Pharma & Healthcare Update

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REGULATORY YEARLY WRAP 2022: MEDICAL DEVICES IN INDIA

INTRODUCTION

The year of 2022 has seen continued efforts on part of the Government to streamline the regulation of medical devices in India. As one may be aware, since 2020, all medical devices are regulated in India and this is in the process of being implemented in a phase-wise manner. This year also saw the introduction of a new law- the Draft Drugs, Medical Devices and Cosmetics Bill, 2022 ("**Draft Bill**") which is proposed to replace the existing Drugs and Cosmetics Act, 1940 ("**D&C Act**"). Our detailed analysis of the Draft Bill is accessible here. The Draft Bill is a culmination of efforts of the Government to regulate medical devices independently from drugs in India. Inter alia, it proposes the creation of independent authorities and boards to take decisions on regulation of medical devices; separate provisions for licenses and violations; clinical investigations and marketing approvals for devices etc.

Another significant development this year was the inclusion of medical devices (such as intrauterine devices; condoms and coronary stents) in the National List of Essential Medicines which was subsequently incorporated into Schedule I of the Drugs (Prices Control) Order, 2013[1]. As a result, such devices will be regulated as scheduled devices and be subject to drug price caps.

In this update we have discussed the key developments in the second half of 2022 in the medical devices sector. In case you missed, do read our 2022 mid-year regulatory update covering developments from January to June in the medical device sector here.

REGULATOR ISSUES RISK CLASSIFICATION FOR MEDICAL DEVICES

By way of background, the ambit of the MDR was significantly expanded last year through a notification issued by the Ministry of Health and Family Welfare ("**Ministry**"). As a result of the said notification, all medical devices in India are regulated under the MDR from April 1, 2020. Consequently, the Central Drugs Standard Control Organization ("**CDSCO**") – India's apex drug and medical device regulator has classified all notified medical devices into classes A to D in ascending order of risk- low risk, low-moderate risk, moderate-high risk, and high risk respectively for the purpose of regulation. This classification is based upon the intended use of the device, risk associated with the use of the device, and the other parameters specified in the First Schedule of the MDR. The risk classification of a medical device determines the regulatory requirements for obtaining approvals and licenses in respect of the device, with manufacturers and importers of Class C and D devices having to comply with more rigorous documentation and inspection requirements than those of Class A and B devices. For this purpose, dynamic risk classification notifications have been issued by the CDSCO.

The CDSCO issued various notices in the second half of the year revising the classification list of medical devices:

1. *1. Risk classification for medical devices pertaining to rehabilitation*

On July 6, 2022[2], the Ministry issued a revised[3] classification notice for medical devices pertaining to rehabilitation. It notifies the risk classification for twenty-two new devices including prosthetics, powered lower extremity exoskeleton, truncal orthosis, congenital hip dislocation abduction splint, denis brown splint, arm sling, crutches, power knee, abdominal support, stocking/medical support among others.

1. *2. Risk classification for medical devices pertaining to surgical instruments*

On September 9, 2022[4], the Ministry issued a classification notification to risk classify medical devices pertaining to non-sterile, nonpowered, hand-held or hand-manipulated surgical Instruments for general use intended to be used in various general surgical procedures.This notification has notified the risk classification for four devices- Cutting and Dissecting Surgical instruments; Clamping and Occluding Surgical instruments; Retracting and Exposing Surgical instruments and; Grasping and Holding Surgical instruments.

1. *3. Risk classification for medical devices pertaining to oncology*

On October 11, 2022[5], the Ministry issued a revised[6] classification for medical devices pertaining to oncology. It notifies the risk classification for several new devices including notified devices including bladder instillation buffer solution, colonic cytology sampling set, electronic clinical breast examination system, antimicrobial post-surgical brassiere, brachytherapy radionuclide phantom test object, alternating electric field antimitotic cancer treatment system generator, alternating electric field antimitotic cancer treatment system among others.

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1. *4. Risk classification for medical devices pertaining to dental healthcare*

On October 10, 2022[7], the Ministry issued a revised notification for medical devices pertaining to dental healthcare. It notifies the risk classification for new devices including orthodontic appliance band, orthodontic elastomeric, orthopedic dental file and dental endodontic enlarger. This was the second revision made to the list this year after the first revision on June 3, 2022[8].

THE PRICING AUTHORITY RENEWS EXTENSION ORDER CAPPING TRADE MARGINS OF FIVE MEDICAL DEVICES

The National Pharmaceutical Pricing Authority ("**NPPA**") – the regulator responsible for controlling the prices of drugs and medical devices issued an order on July 29, 2022 extending the cap placed on the trade margins of five medical devices at 70% ("**Extension Order**") until December 31, 2022[9].

The NPPA previously had issued an order dated July 13, 2021 ("**First Order**")[10] which capped the trade margins of pulse oximeters, blood pressure monitoring machines, nebulizers, digital thermometers, and glucometers at 70% at first point of sale. The maximum retail price ("**MRP**") of these devices are calculated by adding a 70% trade margin to the price at which the distributors procure the devices from the manufacturers. Subsequently, the NPPA issued a second order dated January 31, 2022 ('**Second Order**")[11] to extend the operation of the First Order until July 31, 2022. The present Extension Order has been issued to further extend the operation of the First Order until December 31, 2022.

The present Extension Order was issued under Paragraph 19 of the DPCO. Paragraph 19 of the DPCO empowers the NPPA to cap prices of drugs and medical devices in public interest.

DRUG REGULATOR EXTENDS TIMELINE FOR LICENSE FOR MANUFACTURE AND IMPORT OF MEDICAL DEVICES

The CDSCO has issued a notice on September 30, 2022 announcing that the licensing regime for Class A and B medical devices will commence October 1, 2022 ("**Licensing Notice**")[12]. Manufacturers and importers of Class A and B devices who have applied for a license on or before September 30, 2022 may continue to manufacture or import the device up to March 30, 2023 or until the CDSCO or the respective State Licensing Authority takes a decision on the application for license.

As detailed in the above update, the ambit of medical device regulation was significantly broadened in 2020 by way of a notification issued by the Ministry. As a result of the said notification, all medical devices in India are regulated under the MDR from April 1, 2020. In an effort to regulate all newly notified medical devices in a phase wise manner, specific timelines were introduced for registration and licensing requirements. Accordingly, the compulsory licensing regime for Class A and B devices commenced from October 1, 2022 whereby all manufacturers and importers of these devices are required to compulsorily obtain a license or be held liable for non-compliance with the MDR. The present Licensing Notice provides a relaxation to manufacturers and importers of these devices who have applied for a license, however, are yet to receive a final decision from the CDSCO or the State Licensing Authority.

The Licensing Notice has been issued in light of the representations from stakeholders and associations requesting continuity of business. It was expected that the commencement of the compulsory licensing regime from October 1, 2022 may lead to disruptions in the supply of Class A and B devices.

NEW LICENSE REQUIREMENT FOR SALE OF MEDICAL DEVICES

The Ministry has notified the Medical Devices (Fifth Amendment) Rules, 2022 on September 30, 2022 ("**Amendment Rules**")[13] for introducing new registration requirements for authorized agents, sellers and retailers who want to import, sell, stock, exhibit or distribute medical devices including in- vitro diagnostic medical devices in India.

The Amendment Rules have incorporated Rules 87A, 87B, 87C and 87D to the MDR to provide for the new registration requirement for selling, stocking, exhibiting or offering for sale or distribution of medical device, conditions of the registration and the suspension and cancellation provisions. The conditions to be complied with by the registration certificate holder includes- registration certificate should be displayed at a prominent place in the premises visible to the public; the certificate holder shall provide adequate space and proper storage condition for storage of the medical devices; maintenance of requisite temperature and lighting as per requirements of such medical devices; and the medical devices shall be purchased only from importer or licensed manufacturer or registered or licensed entity etc.

Sellers and distributors who have not obtained a wholesale or a retail license under the Drugs and Cosmetics Rules, 1945 may apply for the registration certificate as per the provisions introduced by the Amendment Rules.

The Amendment Rules have been issued in an effort to regulate the medical device sellers. Previously, in certain states, the State Licensing Authorities required sellers and distributors of medical devices (including non-pharmacists) to obtain wholesale or retail drug licenses to sell, stock, exhibit or distribute medical devices.

RELAXATION FOR PUBLIC PROCUREMENT OF MEDICAL DEVICES

In 2020, the General Financial Rules, 2017 were amended to permit issue of global tenders for only INR 200 crores and above for procurement of products which are not domestically available. However, the Ministry of Finance and/or the Department of Expenditure were enabled to carve out an exemption from the requirements of prior approvals and the above amendment provided under exceptional circumstances.

Several members of the medical device industry made representations to the Ministry of Health and Family Welfare expressing the difficulties in obtaining an approval for floating global tender enquiries. Hence, in January 6 ,2022, an Office Memorandum[14] was issued by the Department of Expenditure, Ministry of Finance to exempt 128 medical devices from the requirement. Subsequently on June 21, 2022, a second Office Memorandum[15] was issued to broaden the list of exempted medical devices to now include 371 medical devices. Hence, the public procurement of these medical devices will now require fewer approvals.

NDA ANALYSIS AND CONCLUSION

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Since February 2020 - the time when all medical devices were brought under regulation, the Government has been focused on extending the applicability and implementing the MDR uniformly across all newly regulated devices. In 2022, we saw these efforts being culminated with the end of the first phase of this transition with all Class A and B devices falling into the compulsory licensing regime. To this extent, the relaxation in terms of enforcement timelines provided to manufacturers and importers of Class A and B devices is a welcome move for the industry.

The insertion of provisions in the MDR for issuing registration certificates to sell, stock, exhibit, or offer for sale or distribute a medical device enables the government to monitor the quantum, source and quality of products that are manufactured and imported into the country as all traders who used to import and sell medical devices will have to obtain the licence and be subjected to scrutiny. With the regulation of sales, it appears that the Government is seeking to ensure patient safety and implementation of good distribution practices in addition to quality manufacturing.

Overall, 2022 was relatively slower for the medical device industry in terms of regulatory movement and witnessed continued efforts to streamline the regulation of all newly notified devices. The revisions and issue of classification notices is a testament to this. Seperately, the relaxation in the public procurement norms for imported medical devices is also laudable since it signifies the efforts of the Government to recognise the gap and the industry-specific market constraints.

– Varsha Rajesh, Eshika Phadke, Darren Punnen & Dr. Milind Antani

You can direct your queries or comments to the authors

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[1] Ministry of Chemicals and Fertilizers Notification dated November 11, 2022, accessible here: https://pharmaceuticals.gov.in/sites/default/files/Drugs%20Prices%20Control%20Amendment%20Order%202022.pdf (last accessed on January 20, 2023).

[2] Ministry of Health and Family Welfare Notification dated July 6, 2022, accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc1Mg== (last accessed on January 20, 2023).

[3] Prior Classification Notice for Medical Devices Pertaining To Rehabilitation is accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Ng== (last accessed on January 20, 2023).

[4] Ministry of Health and Family Welfare Notification dated September 9, 2022, accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTAwOA== (last accessed on January 20, 2023).

[5] Ministry of Health and Family Welfare Notification dated October 11, 2022, accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTExOQ== (last accessed on January 20, 2023).

[6] Prior Classification Notice for Medical Devices Pertaining To Oncology is accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcyNg== (last accessed on January 20, 2023).

[7] Ministry of Health and Family Welfare Notification dated October 10, 2022, accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTExOA== (last accessed on January 20, 2023).

[8] Prior Classification Notice for Medical Devices Pertaining To Dental Healthcare is accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODU0Nw== (last accessed on January 20, 2023).

[9] National Pharmaceutical Pricing Authority Notification dated July 29, 2022, accessible here: https://www.nppaindia.nic.in/wp-content/uploads/2022/08/Gazett-Notification.pdf (last accessed on January 20, 2023).

[10] National Pharmaceutical Pricing Authority Notification dated July 13, 2021, accessible here: https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Notification-TMR-5-Medical-Devices.pdf (last accessed on January 20, 2023).

[11] National Pharmaceutical Pricing Authority Notification dated January 201, 2022, accessible here: https://www.nppaindia.nic.in/wp-content/uploads/2022/02/233003.pdf (last accessed on January 20, 2023).

[12] CDSCO Notification dated September 30, 2022, accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTA1Nw== (last accessed on January 20, 2023).

[13] Ministry Notification dated September 30, 2022 (Amendment Rules), accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTA4MA== (last accessed on January 20, 2023).

[14] Department of Expenditure, Ministry of Finance Office Memorandum dated January 6, 2022, accessible here: https://doe.gov.in/sites/default/files/Relaxation%20on%20Global%20Tender%20Enquiry%20%28GTE%29%20under%20Rule%20161%28iv%29%20of%20General%20Financial%20Rules%20%28GFRs%29%202017%20for%20procurement%20of%20Medical%20Devices_0.pdf (last accessed on January 20, 2023).

[15] Department of Expenditure, Ministry of Finance Office Memorandum dated June 21, 2022, accessible here: https://doe.gov.in/sites/default/files/Relaxation%20on%20Global%20Tender%20Enquiry%20%28GTE%29%20under%20Rule%20161%28iv%29%20of%20General%20 Financial%20Rules%20%28GFRs%29%202017-%20371%20Medical%20Devices.pdf (last accessed on January 20, 2023).
