

Pharma & Healthcare Update

December 28, 2020

REGULATORY YEARLY WRAP 2020: PHARMACEUTICALS IN INDIA

INTRODUCTION

While there has been some significant development in the healthcare sector (specifically in the area of regulating doctors), medical devices sector has clearly witnessed the largest number of developments this year. The most significant and far-reaching of these developments is the introduction of draft rules to regulate all medical devices in the country in a phase-wise manner. Ironically, while releasing draft rules to regulate all medical devices, the drug regulator has simultaneously postponed the regulation of 12 medical devices that were set to be regulated in 2020 to 2021.

Over the past year, we have also observed that the drug regulator is showing a growing inclination to lend a willing ear to the industry's grievances and issue clarifications/amendments in the law to ensure that the medical device industry in India keeps developing. In case you missed it, do read our medical device and healthcare round up covering updates from January to July [here](#) and [here](#).

NATIONAL MEDICAL COMMISSION ACT, 2019 ("NMC Act"),¹ IN THE PROCESS OF BEING IMPLEMENTED

The National Medical Commission Act, 2019 ("NMC Act"),¹ which received Presidential assent earlier this year, is in the process of being implemented.² The NMC Act was enacted with the intention to repeal the Indian Medical Council Act, 1956 ("IMC Act") which comprises the current regulatory framework governing medical colleges and the medical practice in India.³ The NMC Act will also establish the National Medical Commission ("NMC") to replace the Medical Council of India ("MCI") as the apex regulatory body for the governing the medical education and profession in India.

Some of the key provisions of the NMC Act include the following.

Uniform Entry and Exit Test for Admission into and Graduation from Medical Colleges

Provision for a uniform National Eligibility-cum-Entrance Test for admission to undergraduate and postgraduate super-specialty medical education in all medical institutions and a National Exit Test for the purpose of obtaining a license to practice medicine and for admission to postgraduate broad-specialty medical education in medical institutions.⁴ Persons with a foreign medical qualification may also give the National Exit Test for the purpose of obtaining a license to practice medicine and for enrolment in the State Register / National Register.⁵

Provision for CHPs

The NMC is empowered to grant a limited license to practice medicine at mid-level as CHP to persons connected with the modern scientific medical profession who are eligible under the criteria specified by the Government.⁶ The CHP Provision is one of the more controversial provisions under the NMC Act as many doctors believe that the CHP Provision lowers the threshold for entry into the medical profession and encourages quackery.⁷

Power to Give Directions to NMC and Autonomous Bodies

The NMC Act empowers the Central Government issue binding directions to the NMC and the Autonomous Boards with respect to the discharge of their powers and functions. The NMC and the Autonomous Bodies will have the opportunity to express their views as far as practicable.

Currently, the following provisions of the NMC Act have been notified by the Government⁸:

- Constitution of the NMC;
- Constitution of the Medical Advisory Council ("MAC") (a body through which States and Union Territories may put forth their concerns to the NMC); and
- Constitution of the Autonomous Boards (to regulate medical education in India and to maintain national registers of licensed medical practitioners and Community Health Providers ("CHP"))

While the MAC has been constituted, the Government is still in the process of setting up the NMC and Autonomous Bodies.⁹

Separately, the Government has also notified various rules under the NMC Act regulating the qualifications, manner and terms of appointment, the salaries, allowances and conditions of employment of the members of the Autonomous Boards and the MAC¹⁰ as well as the manner of submission of annual accounts, annual statements and other reports by the NMC.¹¹

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The NMC Act has faced vociferous opposition from the medical fraternity. After the passage of the NMC 2019 in Lok Sabha (the lower house of India's Parliament) on July 29, 2019, the IMA had called for a 24-hour withdrawal of non-essential services.¹² After the passage of the NMC Act 2019 in the Rajya Sabha (the upper house of India's Parliament) protests only intensified.¹³ Finally, after a four day tussle with the Central Government, the strike was called off following assurances from the Union Health Minister that the concerns of the doctors will be duly addressed.¹⁴

However, it remains to be seen whether the NMC Act will prove to be an effective replacement for MCI which was plagued with allegations of corruption. Unlike the MCI, which had over 120 members elected from within the medical fraternity, the NMC will comprise 25 members appointed by the Central Government. Only time will tell whether increasing government involvement in regulating the medical profession will defeat corruption or will merely shift the red tape from an autonomous body to a government one.

HEALTH MINISTRY INCLUDES ULTRASOUND EQUIPMENT IN THE LIST OF REGULATED MEDICAL DEVICES

The Ministry of Health and Family Welfare ("**Health Ministry**") published a notification on October 16, 2019 to amend the Medical Device Rules, 2017 ("**MDR**") – rules framed under India's primary drug control legislation, the Drugs & Cosmetics Act 1940 ("**D&C Act**"), to regulate ultrasound equipment as a medical device from November 01, 2020 ("**Notification**").

For a medical device to be regulated under the MDR, it must have been specifically notified by the Health Ministry under the D&C Act. Therefore, medical devices not notified by the Health Ministry are unregulated. The MDR currently regulates fifteen categories of medical devices while eight other devices are regulated as drugs. However, the Health Ministry has added 12 additional medical devices which will be regulated with effect from 2021.

After the Notification comes into effect, manufacturers, importers and distributors of ultrasound equipment will require prior approval of the regulator in accordance with the MDR, to carry out those activities.

HEALTH MINISTRY RELEASES DRAFT NOTIFICATIONS REGULATE ALL MEDICAL DEVICES IN INDIA

The 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**")¹⁵, 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 ("**Registration Notification**")¹⁶ (collectively referred to as the "**Draft Notification**").

If notified, the New Definition Notification will bring all medical devices within the mandate of the Medical Device Rules, 2017 (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.

Interestingly, the NITI Aayog (the Indian Government's policy think-tank) has also reportedly released the Medical Device (Safety, Effectiveness and Innovation) Bill, 2019 which aims to create a separate regulator for medical devices, introduce a Unique Identification Number on all medical devices, increase penalties for non-compliance as well as tighten the regulation applicable to clinical investigations. It is currently unclear how the two legislations will interact with each other or if the proposed bill will replace the MDR.¹⁷

Currently, sixteen medical devices are regulated under MDR, while 8 others are regulated as drugs. Four additional medical devices were set to come under regulation from January 01, 2020¹⁸ and eight more from April 01, 2020¹⁹.

However, the regulation of these devices has been postponed to January 01, 2021²⁰ and April 01, 2021 respectively.²¹ Ultrasound equipment will be added to the list from November 01, 2020.²² The slow pace and method of medical device regulation has been a concern for the industry for a while now, and the Draft Notification is a means of extending the regulatory ambit of the MDR.

For a more detailed analysis, please refer to our hotline on the Draft Notifications [here](#).

DRUG REGULATOR ISSUES CLARIFICATION ON REGULATION OF VITAL SIGN MONITORING DEVICES AND IMPLANTABLE DEVICES.

The CDSCO has issued two notices –clarifying the definition of implantable medical devices ("**IMD Definition**")²³ and medical devices used for monitoring vital signs ("**Monitoring Devices**") such as digital thermometer and blood pressure monitoring devices ("**Monitoring Device Definition**")²⁴ collectively referred to as "**Clarifications**"). The IMD Definition states that all medical devices intended "*(a) to be totally or partially introduced into the human or animal body or a natural orifice; or (b) to replace an epithelial or the surface of the eye; by surgical intervention, and which is intended to remain after the procedure for at least thirty days, and which can only be removed by medical or surgical intervention*" would be considered to be implantable medical devices. The Device Definition states that if the primary intended purpose of the Monitoring Devices is composite and not the individual/unit monitoring of temperature or blood pressure, then such devices will not be considered as Monitoring Devices by the CDSCO.

The Clarifications were requested by the stakeholders in the medical device industry who wished to understand whether their devices would be considered as Monitoring Devices or implantable medical devices under the MDR. Monitoring Devices and implantable medical devices were set to be brought under the purview of the MDR from January 01, 2020²⁵ and April 01, 2020²⁶ respectively. However, the regulation of these devices has now been pushed to January 01, 2021²⁷ and April 01, 2021²⁸ respectively. As a result, manufacturers, importers and sellers of these devices will be required to obtain licenses from the CDSCO to engage in the manufacture, import and sale of these devices.

For a medical device to be regulated under the MDR, it must have been specifically notified by the Health Ministry under the D&C Act. The MDR currently regulates sixteen categories of medical devices while eight other devices are regulated as drugs. 13 additional medical devices, including Monitoring Devices and implantable medical devices will be brought under regulation at various points in 2020 and 2021.

DRUG REGULATOR FORWARDS PROPOSAL TO EXEMPT IMPORTERS OF HIGH-TECH MEDICAL DEVICE EQUIPMENT FROM OBTAINING DRUG SALE LICENSE TO TECHNICAL COMMITTEE FOR CONSIDERATION.

The Drugs Controller General of India ("DCGI") (India's apex drug controller), after a meeting with stakeholders, has decided to recommend to the Drugs Technical Advisory Board ("DTAB") (India's apex body on technical matters relating to drugs) to exempt importers of high-tech medical equipment like X-Ray, MRI, PET, ultrasound and CT Scan from the requirement obtain a sale license.²⁹ However, the importers of such equipment will be required to maintain all records of transactions, installations, maintenance, agreements etc.

Currently, importers of medical devices are required to hold a manufacturing or wholesale license as a pre-condition to be able to import medical devices.³⁰ However, high-tech and high-value equipment such as the devices mentioned above may be imported by a retailer who will directly supply the device to hospitals rather than a wholesaler who will subsequently supply to a retailer. This concern was brought before the DCGI in a stakeholders meeting as X-Ray machines, MRI equipment, PET equipment and CT Scan equipment are set to be regulated under the MDR from April 01, 2020³¹ (now postponed to April 01, 2021)³² while ultrasound equipment will be regulated under the MDR from November 01, 2020.³³

For a medical device to be regulated under the MDR, it must have been specifically notified by the Health Ministry under the D&C Act. The MDR currently regulates sixteen categories of medical devices while eight other devices are regulated as drugs. 13 additional medical devices, including Monitoring Devices and implantable medical devices will be brought under regulation at various points in 2021. Once the above-mentioned devices come under MDR regulation, they will be required to obtain an import license from the drug regulator as a pre-condition to import the medical device.

CONCLUSION

The CDSCO in 2019 has been very receptive to industry feedback on taking a different approach to regulation of medical devices as compared to the approach for regulating drugs. For instance, the CDSCO set up the Medical Devices Technical Advisory Group earlier this year, issued clarifications upon the request of industry representatives and also forwarded a proposal to the DTAB to amend the MDR based on the request of industry representatives. However, the primary concern of the medical device industry, that medical devices be regulated separately from drugs continues to remain unaddressed. Interestingly, the NITI Aayog released the Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 which provides for the establishment for a separate regulator for medical devices. However, this development coincides with the CDSCO releasing a roadmap to regulate all medical devices in India. As a result, there remains some ambiguity on the future of medical device regulation in India. With respect to 2020, it is also clear that the draft rules to regulate all medical devices in India will take the center stage. Currently, there are many ambiguities with respect to how these rules would be implemented and industry representatives have raised concerns regarding some of the compliances required under the rules. Therefore, we hope the obtain some clarity on this subject from the regulator this year. We are especially excited to see whether these rules are indeed notified in 2020 and how the implementation of these rules may play out.

– Shreya Shenolikar, Darren Punnen & Dr.Milind Antani

You can direct your queries or comments to the authors

¹ Notification dated August 8, 2019 by Ministry of Law and Justice, available at: <http://egazette.nic.in/WriteReadData/2019/210357.pdf> (last accessed December 26, 2019)

² News article on 'The President signing the NMC Bill' available at: <https://economictimes.indiatimes.com/news/politics-and-nation/president-ram-nath-kovind-signs-nmc-bill-into-a-law-nmc-to-be-constituted-within-six-months/articleshow/70591981.cms?from=mdr> (last accessed December 26, 2019)

³ Section 60 of the National Medical Commission Act, 2019, when notified, will repeal the Indian Medical Council Act 1956 and dissolve the Medical Council of India.

⁴ Chapter IV of The National Medical Commission Act, 2019.

⁵ Section 15(4) of The National Medical Commission Act, 2019.

⁶ Section 32 of The National Medical Commission Act, 2019.

⁷ News article on 'The Criticism of The National Medical Act 2019', available at: <https://www.thehindubusinessline.com/opinion/unfair-criticism-of-national-medical-bill/article29325240.ece> (last accessed December 26, 2019).

⁸ Notification dated September 2, 2019 by Union Health Ministry, available at: <http://egazette.nic.in/WriteReadData/2019/211946.pdf> (last accessed December 26, 2019)

⁹ Notification dated October 10, 2019 by Ministry of Law and Justice, available at: <http://egazette.nic.in/WriteReadData/2019/213104.pdf> (last accessed December 26, 2019)

¹⁰ National Medical Commission (Manner of Appointment and Nomination of Members, their Salary, Allowances and Terms and Conditions of Service, and Declaration of Assets, Professional and Commercial Engagements) Rules, 2019 and National Medical Commission, Autonomous Boards (Manner of Appointment of Fourth Member and the Salary, Allowances and Terms and Conditions of Service, and Declaration of Assets, Professional and Commercial Engagements of President and Members) Rules, 2019 and National Medical Commission, Medical Advisory Council (Qualification and Experience of Residuary Member) Rules, 2019.

¹¹ National Medical Commission (Annual Statement of Accounts, Submission of Annual Reports and Other Reports and Statements) Rules, 2019.

¹² News article on 'IMA calls country-wide strike' available at: <https://www.theweek.in/news/india/2019/07/30/IMA-calls-countrywide-strike-on-July-31-against-passage-of-NMC-Bill-in-Lok-Sabha.html> (last accessed December 26, 2019).

¹³ News article on 'IMC calls Indian Medical Association Calls Strike on 8 August to protest against NMC Bill', available at: <https://www.livemint.com/news/india/indian-medical-association-calls-strike-on-8-august-to-protest-against-nmc-bill-1565006894181.html> (last accessed December 26, 2019).

¹⁴ News article on 'Doctors call of strike against National Medical Commission Bill', available at: <https://www.livemint.com/news/india/doctors-call-off-strike-against-national-medical-commission-bill-1564923174059.html> (last accessed December 26, 2019).

¹⁵ Public Notice dated October 18, 2019 by Ministry of Health and Family Welfare, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE30A (last accessed December 26, 2019).

¹⁶ Public Notice dated October 18, 2019 by Ministry of Health and Family Welfare, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTE4MQ== (last accessed December 26, 2019).

¹⁷ News article on Medical Device (Safety, Effectiveness and Innovation) Bill, 2019, available at: <https://timesofindia.indiatimes.com/business/india-business/draft-bill-proposes-up-to-rs-1-cr-fine-for-unsafe-medical-devices/articleshow/71828552.cms> (last accessed December 26, 2019).

¹⁸ Notification S.O. 5980(E) dated December 03, 2019.

- ¹⁹ Notification S.O. 775(E) dated February 08, 2019.
- ²⁰ Notification S.O. 4671(E) dated December 27, 2019.
- ²¹ Notification S.O. 4672(E) dated December 27, 2019.
- ²² Notification S.O. 3721 (E) dated October 16, 2019.
- ²³ Notice dated November 08, 2019 by Central Drugs Standard Control Organisation (Medical Devices Division), available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTlyMA (last accessed December 26, 2019).
- ²⁴ Notice dated November 13, 2019 by Central Drugs Standard Control Organisation (Medical Devices Division) **Clarifying the Definition of Vital Sign Monitoring Devices**, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTlyOQ (last accessed December 26, 2019).
- ²⁵ Notification S.O. 5980(E) dated December 03, 2019.
- ²⁶ Notification S.O. 775(E) dated February 08, 2019.
- ²⁷ Notification S.O. 4671(E) dated December 27, 2019.
- ²⁸ Notification S.O. 4672(E) dated December 27, 2019.
- ²⁹ Notice dated November 08, 2019 by Central Drugs Standard Control Organisation (Medical Devices Division), available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTlyMg (last accessed December 26, 2019).
- ³⁰ Rule 65 of Drugs and Cosmetics Rules, 1945.
- ³¹ Notification S.O. 775(E) dated February 08, 2019.
- ³² Notification S.O. 4672(E) dated December 27, 2019.
- ³³ Notification dated 16 October, 2019 by Ministry of Health and Welfare, available at: <http://egazette.nic.in/WriteReadData/2019/213288.pdf> (last accessed December 26, 2019).
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