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All medical devices in India regulated & requires registration

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The medical devices, effective April 1, 2020 require registration in India. This is particularly applicable to all the manufacturers and importers of medical devices. It applies for practically all the medical devices. Prior to the amendment, only 37 categories of medical devices were regulated. However, from 1st April 2020, all medical devices have been roped in for registration.

On February 11, 2020, the Government of India issued two notifications – a new definition of medical devices and **The Medical Devices (Amendment) Rules, 2020**. The cumulative effect of these two notifications is that all medical devices will be brought under the fold of quality and safety regulation from the effective date of both notifications – April 1, 2020.

The standards of quality and safety of medical devices are regulated in India by a law called The **Drugs and Cosmetics Act, 1940** ("DCA"). The scope of DCA is restricted to only those medical devices which are notified by the Government from time to time as "drugs" (commonly referred to as "notified medical devices").

The Medical Devices Rules, 2017 ("MDR") have been framed under DCA. These rules lay down comprehensive quality requirements to be followed by marketers / importers / manufacturers / sellers of notified medical devices.

DCA and MDR ensure quality and safety of notified medical devices at all levels of the supply chain by enforcing a mandatory license requirement. All importers / manufacturers / sellers of notified medical devices must obtain a license from the appropriate licensing authority before undertaking any commerce in notified medical devices. A license is issued only after quality checks. The license holder's business premise is subject to periodic inspection. A license holder is also required to maintain detailed records of the sale-purchase undertaken in relation to notified medical devices and ensure traceability in the event of a quality or safety-related failure or complaint.

Until February 11, 2020, the Government had regulated or notified 37 categories of medical devices as drugs (see list of these 37 categories of medical devices at the end of the article). On February 11, 2020, the government exercised its powers to notify one or more categories of medical devices as "drug" to actually notify a new definition of medical devices.

As per the notification, effective April 1, 2020, the medical devices that fall under the following definition will be regulated as "drug" under the DCA and MDR:

All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of – (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; and (vi) control of conception.

The above new definition is intended to cover all medical devices. Thus, by virtue of this definition, all medical devices sold in India gets regulated from April 1, 2020, when the definition takes effect.

For the purpose of this article, all medical devices which were not notified until February 11, 2020 (i.e. other than the list of 37 categories of medical devices listed at the end of this article), and will now be covered by the new definition of medical devices will be referred to as "**Newly Notified Medical Devices**".

The manufacturers or importers of Newly Notified Medical Devices will be required to compulsorily register their medical devices with the Drugs Controller General of India ("DCGI") before October 1, 2021. The DCGI has started accepting applications for registration through a dedicated online portal called "Online System for Medical Devices" from April 1, 2020. There is no time-frame prescribed as of now for processing of the application for registration by DCGI.

If an importer or manufacturer is unable to obtain registration for its Newly Notified Medical Device before October 1, 2021, then it will not be able to market and sell its medical device in India until a registration is obtained. The importer or manufacturer of a medical device which belongs to one of the 37 categories of medical device regulated or notified prior to February 11, 2020 are exempt from the requirement to obtain registration for its medical device and therefore can continue to carry on their business on the strength of the license issued by appropriate licensing authority.

Every manufacturer and importer who obtains a registration number for its medical device will have to display the registration number on its label. The requirement to declare registration number is not tied to the deadline for registration (October 1, 2021). Rather it is an immediate requirement and will trigger from the time the registration number is issued, unless otherwise mandated by DCGI.

There is no consequence of registration of medical device on its supply chain. The supply chain will not be required to obtain registration.

A certificate of compliance with ISO-13485 (Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes) is mandatory for registration of Newly Notified Medical Device. Therefore, an importer or manufacturer of a registered medical device will have to ensure that the requirements of ISO 13485 are met at all times. Broadly speaking, ISO 13485 requires creation, documentation and implementation of a quality management system which is to be supplemented by an independent audit from time to time.

Once an importer or manufacturer registers its medical devices, it will have to strictly conform to its documented quality management system.

If any gap is found in the implementation of quality management system by DCGI, it will have the right to suspend or cancel the registration of the medical device. An order of suspension or cancellation of registration for medical device will prevent the importer or manufacturer of said medical device to further import or manufacture said medical device.

In addition to registration, importers and manufacturers of Newly Notified Medical Devices will have to obtain a license under MDR before the prescribed deadline.

Class of medical devices	**Licensing Authority**	**Stipulated timeline for processing application**	**Deadline for obtaining license**
Class A and B (import)	DCGI	Up to 9 months from the date of application	August 11, 2022
Class C and D (import)	DCGI	Up to 9 months from the date of application	August 11, 2023
Class A (manufacture)	State-level Licensing Authority	Up to 45 days from the date of application	August 11, 2022
Class B (manufacture)	State-level Licensing Authority	Up to 140 days from the date of application	August 11, 2022
Class C and D (manufacture)	DCGI	120 – 180 days (estimated)	August 11, 2023

The risk-classification of all medical devices (Class A, B, C, D) will be done by the DCGI.

The supply chain of Newly Notified Medical Devices (including marketers) will also have to obtain appropriate license for distribution (i.e.Wholesale) or retail sale before the deadline for obtaining a license for respective class of devices expires.

If a license is obtained much in advance before the deadline gets over, it will not obligate the manufacturer or importer to comply with the requirements of MDR only on the grounds that a license has been obtained. For example, if a Class C or Class D medical device importer or manufacturer obtains a license before the deadline of August 11, 2023, the said importer or manufacturer will not have to declare the import license number on the label. The supply chain of the said device also will not require a license just because the medical device importer or manufacturer has applied for and received a license. However, after the deadline gets over, all the compliances stipulated under MDR including the requirement to obtain license by the entire supply chain will have to be met. The routine inspections of warehouses or manufacturing premises will also begin only after the prescribed deadline gets over.

The government has given time to the medical device industry to transition into the regulatory framework and to obtain ISO 13485 certification, if not already obtained.

The government has relaxed the requirement to obtain registration and license for Newly Notified Medical Devices for the following period:

- **April 1, 2020 to October 1, 2021** – Not mandatory to obtain registration or license to manufacture, import, distribute or sell Newly Notified Medical Devices; thus it is a voluntary exercise.
- **October 1, 2021 to August 10, 2022** – Registration will be required to import or manufacture such medical devices, but no license will be required;
- **August 11, 2022 to August 10, 2023** – License will be required to manufacture, import, distribute or sell Class A or Class B medical devices, but no license will be required to manufacture, import, distribute or sell Class C or Class D medical devices; and
- **After August 11, 2023** – License will be required to manufacture, import, distribute or sell Class C and Class D medical devices as well.

If an importer or manufacturer of a Newly Notified Medical Device fails to obtain a registration until October 1, 2021, then it will have to cease import or manufacture of said medical device until such time the registration is obtained. It will be easy for the DCGI or State-level Licensing Authority to know whether a medical device is manufactured or imported without registration. Therefore, if a declaration exists on the label of a medical device that the medical device has been imported or manufactured on or after October 1, 2021, but the label does not show a DCGI registration number, then it will be confiscated by DCGI or appropriate State-level Licensing Authorities and action will be taken against the importer or manufacturer.

Any violation of MDR including failure to obtain registration or license before stipulated deadline may result in criminal prosecution resulting in imprisonment and fine. Any stock of medical device that is sold without registration or license could also be confiscated.

The Government has now given sufficient time for the industry to adopt ISO 13485 and obtain registration for hitherto unregulated medical devices. Therefore, we are of the view that though obtaining registration is voluntary till 1st Oct 2021, and mandatory thereafter, it is advised that the companies start taking the registrations from now onwards itself. This is to avoid the last minute rush to get the registration since the department will also be over occupied to grant the registrations at the last minute. And not to mention, if the timely registration before the mandatory dates are not taken, the manufacturer and the importer will not be able to sell the medical devices in India which could have huge monetary implications as well.

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