeling particulars to be printed on the label or the sticker. The full list is present in **Annexure-B**.

Medical devices that are exported need not comply with the full labeling particulars and requirements specified in Annexure-A. A separate list of labeling particulars has been notified and is reproduced herein **Annexure-C**.

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4. SHELF-LIFE OF MEDICAL DEVICES PRESCRIBED:

While no shelf life for medical devices was prescribed, it has now been made clear that the shelf life of such medical devices will not exceed 60 months from the date of manufacture.

5. IMPORT AND MANUFACTURE OF CUSTOM MADE MEDICAL DEVICES RECOGNIZED AND EXEMPTED FROM REGULATORY FRAMEWORK:

The Ministry of Health has recognized application of custom made medical devices which are made according to the written prescription of duly qualified medical practitioner, under his responsibility, in accordance with specific design characteristics and intended for sole use of a particular patient. Such custom made devices, when imported or manufactured bearing the label "custom made device", will be exempt from the regulatory framework applicable to medical devices, for instance, from requirement to obtain a license to manufacture, license for sale, requirement to obtain and produce prescription of a registered medical practitioner for purchase of medical device *etc*.

6. STANDARDS OF MEDICAL DEVICES CLARIFIED:

The Ministry of Health has expanded the list of standards that are required to be met by medical devices. Earlier, standards were prescribed only for sterile disposable perfusion sets for single use only, sterile disposable hypodermic syringes for single use only and sterile disposable hypodermic needles for single use only. No standards were prescribed for other devices. This led to confusion over the standards to be met by manufacturers of other medical devices. The issue has been addressed by Ministry of Health now. Henceforth, all medical devices will have to conform to the Indian Standards laid down from time to time by the BIS. If there are no standards laid down by BIS, then the medical devices will have to conform to the International Standards, like International Organisation for Standardisation, or other International Pharmacopeia Standards and such other standards as may be specified for this purpose. Where national or international standards are not available, the medical devices will have to conform to the manufacturer's validated standards.

DRUGS CONTROLLER GENERAL OF INDIA CLARIFIES THAT NON- NOTIFIED MEDICAL DEVICES ARE NOT COVERED BY REGULATORY FRAMEWORK OF DRUGS AND COSMETICS ACT, 1940 AND DRUGS AND COSMETICS RULES, 1945:

With a view to rest speculations and doubts about selective applicability of regulatory framework under Drugs and Cosmetics Act, 1940 (D&C Act) and D&C Rules to certain medical devices, the apex medical device regulator in India, the Drugs Controller General of India, has clarified through an office order dated July 09, 2014 (available here) that the regulatory framework will be applicable to only those medical devices which have been notified by the Ministry of Health and Family Welfare. The Order further states that all non-notified devices do not require any registration, license, permission or NOC for their import, manufacture, sale and distribution under D&C Act and D&C Rules. A list of these notified medical devices is reproduced in **Annexure-A**.

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You can direct your queries or comments to the authors

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