The Medical Devices Rules, 2017 – Industry implications and action required

Hitender Mehta, Partner and Abhijeet Das, Senior Associate, Vaish Associates Advocates, give an insight on key steps that need to be undertaken by the entities engaged in import, manufacture, sale or distribution and clinical investigation of the medical devices

The medical devices sector has largely enjoyed a free hand from the regulators in India, as the sphere has largely gone unregulated thus far. Presently, there is no medical devices-specific legislation specifying inter alia standards of safety and quality for most of the medical devices. Only a handful of devices such as cardiac stents, disposable hypodermic needles/syringes, catheters, etc. are the cut of being classified as ‘drugs’ and thus being regulated under the Drugs and Cosmetics Act, 1940 (Act). Other medical devices presently have no legal provisions governing the aspects of manufacture, product standards, sale or distribution. This unwarranted but long-standing position is extremely short-lived, with the Medical Devices Rules, 2017 (MDR 2017) coming into effect on January 1, 2018. While the wheels of this regulatory framework were set in motion with its notification on January 31, 2017, the Government thought it best to give the stakeholders ample time to prepare for the paradigm shift in the regime. That being said, the first National Accreditation Board (Board) has already been recognised under the MDR 2017 with effect from January 31, 2017 itself. The Board is going to start entertaining applications for registration as Notified Bodies from January 1, 2018. 

Interestingly, the MDR 2017 is silent on the aspect whether representation can be made by the applicants with respect to categorisation of medical devices. However, in the absence of any restriction/prohibition, it would be worthwhile for the concerned individuals/entities to make proper representations, in order to assist the DCG(I) make appropriate classification of medical devices.

Taking the right first steps are often the most important bit of the journey. In view of the impending MDR Rules, below are some key steps that need to be undertaken by the entities engaged in import, manufacture, sale or distribution and clinical investigation of the medical devices:

- Determining whether the products fall within the MDR 2017 categorisation

The first and most important step, is to identify the substances that fall within the ambit of the term medical device under the MDR 2017. In addition to the aforementioned devices specifically notified to fall under the definition of drugs under the Act, the following would come within the scope of the MDR 2017: (i) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant used (internally or externally) for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals; and (ii) substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides as notified from time to time:

With regards the categorisation, the Drugs Controller General (India) (DCG(I)) has been put in charge in terms of the MDR 2017, for categorisation/classification of medical devices based on its usage (in vitro diagnostic medical devices and otherwise) as well as risk associated with the medical devices. The risk categorisation falls in four classes i.e., Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). Further, the criteria for assessing risk by DCG(I) has been very broadly specified in the MDR 2017, separately for in vitro medical devices and the other devices. The MDR 2017 does not set a date as to when the categorisation would be finalised/published, but it may be assumed that the same has to be done well before the MDR 2017 comes into effect on January 1, 2018.

In view thereof, it would be advisable for the stakeholders to gauge the possibility of its/their devices/substances falling within the MDR 2017, as well as the probable risk classification thereof. The objective of this exercise would be two pronged, firstly, to identify the possible ramifications i.e., compliances applicable on the medical devices post January 1, 2018; and secondly, in case the medical device is mis-categorised by the DCG(I), this exercise will allow the affected individuals/entities take timely remedial action, may be even before the adverse impact actually commences.

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Further, although the MDR 2017 does not provide for an appeal mechanism to the categorisation of medical devices, given its express power to effect modifications thereto, in case of mis-categorisation of a device to a higher risk level (entailing greater compliances), representations against such decision should be made to the DCG(I) and failing which, judicial intervention may also be sought, to rectify the error.

Identification of applicable product standards

While several classifications under the MDR 2017 need to wait for the aforesaid categorisation of the medical devices, the applicable product standards can be assessed and identified now as well. This will allow the concerned persons/entities to make necessary modifications in the respective medical devices, if required, before the MDR 2017 takes effect.

The product standards applicable would be as laid down by the Bureau of Indian Standards or as may be notified by the Ministry of Health and Family Welfare for the relevant medical device/s. In absence thereof, standards laid down by the International Organisation for Standardisation or the International Electrotechnical Commission (IEC), or by any other pharmacopoeial standards would be applicable to the device. Further, in case no such standards are specified even, the device is required to conform to the validated manufacturer’s standards.

Approximation of the applications/compliances required

Although, the appropriate authority, application process, etc., would be largely dependent on the class of the medical device, it would be advisable that the process and requirements be identified based on the internal assessment of the class of the medical device for a seamless transition into the new regime under the MDR 2017. For instance, the requirements such as the quality management system, presence of qualified technical staff, would need to be ascertained and met before an application for manufacturing, sale or distribution.

Licenses/registrations of medical devices under the Act subsisting as on January 1, 2017, would be valid under the MDR 2017

Further, in relation to an import license, existence of a free sale certificate in respect of any medical device by the national regulatory authority or other competent authority of any of the countries, namely – Australia, Canada, Japan, European Union Countries, or the US, would enable the licence to be granted without carrying out any clinical investigation. On the other hand, a license for import of higher risk category medical devices (viz., Class C and D) from other territories would entail a clinical investigation in India under the MDR 2017. Similarly, criteria for applications for clinical investigation in investigational medical device in human participants as well as in vitro medical devices, should also be evaluated.

It is pertinent to mention, that the licenses/registrations of medical devices under the Act subsisting as on January 1, 2017, would be valid under the MDR 2017 for a duration being the later of (i) July 1, 2018, or (ii) the original period of such licenses/registrations. Therefore, the medical devices entitled to this benefit should also be identified for such timeline for implementation of the MDR 2017.

Labelling of medical devices and shelf-life

The labelling requirements would need to be implemented as soon as the MDR 2017 takes effect from January 1, 2018. In view thereof, adequate preparations, as prescribed/required, should be in place. Further, the MDR 2017 specifies that a shelf-life exceeding sixty months need prior approval of the DCG(I). Therefore, in case of products where the shelf-life exceeds sixty months, the evidence in support of the extended shelf-life, e.g., approved shelf-life in other countries, stability data, etc., should be procured beforehand to be submitted along with the application for manufacture and/or import of the corresponding medical devices. Another point to be noted is that import of medical devices after the expiry of a specified percentage of its shelf-life, has also been prohibited under the MDR 2017.

The foregoing represent some of the key considerations that are required to be kept in mind by the stakeholders vis-à-vis the imminent MDR 2017 to avoid any last minute helter-skelter and ensure a smooth transition to the new regulatory regime. There are numerous other considerations that would need to be examined after the categorisation/classification is put in place by the DCG(I).

Policies and bearers of the present regulatory environment are likely to be aligned with the objectives of the MDR 2017, which would need to be evaluated.

The foregoing represent some of the key considerations that are required to be kept in mind by the stakeholders vis-à-vis the imminent MDR 2017 to avoid any last minute helter-skelter and ensure a smooth transition to the new regulatory regime. There are numerous other considerations that would need to be examined after the categorisation/classification is put in place by the DCG(I). However, the aforesaid represents the basic initiative that the industry as a whole should take, which would act as the proverbial ‘stitch in time’.

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