Pharma & Healthcare Update

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MEDICAL DEVICE REVAMP: REGULATORY PATHWAY OR REGULATORY MAZE?

- The Ministry of Health and Family Welfare has released two draft notifications to regulate all medical devices in India under the Medical Device Rules, 2017.
- If notified, the first draft notification will notify all medical devices thereby requiring the manufacturers, importers and sellers of the medical devices to obtain permission to engage in the import, manufacture and sale of the medical devices.
- The second draft notification will require all devices notified under the first draft notification to register themselves online on a portal developed by the drug regulator for this purpose. The registration will be on a voluntary basis for the first 18 months and compulsory thereafter.
- Once a medical device has been registered on the portal, the medical device will be exempt from all regulatory compliances under the Medical Device Rules, 2017 for a period of 30 months from the date of the second notification for Class A and Class B devices and a period of 42 months from the date of the second notification in case of Class C and Class D devices.

A. INTRODUCTION

The Ministry of Health and Family Welfare ("**Health Ministry**") on October 18, 2019 released two draft notifications, one which proposes to bring all medical devices under the ambit of regulation ("**New Definition Notification**"), and the other requiring the registration of all medical devices on a portal ("**Portal**") developed by the Central Drugs Standard Control Authority ("**CDSCO**") – India's apex drug regulator – for this purpose ("**Registration Notification**") (collectively referred to as the "**Draft Notification**").

In this hotline, we have summarized the key features of this Draft Notification. We have also analyzed the Draft Notification for its impact on the industry and our expectations on how the Draft Notification will be enforced.

B. BACKGROUND

Medical Device Regulation

Medical devices in India are governed under the Medical Device Rules, 2017 ("**MDR**") – a set of rules framed under India's primary drug legislation, the Drugs and Cosmetics Act, 1940 ("**D&C Act**") – which came into force on January 01, 2018. The MDR currently only regulates medical devices which have been notified by the Health Ministry for regulation under the MDR. As of this writing, sixteen medical devices are regulated under MDR while 8 others are regulated as drugs. Four additional medical devices will come under regulation from January 01, 2020, eight more from April 01, 2020 and ultrasound equipment will be added to the list from November 01, 2020. The complete list of medical devices is provided below in **Table 1**.

The MDR provides for a risk-based classification system with four categories from A to D for low risk, low moderate risk, moderate high risk and high risk respectively.[1]

The slow pace and method of medical device regulation has been a concern for the industry for a while now. There are over 1700 types of medical devices in the global market[2] out of which only 29 will be governed under MDR if things progress at their current pace. It is also not feasible for the Health Ministry to notify all 1700 medical devices to bring them under the MDR. To remedy this, the Health Ministry has released the Draft Notification to regulate all medical devices in a phase-wise manner within 3.5 years from when the Draft Notification comes into force.

Implications of Being Regulated by MDR

The implications being of a medical device being regulated device by the MDR ("**Regulated Device**") are manifold. The MDR divides the regulation of medical devices into the following broad activities – clinical investigation, import, manufacture and sale. At each stage of the production to consumption cycle, appropriate permissions are required to be obtained from the CDSCO (or other relevant state authority, as the case may be) in respect of the relevant activity. To elaborate, different permissions (in the form of licenses) are granted for importing medical devices, for conducting clinical investigations and for manufacture and sale of such devices. Therefore, the level of compliance required to be undertaken by a manufacturer or importer of a Regulated Device will increase significantly.

In addition to procuring the appropriate licenses, the MDR also imposes strict quality control requirements on medical devices. Regulated Devices are required to follow standards set by the Bureau of India Standards ("**BIS**"). In the absence of BIS standards, manufacturers of Regulated Devices should follow standards laid down by the Health Ministry, the International Standards Organization or the International Electrotechnical Commission in that order.[3] The MDR also prescribes a Quality Management System to be followed by manufacturers of Regulated

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Devices.[4]

Regulated Devices could also be subject to price control under the Drugs (Prices Control) Order, 2013, either by being restricted from increasing the price of the product by more than 10% over the preceding twelve months[5] or having its ceiling price[6] notified by the National Pharmaceutical Pricing Authority.

The Health Ministry will also have more control over medical devices once they have been brought under the purview of the MDR. The Health Ministry can change or introduce new standards for regulating medical devices and even ban devices that are not proven safe and efficacious for patient use.[7] The CDSCO will have the power to inspect premises where medical devices are manufactured and sold to ensure that such premises are as per standards prescribed by law.

Overview of the New Definition Notification

The Draft Notification was released for comments in two parts on the same day – the New Definition Notification and the Registration Notification. The content of both parts of the Draft Notification is interconnected such that they may even be notified on the same day. The New Definition Notification does not change the existing definition of medical devices under section 3(zb) of MDR.[8] Instead the New Definition Notification notifies a catch-all definition effectively bringing all medical devices under the regulation of the MDR. The definition of medical in the New Definition Notification is 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 -

1. *diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;*
2. *diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;*
3. *investigation, replacement or modification or support of the anatomy or of a physiological process;*
4. *supporting or sustaining life;*
5. *disinfection of medical devices; and*
6. *control of conception."*

Overview of the Registration Process

The Registration Notification is largely based on the roadmap for medical devices discussed by the Drugs Technical Advisory Board ("**DTAB**") – India's apex body on technical matters related to drugs –in April 2018.[9] Under the Registration Notification, the MDR will apply to all medical devices (as defined above) except for the devices in Annexure A ("**New Devices**"). Annexure A contains the list of medical devices that have been specifically notified thus far.

However, once the New Device has been registered on the Portal, such device will be exempt from the MDR for a period of 30 months from when the Registration Notification comes into effect if the New Device is a Class A or Class B device and for a period of 42 months if the New Device is a class C or Class D device ("**Exemption Provision**").

Notably, the registration of New Devices on the Portal is on an optional basis for 18 months and mandatory thereafter. However, as the Exemption Provision is applicable only for New Devices that have been registered on the Portal, manufacturers and importers have a strong incentive to register their New Devices as soon as the Portal becomes operative.

The details required to be uploaded by manufacturers and importers of the New Devices are specified in **Table 2**.

C. ANALYSIS

The Draft Notification is the biggest leap that India has taken in terms of medical device regulation after the enactment of the MDR in 2017. However, there are some concerns with respect to both clarity and expected impact with respect to the Draft Notification as outlined below.

Ambiguity in Timelines for Notifying the Draft Notification

The New Definition Notification states that it may come into force on December 01, 2019 while no date has been specified with respect to the Registration Notification. However, the New Definition Notification is still in the draft stage and therefore may not be notified before next year. Regardless, there remains some ambiguity with respect to when both parts of the Draft Notification will be notified. For the registration process to be carried out smoothly, both parts of the Draft Notification should come into force simultaneously. If only the Registration Notification is notified no device would be required to be registered under the Registration Notification. If only the New Definition Notification is notified, all medical devices will be brought under the regulation of the MDR in one fell swoop without allowing manufacturers and importers to avail of the Exemption Provision.

However, from the language of the Draft Notification, we anticipate that both parts of the Draft Notification will come into force at the same time, with the New Definition Notification kicking off the registration of medical devices under the Registration Notification.

Tight Timelines for Ensuring Compliance

Registering the New Devices is a pre-condition to availing the Exemption Provision. Therefore, manufacturers and importers will be compelled to register the New Devices to avail the Exemption Provision or not import/manufacture the New Device until they obtain the requisite licenses. Once the registration process is complete, manufacturers and importers will be required to apply for manufacturing and import licenses with the CDSCO – a process that typically takes nine months to complete. However, given the large volume of applications the CDSCO is bound to receive,

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processing the applications may take even longer. Given that the CDSCO is currently staffed to deal with both pharmaceutical as well as medical device related applications, the timelines for processing of the applications may also be impeded.

As a result, manufacturers and importers who have not been granted the required licenses at the expiry of the Exemption Provision despite having registered their New Devices and applied for licenses well in time will be forced to halt operations. To address this concern, the Exemption Provision should be de-linked from the requirement to register the device. This way, New Device manufacturers/importers will have the full 30 to 42 months to register their New Device. Additionally, manufacturers and importers who have registered their New Device on the Portal and applied for a manufacturing/import license should be permitted to carry on business activities on a provisional basis at the expiry of the Exemption Provision even though the license has not been granted yet. This will help stagger the workload on the CDSCO without requiring medical device companies to halt their business activities.

Ambiguities on Registration Process

The details required to be uploaded by the manufacturer and importer specified in Table 2 contemplate the manufacture of import of a medical device as a whole. However, a medical device could also be partly manufactured in India and partly imported. Additionally, spare parts of medical devices may also be imported separately for repairing the medical device. Clarification is required from the CDSCO on how registration numbers will be generated for medical devices which cannot be registered as a whole.

The manufacturer or importer is also required to specify the class of the medical device sought to be manufactured or imported when entering the details of the medical device on the Portal. The CDSCO will therefore be required to classify a large number of medical devices before the registration requirement comes into effect which, given the impending timeline, appears to be a herculean task.

D. CONCLUSION

The Draft Notification is clearly a step in the right direction. Bringing medical devices under MDR regulation will lead to improvements in the quality of medical devices and consequently an increase in patient safety. Wider medical device regulation will also lead to uniformity in medical device standards across all brands and manufacturers thereby reducing danger to patient safety and decreasing the need for constant medical supervision. Manufacturers will also have a definite set of standards to keep track of as opposed to attempt to set their own methods of validating medical devices.

However, while the intention of the Draft Notification is laudable, clarifications are required from the CDSCO on how the implementation will take place. Effective implementation may lead to gains for patients while delayed or ineffective implementation could lead to huge losses for medical device companies. Even aside from the Draft Notification, the medical device regulation space has been experiencing a lot of activity. Earlier in November, the NITI Aayog – the Indian Government's policy think tank – submitted a draft bill to the Indian Government proposing to create a separate regulator for medical devices. The bill, titled the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 also aims to introduce a Unique Identification Number on all medical devices, increase penalties for non-compliance as well as tighten the regulation applicable to clinical investigations.[10] It is currently unclear how the two legislations will interact with each other or if the proposed bill will replace the MDR. The medical device industry can certainly expect exciting times ahead.

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You can direct your queries or comments to the authors

1 Rule 4 MDR
2 https://www.ncbi.nlm.nih.gov/books/NBK222708/
3 Rule 7 MDR.
4 Fifth Schedule MDR.
5 Paragraph 20 DPCO.
6 Paragraph 4 DPCO.
7 S.10A D&C Act.
8 "medical device" means, -
(A) 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 covered under sub-clause (i),
(B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),
(C) devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act;
Explanation: For the purpose of these rules, substances used for in vitro diagnosis shall be referred as in-vitro diagnostic medical device.
9 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=ODc5
10 https://timesofindia.indiatimes.com/business/india-business/draft-bill-proposes-up-to-rs-1cr-fine-for-unsafe-medical-devices/articleshow/71828552.cms