

Pharma & Healthcare Update

December 29, 2020

REGULATORY YEARLY WRAP 2020: MEDICAL DEVICE IN INDIA

INTRODUCTION

This year has been perhaps the most significant year for medical device companies from a regulation perspective since the Medical Device Rules, 2017 (explained below) came into force on January 01, 2018. The Government has amended medical device regulation to significantly expand the reach of medical device regulation. There is also some discussion on enacting a new legislation altogether specifically for medical devices (medical devices are currently regulated as drugs). The sector has also been largely unaffected by the COVID-19 pandemic and the regulator provided for relaxations in regulatory compliances as required.

In this wrap, we have covered some of the significant developments in the medical device space this year and what we hope to see ahead in 2021.

HEALTH MINISTRY ISSUES NOTIFICATIONS TO REGULATE ALL MEDICAL DEVICES IN INDIA

The Ministry of Health and Family Welfare ("Health Ministry") on February 11, 2020 released two notifications, one which brings all medical devices under the ambit of regulation ("New Definition Notification")¹, and the other requiring the initial registration (and subsequent licensing) of these medical devices on a portal developed by the Central Drugs Standard Control Authority ("CDSCO") – India's apex drug regulator for this purpose ("Registration Notification")² (collectively referred to as the "MD Notifications"). The Notifications came into force on April 01, 2020.

The New Definition Notification will bring all medical devices within the mandate of the Medical Device Rules, 2017 ("MDR") (a set of rules framed under India's primary drug control legislation to regulate 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. However, if a device is registered as per the Registration Notification, such device will be exempt from compliances under the MDR for a period of 30 months from the date of the Registration Notification in case the device is a low risk or a low-medium risk device and for a period of 42 months from the date of the Registration Notification in case the device is a high risk or a medium-high risk device. The registration will be on a voluntary basis for the first 18 months and compulsory thereafter. However, as the exemption outlined above is applicable only for devices that have been registered, manufacturers and importers have a strong incentive to register their devices as soon as the Registration Notification comes into effect.

Currently, sixteen medical devices are regulated under MDR, 8 others are regulated as drugs and 13 additional devices are to be included in the MDR over 2021. The slow pace of medical device regulation has been a concern for the industry for some time now. Therefore, while the move to regulate all medical devices has been welcomed by the industry, stakeholders have expressed concerns regarding whether the registration process will take place smoothly. Impediments in the registration process (such as delays on part of the CDSCO in granting import and manufacturing licenses before the end of the 30/42-month exemption period) can lead to loss of revenue and business for medical device companies and create a supply deficit in the market, thereby endangering the health and safety of patients. Notably, the Health Ministry had published a draft version of the MD Notifications for public comments in October 2019. However, none of the comments from received from the industry have been incorporated in the final version.

DRUG REGULATOR RELEASES RISK CLASSIFICATION FOR MEDICAL DEVICES BROUGHT UNDER REGULATION IN APRIL 2020

The CDSCO has released a draft risk classification list for medical devices brought under regulation by way of the New Definition Notification.³ The risk classification list divides medical devices into 24 broad categories (as per international classification norms) with stand-alone software categorized as a separate category.

The MDR classifies medical devices in four classes – Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk) and Class D (high risk). The classification is the basis for how the device would be regulated with Class C and D devices being regulated more stringently than Class A and B devices.

The draft classification list was long-awaited by industry members as it provides clarity on how their device would be regulated. The draft classification list has also clarified that standalone software would be regulated as a medical device, a point of concern for some stakeholders.

HEALTH MINISTRY POSTPONES THE DATE ON WHICH 13 MEDICAL DEVICES WERE SET TO COME UNDER REGULATION.

The Health Ministry by way of three notifications dated December 27, 2019 and October 21, 2020, postponed the

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effective date of previous notifications which in turn brought 13 new categories of medical devices under regulation ("New Device Notifications"). The first of the New Device Notifications amended the effective date of a previous notification dated December 03, 2018 by the Health Ministry (bringing nebulizers, blood pressure monitoring devices, digital thermometers and glucometers under regulation) from January 01, 2020 to January 01, 2021.⁴ The second of the New Device Notifications amended the effective date of notification dated February 08, 2019 (bringing all implantable medical devices, CT scan equipment, defibrillators, dialysis machine, PET equipment, X-Ray machine and bone marrow cell separators under regulation) from April 01, 2020 to April 01, 2021.⁵ The third of the New Device Notifications amended the effective date of notification dated October 16, 2019 (bringing ultrasound equipment under regulation) from November 01, 2020 to November 01, 2021.⁶

Effectively, the New Device Notifications have postponed the date from which the above devices would be regulated under the MDR. The MDR only applies to medical devices specifically notified by the Health Ministry as regulated medical devices. However, as covered in the previous update, the Health Ministry has significantly expanded the list of medical devices covered under the MDR with effect from April 01, 2020 by way of New Definition Notification. The 13 devices mentioned in this update were not covered under the New Definition Notification as they were separately notified earlier and will therefore come under regulation over the course of 2021.

As covered above, once a device is regulated under the MDR, persons engaged in the manufacture, import and sale of medical devices are required to obtain a license from the relevant drug regulatory authorities to do so. Further, regulated medical devices are also subject to price control and manufacturers and importers of medical devices are either required to price their device in accordance with a ceiling price notified by the Government or are restricted from increasing the price of the device by more than 10% in any given ten-month period.

DRUG REGULATOR PROVIDES RELAXATIONS ON REGULATORY COMPLIANCE IN LIGHT OF COVID-19 PANDEMIC.

The CDSCO – India's apex drug regulator – issued the following public notices relaxing compliance requirements under the D&C Act.

- Public notice on April 23, 2020 exempting applicants for medical device import license from submitting notarized/apostilled documents ("**Import Relaxation**")⁷;
- Public Notice dated May 01, 2020 extending the validity of the Good Manufacturing Practice ("**GMP**") Certificate expiring between March 2020 and August 2020 by another six months ("**GMP Relaxation**")⁸;
- Notification dated July 27, 2020 under Section 26B of the D&C Act extending the validity of the registration certificate granted to foreign drug manufacturers seeking to export drugs into India for the purposes of sale for a period of six months ("**RC Notification**")⁹; and
- Notification dated November 26, 2020 under Section 26B of the D&C Act extending the validity of the import license granted to importers of drugs for the purposes of sale for a period of six months ("**Drug Import Notification**").¹⁰

We have covered the background and rationale behind each relaxation below.

Import Relaxation

Under the MDR, importers of medical devices are required to make an application to the CDSCO to obtain an import license prior to importing medical devices into India. As part of the application for the import license, the applicant is required to notarize and apostille certain documents. The Import Relaxation gives applicants the option of submitting these documents after self-attestation along with an undertaking that the applicant will provide the notarized/apostilled documents within four months or after the '*normalisation of the situation*', whichever is earlier. The CDSCO may grant an import license on a provisional basis based on the self-attested documents if the application as a whole is in order.

A subsequent public notice on August 31, 2020 extending the duration of the Import Relaxation by another four months until the end of 2020.¹¹

GMP Relaxation

The CDSCO issues a Certificate of Pharmaceutical Product ("**CoPP**") under the WHO-GMP certification scheme for the purpose of registration of Indian pharmaceutical products in foreign countries so that Indian companies can export their drugs. The CoPP certificates granted are valid for a period of three years. The GMP Relaxation extends this period by six more months from the date of expiry for CoPPs expiring between March 2020 and August 2020 to maintain continuity of essential activities in the pharmaceutical industry.

RC Notification

The RC Notification was issued in response to representations made by foreign pharmaceutical companies whose registration certificates (a pre-requisite for foreign pharmaceutical companies seeking to export drugs to India) were set to expire soon. The RC Notification aims to prevent adverse impact on the supply of drugs in light of the COVID-19 pandemic.

To avail the exemption granted by the RC Notification, registration certificate holders would be required to apply for a fresh registration certificate prior to the expiry of the existing one. Once the application has been made, the existing registration certificate will be valid either until the expiry of six months from July 27, 2020 or until a decision is made on the application for grant of a fresh registration certificate.

To import a drug for the purposes of sale/distribution, the CDSCO grants a registration certificate to the foreign manufacturer of the drug and a corresponding import license to the India-based importer. Both a valid registration certificate and an import license are pre-requisites for importing drugs into India.

Drug Import Notification

The Drug Import Notification was issued in response to representations made by pharmaceutical companies whose import licenses were set to expire soon. The Drug Import Notification aims to prevent adverse impact on the supply of

drugs in light of the COVID-19 pandemic.

To avail the exemption granted by the Drug Import Notification, import license holders would be required to apply for an import license prior to the expiry of the existing one. Once the application has been made, the existing import license will be valid either until the expiry of six months from November 26, 2020 or until a decision is made on the application for grant of a fresh import license.

The relaxations provide a welcome measure to ensure the continuity of business in these tough times.

CONCLUSION

The pandemic appears to have had little impact on the medical device industry. Separately, the CDSCO appears to be intent on enforcing the MD Notifications and over time has put in place the infrastructural requirements to do so. The industry is now looking at two key developments in the horizon of 2021 – whether the required licenses for import/manufacture of thousands of medical devices now regulated will be granted in a timely manner by the CDSCO and whether any progress will be made on a separate legislation to regulate medical devices.

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You can direct your queries or comments to the authors

¹ New Definition Notification, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA==

² Registration Notification, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OQ==

³ Draft Classification List, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ1MA==

⁴ Notification, available at: <http://egazette.nic.in/WriteReadData/2019/214934.pdf>

⁵ Notification, available at: <http://egazette.nic.in/WriteReadData/2019/214933.pdf>

⁶ Notification, available at: <http://egazette.nic.in/WriteReadData/2020/222617.pdf>

⁷ Import Relaxation, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg4NQ

⁸ GMP Relaxation, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTg5OA

⁹ RC Notification, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjMyOQ==

¹⁰ Drug Import Notification, available at: <http://egazette.nic.in/WriteReadData/2020/223363.pdf>

¹¹ Public notice extending the import relaxation, available

at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQyOQ==

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