Legal Aspect of Indian Medical Device Sector

written by Kulin Dave | May 9, 2019

Legal Aspect of Indian Medical Device Sector - Indian medical device sector is considered as Asia's fourth largest market. At present, multi-national companies prevail India's medical device sector, which is evident from the fact that about eighty percent of the sales are generated by imported medical devices. On the contrary the domestic entities focus on low cost devices. India export more than sixty percent of their output as Indian markets are dominated by such imported medical devices. The sector is at present growing at a high pace. Most of the purchasers of medical devices are private medical institutions and hospitals. Further, the sector is witnessing strong Foreign Direct Investments inflows. This reflects the confidence and interest of global players in the Indian market.

Legal Aspect of Indian Medical Device Sector - Legal and Regulatory Regime

The Drugs and Cosmetics Act, 1940 ("DCA/Act") regulates the Indian medical device sector. The Central Government and the State Governments are responsible for the enforcement of the Act. The Central Drugs Standard Control Organization ("CDSCO") which is headed by the Drugs Controller General of India ("DCGI") is primarily responsible for coordinating the activities of the State Drugs Licensing Authorities, formulating policies, and ensuring uniform implementation of the Act throughout India. The Medical Device Rules, 2017 (MDR), issued under the DCA, regulate the following categories of substances –

1. Some categories of devices have been notified by the government ("Notified Medical Devices"). These specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals. These devices are notified by the government from the time to time under the DCA.
2. Substances intended to affect the structure or any function of the human body which are notified by the government under the DCA. The substances notified till date are mechanical contraceptives (example: condoms, intra-uterine devices, tubal rings), insecticides and disinfectants.
3. Surgical staples, surgical dressings, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant, surgical bandages;
4. Substances used for in vitro diagnosis.

The objective of Drugs and Cosmetics Act, 1940 (DCA), and Medical Device Rules, 2017 (MDR) is to:

1. Regulate the import, manufacture, distribution and sale of Notified Medical Devices.
2. Ensure the availability of standard quality Notified Medical Devices to the consumer.

Manufacture of Notified Medical Device in India

Each manufacturing location requires a separate license for each Notified Medical Device at such manufacturing location. The license for manufacturing a Class A or B device is issued by the State Licensing Authority whereas the licensing to manufacture a Class C or D device is issued by the Central Licensing Authority. On the contrary, importing a Notified Medical Device into India requires additional legal formalities. The import of medical devices is governed under the provisions of the Export and Import Policy of India.

Standards of Manufacture

All medical devices are required to conform to the following standards, in the same order of relevance:

1. A standard notified by central government for the medical device specifically or which has been laid down by the Bureau of Indian Standards ("BIS"); or
2. Where (i) is absent, to a standard laid down by International Organisation for Standardisation ("ISO") or the International Electro Technical Commission ("IEC"), or by any other pharmacopoeial standards; or
3. Where both (i) and (ii) are absent, to the validated manufacturer's standards.

Moreover, MDR in its fifth schedule lays down 'Quality Management System' (QMS) that is to be followed during the manufacture of medical devices and in-vitro diagnostics.

Labelling

The labelling of Notified Medical Devices is governed by three statutes:

1. The Medical Devices Rules, 2017 ("MDR") – A Notified Medical Device must be labelled according to specifications outlined in the MDR before it is sold or distributed in India. It is permissible for importers to print the mandatory declarations on a label and stick the label to the package. The MDR prescribes the contents of the label to the package such as name of the medical device, name of manufacturer and address of manufacturing premises, the details necessary for the user to identify the device and its use, etc.
2. The Legal Metrology (Packaged Commodity) Rules, 2011 – These Rules, notified under the Legal Metrology Act, 2009, regulates the packaging and labelling of pre-packed commodities in India. Since 1st January, 2018, Notified Medical Devices are required to bear additional declarations and particulars on retail package as prescribed under the Legal Metrology (Packaged Commodity) Rules,

2011.

3. Drug (Prices Control) Order, 2013 – It requires all manufacturers and importers of Notified Medical Devices to declare the MRP on the label.

Penalties

The Government of India through Ministry of Health and Family Welfare notified an amendment to the Act in 2009 which attempts to strengthen the existing law against the menace of spurious and counterfeit medical devices in India. The said amendment has changed certain provisions of the Act that specifically relate to the offences of manufacture and trade of spurious Notified Medical Devices.

The penalties have been enhanced through the amendment for manufacture, sale, and distribution. Exhibiting or offering for sale or distribution of spurious or counterfeit Notified Medical Devices attracts a penalty up to INR 1,000,000 (appx. USD 16,667) or 3 times the value of the Notified Medical Device confiscated, whichever is higher and imprisonment of not less than 10 years which may extend up to life, for spurious or counterfeit Notified Medical Device leading to death or grievous hurt.

Exim Restrictions

With regard to Legal Aspect of Indian Medical Device Sector in Imports and exports, it is regulated by the Foreign Trade (Development and Regulation) Act, 1992, the Customs Act, 1962 along with Export-Import Policy (EXIM Policy), issued by the Ministry of Commerce and Industry of the Government of India. The present EXIM policy also known as the Foreign Trade Policy covers the period 2015 – 2020. The objective of the EXIM policy is to improve export performance, develop export potential and create a favourable balance of payments positions.

Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

The application of above legislation, earlier applied only to drugs, has been extended to medical devices by the Indian Courts. The Act prohibits advertisements about diagnosis, cure, mitigation or prevention of (54) diseases and enumerated disorders such as rheumatism, heart diseases, cancer, diabetes, etc.

The Competition Act, 2002

The continuous growth of medical devices industry, raises competition law issues (anti-trust). However, the medical devices are protected under several Intellectual Property laws. The need to provide protection to medical device companies for their innovation is well recognized under the Competition Act, 2002, however the same is restricted by providing specific inclusions under Section 3(5) of the Competition Act.

Patent Protection - Legal Aspect of Indian Medical Device Sector

The patent rights in India is governed by the Patents Act of 1970 under which the Patents Rule, 2003 have been passed. This Patents Act of 1970 provides for patenting of both, products and well as processes for a span of 20 years.

The invention of a medical device is granted patent in India. A patent right with respect to any invention is created only upon grant of the patent by the Patent Office following the procedure established by the Patents Act and the Patent Rules there under. As a conclusion to Legal Aspect of Indian Medical Device Sector it can be said that India complies a declarative system with respect to patent rights. Patents in India are granted on a 'first to file' basis.

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