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CLASSIFICATION FOR NEWLY NOTIFIED MEDICAL DEVICES

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Introduction

On 3 September 2020, the Central Drugs Standard Control Organization (CDSCO), the national regulatory body for Indian pharmaceuticals and medical devices released draft classifications for newly notified devices. This is a significant development. As covered in an earlier ERGO from our firm *available* here, in February 2020, the Ministry of Health and Family Welfare (MoHFW) had: (a) adopted a "catch-all" definition of medical devices bringing all devices which were previously excluded (New Notified Devices) within the scope of the Medical Device Rules, 2017; and (b) required all importers and manufacturers to provisionally register these New Notified Devices with the CDSCO, effective from 1 April 2020. Upon registration, such New Notified Devices would enjoy exemptions from the remaining provisions of the Medical Device Rules, 2017 for a period 30 – 42 months (based on the Class of medical device).

On a plain reading of the text of the notifications, it seemed clear that medical device manufacturers and importers would have to register their devices on 1 April 2020 itself, as they would be ineligible for the regulatory exemptions from the rest of the provisions of the Medical Device Rules, 2017 which would have been applicable 1 April 2020. At the time of registration, manufacturers and importers were required to specify the Class of medical device (Class A to D). However, due to interruptions caused by the COVID-19 crisis, the New Notified Devices remained unclassified by the CDSCO, and with no online portal for registration set up.

Draft Classifications Published

As a first step in facilitating the online registration requirement, the CDSCO has released draft classifications for 1,866 New Notified Devices for public stakeholder comments. Devices are now classified into 24 categories, apparently as per international norms and divided into Classes based on risk. Currently, the document is in the form of a draft, pending stakeholder comments and finalisation within 30 days from the date of issue of the notification. Given the expedited speed at which other regulations have been notified, where stakeholders believe that a classification is inappropriate, it is advisable to raise those concerns with the CDSCO at the earliest.

Notable Inclusions

While prior to the notifications in February, the CDSCO only regulated 37 medical devices, the current approach seems to be much wider with several commonly used products included in the list such as:

- Spectacles (frames and lenses);
- Contact lenses;
- Public respirator masks (2 and 3 ply) – described as a "filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates during a public health medical emergency.";
- Device, Fertility, Diagnostic, Contraceptive, Software Application – described as software "Designed to monitor and provide fertility information to prevent pregnancy (contraception)" e.g., Clue, Flo and other available mobile applications.

Conclusions

While the relative inaction of the CDSCO with regard to the amendments has given medical device companies some time to adjust to the new amendments, preparedness on the part of such companies would be key. As part of the application, they would be required to provide documentation such as: (a) a certificate of compliance with respect to the ISO 13485 standards (from an organisation accredited by the National Accreditation Board for Certification Bodies or International Accreditation Forum); and (b) a free sale certificate from the country of origin of the medical device (applicable only to imported devices).

Companies should first assess whether their products fall within the list provided, and then make adequate arrangements with respect to the accompanying documents for the registration. Since these steps would have to be undertaken once the final Classifications are notified, companies would be well placed in keeping their documentation ready for the application.

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