Pharma & Healthcare Update

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REGULATORY YEARLY WRAP 2021: MEDICAL DEVICE IN INDIA

INTRODUCTION

This year has seen a continuation of the medical device regulator's efforts (following notifications issued in February 2020) to regulate all medical devices in India in a phase-wise manner. To this end, the regulator has issued the risk classification of hundreds of medical devices in 2021.

Medical devices were also on the price regulator's radar this year with the regulator adopting a trade margin rationalisation approach to cap the prices of pulse oximeters, blood pressure monitoring machines, nebulizers, digital thermometers, and glucometers.

We have discussed the major developments in the medical device industry in 2021 in this update. For the developments in the pharma, healthcare and digital health sector, please refer to our pharma, healthcare and digital health updates respectively.

RELAXATION OF LICENSING REQUIREMENTS FOR MEDICAL DEVICES BROUGHT UNDER REGULATION

The Central Drugs and Standard Control Organization ("**CDSCO**") – India's apex drug regulator – by way of three orders dated December 28, 2020[1], April 18, 2021[2] and November 03, 2021[3] ("**Medical Devices Compliance Order(s)**").

Through the Medical Device Compliance Order, the CDSCO initially relaxed the manufacturing and import license requirements for nebulizers, blood pressure monitoring devices, digital thermometers and glucometers. Subsequently, a similar relaxation was introduced for the manufacturers/ importers of implantable devices, CT scan equipment, MRI equipment, defibrillators, PET equipment, dialysis machine, X-ray machine, and bone marrow cell separator ("**Notified Devices**"). The Medical Devices Compliance Orders state that existing manufacturers/importers of the Notified Devices may continue their manufacture/import activities up to June 30, 2022 provided they have already made an application for the relevant license to the CDSCO before April 18, 2021.

Medical devices in India are regulated under the Medical Device Rules, 2017 ("**MDR**") which only applies to medical devices specifically notified by the Ministry of Health and Family Welfare ("**MoHFW**") as regulated medical devices. 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 undertake such activities pertaining to the notified medical devices.

The Medical Devices Compliance Orders relaxes the requirement for manufacturers and importers of Regulated Devices to have obtained a manufacturing and import license respectively prior to manufacturing/importing the Regulated Devices. It states that manufacturers and importers who have already been dealing in the Regulated Devices may continue to do so even if the manufacturing/import license has not been granted by the CDSCO provided the manufacturer/importer has made an application for the requisite license. The application for manufacturing/import license will be deemed as a valid license up to June 30, 2022 or until a decision is made on the application, whichever is earlier.

The Medical Devices Compliance Orders have been issued to ensure continuity of business for manufacturers and importers of the Regulated Devices who may have applied for a license but not received it prior to April 18, 2021 (cut-off date). The process of obtaining a manufacturing and import license includes multiple steps such as inspection of the manufacturing facilities and examination of documents. Given the large volume of applications from manufacturers/importers of Regulated Devices that were under review, representations were made to the CDSCO to extend the date on which the Regulated Devices will come under the purview of the MDR, based on which the Medical Devices Compliance Orders were issued.

From July 01, 2022 importers/manufacturers are required to operate with a license and print the license number on the label of the Regulated Device. All incomplete applications submitted before April 18, 2021 are required to be completed with necessary documents before March 31, 2022. The Order also requires the Licensing Authority to dispose of applications within three months of the date of receipt of the application.

DRUG PRICE REGULATOR CAPS 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 13, 2021,[4] capping the trade margins of five medical devices at 70% ("**Trade Margins Order**").

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The Trade Margins Order caps the trade margins of pulse oximeters, blood pressure monitoring machines, nebulizers, digital thermometers, and glucometers at 70%. The maximum retail price ("**MRP**") of these devices is now required to be calculated by adding a 70% trade margin to the price at which the distributors procure the devices from the manufacturers. The 'Price to Distributor' i.e. the price at which the distributor procures the medical device from the manufacturer is calculated by dividing the sum of net sales realized in respect of the medical devices from all channels by the total quantity of the product sold during the period April 01, 2020 to March 31, 2021.

The NPPA has stated that the intention behind issuing the Trade Margins Order was to ensure that these five devices are available to the public at affordable prices during the pandemic. The Order also notes that trade margins of up to 709% were observed in the market prior to the issuance of the Order. The Order is effective from July 20, 2021. All manufacturers, distributors, and retailers of pulse oximeters, blood pressure monitoring machines, nebulizers, digital thermometers, and glucometers are required to ensure that the prices of their products are in conformity with the order issued by the NPPA.

The Trade Margins Order has been issued under Paragraph 19 of the Drugs (Prices Control) Order, 2013 ("**DPCO**") – India's primary drug price control regulation. Paragraph 19 of the DPCO empowers the NPPA to cap prices of drugs and medical devices in public interest. The Order will remain in force until January 31, 2022 or until further orders, whichever is earlier.

RISK CLASSIFICATION FOR MEDICAL DEVICES INTRODUCED

The CDSCO has issued numerous notices between July 12, 2021 to September 27, 2021 specifying the risk classification for medical devices pertaining to anesthesiology,[5] In-vitro Diagnostic medical devices,[6] dermatology and plastic surgery,[7] interventional radiology,[8] physical support,[9] rehabilitation,[10] cardiology,[11] ENT,[12] respiratory,[13] radiotherapy,[14] ophthalmology,[15] dental,[16] obstetrics and gynecology,[17] urology,[18] pediatrics and neonatology[19], neurology[20], gastroenterology[21], oncology[22], nephrology and renal care[23], operation theatre[24], general hospital[25], pain management[26], personal protective equipment[27] and software[28] ("**Risk Classification Notices**").

The Risk Classification Notices categorize the medical devices into classes A to D in ascending order of risk. The devices are categorized as low risk, low-moderate risk, moderate-high risk, and high risk respectively. 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 MDR.

The ambit of the MDR was significantly expanded last year by way of a notification issued by MoHFW. As a result of the notification, all medical devices in India are regulated under the MDR from April 01, 2020. Subsequently, a draft Medical Device Risk Classification was released on September 17, 2020 ("**MDR Risk Classification Draft**"), which categorized medical devices into twenty-four categories and called for public comments on the classification. The Risk Classification Notices have finalized the risk classification for the twenty-four categories of medical devices enumerated above. They have also revised the list of medical devices contained in the MDR Risk Classification Draft in furtherance of which some products such as sanitary pads and spectacles will no longer be regulated under the MDR.

The risk classification of a medical device is important in terms of determining 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.

VOLUNTARY REGISTRATION PERIOD FOR MEDICAL DEVICES COMES TO AN END WITH CDSCO CONSIDERING RELAXATION IN ISO COMPLIANCE

The CDSCO issued a notice on September 28, 2021[29] announcing that the voluntary registration period for medical devices expired on September 30, 2021 ("**Voluntary Registration Notice**") and in furtherance of which the MoHFW notified Draft Medical Device Amendment Rules, 2021 ("**Draft Amendment Rules**") on October 12, 2021 which propose an extension for submission of ISO 13485 compliance for the purpose of registration of medical devices.[30]

Once legislated, the Draft Rules will relax the norms related to registration of medical devices by allowing more time to comply with ISO 13485 standard which is a pre-requisite for the registration. The Draft Rules propose to insert provisions in the MDR enabling the applicant to receive a provisional registration for its medical device by submitting an undertaking on or before the November 30, 2021 stating that an ISO 13485 compliance certificate will be obtained by May 31, 2022. If the applicant fails to obtain an ISO 13485 compliance certificate within this stipulated time, then the provisional registration shall be deemed to have been cancelled.

The CDSCO has previously brought all medical devices under the MDR by way of a notification dated February 11, 2020. The registration requirement is part of the process to regulate all medical devices in a phase wise manner. Compliance with this registration requirement was voluntary until October 01, 2021 subsequent to which all manufacturers and importers must register their medical devices in addition to obtaining licenses under the MDR. **the Draft Amendment Rules have been introduced as a result of industry representations received by the regulatory authority on lack of preparedness for the regulation of the medical devices.**

CEILING PRICE APPLICABLE TO ORTHOPAEDIC KNEE IMPLANTS EXTENDED

NPPA issued an order on September 10, 2021, extending the validity of ceiling prices previously fixed for orthopaedic knee implants up to September 15, 2022 ("**Knee Implant Order**").[31]

The Knee Implant Order has been issued in the light of series of developments to regulate the price of orthopaedic knee implants. Under the DPCO, affordability of essential drugs is ensured by way of price capping which is implemented either through inclusion of drugs in the NLEM or by notifying drugs under Paragraph 19 of the DPCO which empowers the NPPA to cap prices of 'drugs' including medical devices in public interest. The MoHFW through an Order dated October 06, 2005, notified orthopaedic implants to be 'drugs' within the ambit of the D&C Act and D&C Rules. Subsequently, ceiling prices of orthopaedic knee implants were fixed by the NPPA through an Order dated August 16, 2017[32] under Paragraph 19. The present Knee Implant Order extends the applicability of ceiling

April 01, 2025

Vaibhav Parikh, Partner, Nishith Desai Associate on Tech, M&A, and Ease of Doing Business
March 19, 2025

SIAC 2025 Rules: Key changes & Implications
February 18, 2025

prices previously fixed by the NPPA till September 15, 2022 or until further orders, whichever is earlier.

The intent of the NPPA in regulating price of orthopaedic knee implants is to ensure its availability to patients at a reasonable price by capping high trade margins of manufacturers and importers.

DRAFT AMENDMENT RULES PROPOSED TO EASE IMPORT OF MEDICAL DEVICES FROM UNITED KINGDOM

The MoHFW has notified Draft Medical Device Amendment Rules, 2021 on December 10, 2021 ("**Draft Import Rules**") to amend the MDR in order to ease the import of medical devices into India from United Kingdom.[33]

The Draft Import Rules propose that if a free sale certificate has already been issued in respect of any medical device by the national regulatory authority or other competent authority in the United Kingdom, then a licence shall be granted as per the provisions of MDR, without carrying out clinical investigation. The draft rules will be taken into consideration on or after forty-five days from the date of its publication; and after objections and suggestions have been received with respect to the proposed amendment.

Under the MDR, an exemption from conduct of clinical investigation has been provided for medical devices imported from Australia, Canada, Japan, European Union Countries and the United States of America. The proposed amendment proposes to add United Kingdom to this existing list of jurisdictions for the purpose of relaxation of import requirements.

CONCLUSION

While a number of developments have been introduced in regulation of various medical devices in India, the changes brought in further clarify and develop upon last year's key development of bringing all medical devices in India under the ambit of MDR. The classifications introduced for all newly notified medical devices is a significant headway in the process of regulating all medical devices within the scope of MDR. Further, this year also saw the adoption of trade margin rationalization approach to regulate the pricing of medical devices on numerous occasions and signifies a shift towards price regulation of medical devices in addition to drugs.

In the light of this regulatory approach, various representations from the industry have expressed the necessity to frame a separate comprehensive medical device legislation. It is hoped that a comprehensive law will help the medical devices industry grow better and innovate faster. Nonetheless, it remains to be seen how the regulation of medical device in India will take shape in the wake of the changes introduced in the past year and representations being made by the industry.

– Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr. Milind Antani

You can direct your queries or comments to the authors

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[1] CDSCO order dated December 28, 2020, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc5Mg==

[2] Order issued by Central Drugs Standard Control Organization dated April 18 2021, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzE0Nw==

[3] CDSCO order dated November 03, 2021, available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Nzg0Mw==

[4] Order Issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated July 13 2021, available at: https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Notification-TMR-5-Medical-Devices.pdf

[5] Notice issued by Central Drugs Standard Control Organization pertaining to anesthesiology dated July 12, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQyNg==

[6] Notice issued by Central Drugs Standard Control Organization pertaining to IVDs dated July 23, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Mg==

[7] Notice issued by Central Drugs Standard Control Organization pertaining to dermatology and plastic surgery dated July 26, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Mw==

[8] Notice issued by Central Drugs Standard Control Organization pertaining to interventional radiology dated July 26, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1NA==

[9] Notice issued by Central Drugs Standard Control Organization pertaining to physical support dated July 26, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1NQ==

[10] Notice issued by Central Drugs Standard Control Organization pertaining to rehabilitation dated July 26, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ1Ng==

[11] Notice issued by Central Drugs Standard Control Organization pertaining to cardiovascular medical devices dated July 26, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzQ5Mg==

[12] Notice issued by Central Drugs Standard Control organization on ENT dated August 06, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2Nw==

[13] Notice issued by Central Drugs Standard Control Organization pertaining to respiratory medical devices dated August 06, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2NQ==

[14] Notice issued by Central Drugs Standard Control Organization pertaining to radiotherapy dated August 06, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU2Ng==

[15] Notice issued by Central Drugs Standard Control Organization pertaining to ophthalmology dated August 09, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU3MA==

[16] Notice issued by Central Drugs Standard Control Organization pertaining to dental dated August 23, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5MQ==

[17] Notice issued by Central Drugs Standard Control Organization pertaining to obstetrical and gynaecology dated August 23, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5NA==

[18] Notice issued by Central Drugs Standard Control Organization pertaining to urology dated August 23, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5Mg==

[19] Notice issued by Central Drugs Standard Control Organization pertaining to paediatrics and neonatology dated August 23, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzU5Mw==

[20] Notice issued by Central Drugs Standard Control Organization pertaining to neurology dated September 27, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcyNQ==

[21] Notice issued by Central Drugs Standard Control Organization pertaining to gasteroentology dated September 27, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcyNw==

[22] Notice issued by Central Drugs Standard Control Organization pertaining to oncology dated September 27, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcyNg==

[23] Notice issued by Central Drugs Standard Control Organization pertaining to nephrology and renal care dated September 13, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2Mw==

[24] Notice issued by Central Drugs Standard Control Organization pertaining to operation theatre dated September 13, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2Mg==

[25] Notice issued by Central Drugs Standard Control Organization pertaining to general hospital dated September 13, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2NA==

[26] Notice issued by Central Drugs Standard Control Organization pertaining to pain management dated September 13, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcyOA==

[27] Notice issued by Central Drugs Standard Control Organization pertaining to personal protective equipment dated September 13, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY2MA==

[28] Notice issued by Central Drugs Standard Control Organization pertaining to software dated September 13, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzY1OQ==

[29] Notice issued by Central Drugs Standard Control Organization pertaining to extension of voluntary registration of medical devices September 28, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzczMA==

[30] Draft Amendment Rules dated October 12, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzgyMQ==

[31] Order Issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated September 10, 2021, available at: https://www.nppaindia.nic.in/wp-content/uploads/2021/09/Gazette-Notification-3670-E_Knee-Implants_10092021.pdf

[32] Order Issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated August 16, 2017, available at: http://www.nppaindia.nic.in/wp-content/uploads/2018/08/NPPA-has-fixed-Ceiling-prices-of-orthopedic-implants-knee-replacements-under-para-19-of-Drugs-prices-control-order-DPCO-2013-1.pdf

[33] Draft Amendment Rules on import of medical devices from United Kingdom dated December 10, 2021 available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Nzk3MQ==