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ALL MEDICAL DEVICES NOTIFIED TO BE REGULATED

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Background

- About 80% to 90% of India's requirement of medical devices is met through imports. As the present government pushes for its "make in India" agenda, the medical device industry can play a significant role. A specific law regulating all the medical devices was needed *inter alia* to ensure minimum standard quality of the medical devices imported, manufactured and sold in India.

- The Medical Devices Rules, 2017 (MD Rules) under the Drugs and Cosmetics Act, 1940 (DC Act) came into effect from 1 January 2018. However, only a limited number of medical devices were notified and regulated by the MD Rules. The MD Rules and the DC Act currently only regulate 24 notified medical devices and additional 13 medical devices are proposed to be regulated from a specified date under the MD Rules (Notified Devices).

Amendment Notification and Definition Notification

- New Chapter IIIA added: On 11 February 2020, the Ministry of Health and Family Welfare notified an amendment to the MD Rules (Amendment Notification). Chapter IIIA has been added in the MD Rules which requires *all devices notified under Section 3(b)(iv) of the DC Act,* except the Notified Devices, to be registered under the provisions of Chapter IIIA of the MD Rules.

- Medical Devices Notified: Simultaneous with the Amendment Notification, on 11 February 2020, the Ministry of Health and Family Welfare has also notified an all-encompassing definition of medical devices (Definition Notification) under Section 3(b)(iv) of the DC Act. The definition reads as follows:

  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:

  – *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*

- *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*
- *investigation, replacement or modification or support of the anatomy or of a physiological process;*
- *supporting or sustaining life;*
- *disinfection of medical devices; and*
- *control of conception.*

➢ Effective Date of Notifications: The Amendment Notification and the Definition Notification will both come into effect from 1 April 2020.

➢ Voluntary Online Registration: Pursuant to the Amendment Notification, all importers and manufacturers of medical devices are required to be registered on a voluntary basis. The registration will be through an identified "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation. The registration number generated upon completion of the registration process is required to be mentioned on the label of the medical device.

➢ Information to be uploaded: The Amendment Notification provides a list of information required to be uploaded on the online portal by the manufacturer or importer at the time of registration which *inter alia* includes a certificate of compliance with respect to the ISO 13485 standard accredited by the National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical devices. Additionally, in case the registration is being undertaken by an importer, a free sale certificate from country of origin is also required to be provided. Moreover, as part of the registration process, the manufacturer or importer is also required to specify the class of the medical device.

➢ Exemptions or Relaxations: To provide for a phase wise implementation of the Amendment Notification, the following two relaxations or exemptions have been included:

- Registration under the chapter is on a voluntary basis for a period of 18 months from the commencement of the chapter (i.e., 1 April 2020).
- Except for the Notified Devices, (i) all Class A (low risk) and Class B (low moderate risk) devices have been exempt for a period of 30 months; and (ii) all Class C (moderate high risk) and Class D (high risk) devices have been exempt for a period of 42 months, from the date of the Amendment Notification (i.e., 11 February 2020), from the application of all the provisions of the MD Rules in the event that such medical devices have been registered under Chapter IIIA (notified by virtue of the Amendment Notification). (collectively, the above two exemptions are referred to as Exemption Timelines)

Some Ambiguities and Challenges

➢ *Which devices does the Definition Notification cover?*

- It has been estimated that by virtue of these notifications, approximately 1700 medical devices would become regulated in India.

- The notified definition for medical devices is very wide and subjective and is aimed at including all medical devices being sold in the Indian market. This approach is a stark alteration to the approach adopted by the government so far, wherein, only a minimal number of notified medical devices were regulated, and all other medical devices were unregulated.

- Given the wording of the definition and absence of a specific list of medical devices, it appears that all sorts of medical devices in the market would get covered by the definition. For example, it would not be a stretch that spectacles, wheelchairs or physiotherapy equipment such as weights would also get subsumed within the definition. It cannot be said with clarity if the intention was to also include such devices withing the ambit of MD Rules. Therefore, businesses will need to ascertain whether their products would be covered as medical devices under the MD Rules.

➢ *Relaxation or Exemption Timelines*:

- Commencement of the Exemption Timelines: The Notification becomes effective from 1 April 2020. However, it appears that the Exemption Timelines start from 11 February 2020 itself.

- Medical Devices not registered on 1 April 2020: In the event the medical devices are not registered on 1 April 2020, the manufacturers and importers will not be able to avail of the Exemption Timelines. In other words, such medical devices would become subject to the MD Rules from 1 April 2020 itself and the manufacturers and importers will not be able to continue to carry on their business from 1 April 2020 without obtaining relevant licenses under the MD Rules and complying with other provisions of the MD Rules as they would not have obtained registration under Chapter IIIA.

- Relevance of 18 months voluntary registration period: Although the notification contemplates registration on a voluntary basis, from a practical perspective, it is mandatory. This is because the medical devices would need to comply with MD Rules from 1 April 2020 itself if they are not registered.

➢ *Absence of a deeming provision:* It is not clear whether the Exemptions Timelines would be available on filing the application for registration or whether the applicant will have to wait for the registration to be granted to be eligible for the Exemption Timelines. The process and timelines for registration has not been provided. In the event registration is not completed immediately upon the submission of application, then it is not clear whether the exemption will be available on the basis of an application itself.

➢ *Classification of Medical Devices*: The authorities will need to quickly notify a list specifying the class of each medical device as no such classification has been provided so far.

Conclusion

This change in the MD Rules will have a substantial impact on the medical device industry. Businesses will have to consider the compliance requirements and costs for such compliances under the MD Rules.

The regulation of medical devices and subjecting them to internationally recognised standards in accordance with the MD Rules may aid export of Indian manufactured medical devices.

Preparedness and the infrastructure for the registration of medical devices at such a vast scale within the proposed time period would be extremely important. This would

cause a huge shift in the manner in which the medical devices industry currently operates and the market players should prepare for the shift without any delay.

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