Pharma & Healthcare Update

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MID-YEAR REGULATORY UPDATE 2022: MEDICAL DEVICE INDUSTRY IN INDIA

INTRODUCTION

In 2020, the Indian Government notified all medical devices to be 'drugs' in India. As the medical device industry and the regulators continue to navigate the challenges posed by this step, numerous developments have been introduced since the begin of this year in efforts of facilitating this shift in regulation. Additionally, progress in regulations in allied industries such as e-waste management and machine to machine ("**M2M**") regulation also has immense impact on the medical device industry.

Some of the key developments that have taken place in the first half of 2022 in the medical device sector are captured below:

RELAXATION FOR COMPLIANCE WITH MEDICAL DEVICES REGISTRATION REQUIREMENT IN INDIA COMES TO AN END

The Ministry of Health and Family Welfare ("**Ministry**") had notified the Medical Device Amendment Rules, 2022 on January 18, 2022 to extend submission of ISO 13485 compliance for the purpose of registration of medical devices ("**Amendment Rules**").[1] ISO 13485 standard is an internationally recognised quality standard in the medical device industry that comprises of strict standards for quality management systems.

The Amendment Rules inserted provisions in the Medical Device Rules, 2017 ("**MDR**") enabling the applicant to receive a provisional registration for its medical device by submitting an undertaking on or before February 28, 2022 stating that an ISO 13485 compliance certificate will be obtained by May 31, 2022. Based on such undertaking, the applicant would receive a provisional registration number which can be used for the purposes of the Act. If the applicant fails to obtain an ISO 13485 compliance certificate within the stipulated time, then the provisional registration shall be deemed to have been cancelled.

The registration requirement is a part of the process to regulate all medical devices in a phase wise manner.[2] Previously, upon the expiry of the voluntary registration period for Class A and B medical devices on October 1, 2021 the Central Drugs Standard Control Organization ("**CDSCO**") had considered an extension of the voluntary registration period based on the representation from the industry. Subsequently, the draft Rules proposing a relaxation for obtaining ISO 13485 were introduced on October 12, 2021.

This relaxation granted under the Amendment Rules to obtain ISO 13485 Compliance by May 31, 2022 has come to an end, without any further directions or extensions by the CDSCO in this regard.

MEDICAL DEVICES RULES AMENDED TO EASE IMPORT OF MEDICAL DEVICES FROM UNITED KINGDOM

The Ministry has notified the Medical Devices (Second Amendment) Rules, 2022 on March 04, 2022 ("**Second Amendment**") to amend the in order to ease the import of medical devices into India from United Kingdom.[3]

The Second Amendment lays down 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.

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 Third Amendment extends the exemption to medical devices imported from United Kingdom for the purpose of relaxation of import requirements.

PROVISIONS FOR SUSPENSION AND CANCELLATION OF IMPORT LICENSE INTRODUCED

The Ministry has notified the Medical Devices (Third Amendment) Rules, 2022[4] ("**Third Amendment**") to provide for the cancellation or suspension of import license has been included in the Medical Devices comply with MDR. The Second Amendment stipulates that where a manufacturer or licensee fails to comply with any conditions of an import license, or the provisions of the applicable law, the Central Licensing Authority ("**CLA**") may cancel or suspend the license upon giving an opportunity to the party to show cause.

The suspension of the import license may be done either wholly or in part with respect to any of the medical devices to which the license relates or the CLA may order the licensee to stop the import/sale/distribution of the said medical device. It may also require the licensee to destruct any stock of such medical device in respect of which the licensee has failed to be in compliance of the applicable law.

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The Third Amendment has been introduced more than five years after the enactment of the MDR and also provides the aggrieved party with the right to appeal the order of the CLA to the Central Government.

LIST OF BIS STANDARDS FOR MEDICAL DEVICES PUBLISHED

The Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers has issued a Public Notice on February 1, 2022[5] ("**BIS Notice**") which provides the list of Bureau of Indian Standards (BIS) for medical devices. Rule 7 of MDR, medical devices are required to comply to the standards set by the BIS.

All importers and manufacturers of notified medical devices in India should align their products with the BIS standards prescribed as per the BIS Notice.

DRUG PRICE REGULATOR EXTENDS CAP ON TRADE MARGINS OF FIVE MEDICAL DEVICES

The National Pharmaceutical Pricing Authority ("**NPPA**") has issued an order under Paragraph 19 of the Drugs (Prices Control) Order, 2013 ("**DPCO**") on January 31, 2022 extending the cap placed on the trade margins of five medical devices- Pulse Oximeter, Blood Pressure Monitoring Machine, Digital Thermometer and Glucometer. The trade margins of these devices are capped at 70% ("**Extension Order**") at the first point of sale until July 31, 2022.[6]

Previously on July 13, 2021[7], the trade margins of the above-mentioned devices were capped. The present Extension Order extends the validity of the said order by six months.

GOVERNMENT RELAXES PROCUREMENT OF SPECIFIED MEDICAL DEVICES

The national procurement policy is determined through General Financial Rules, 2017 and various notifications issued thereunder from time to time. Accordingly, the Central Government and its instrumentalities are prohibited from inviting bids from global suppliers if the value of the tender is less than INR 2 crores.

However, the Government has now relaxed these rules through an Office Memorandum issued on January 6 2022,[8] to permit the procurement of 128 medical devices and equipment (including VATS and minimally invasive surgery instrument set, Fully Automated IHC Stainer, Radio surgery equipment, Electro Physiology System, NAT Analyzer, Video Endoscopy Systems etc.), for which it found that there were no domestic manufacturers available. This relaxation is valid up to March 31, 2023.

Meanwhile, the Ministry has been instructed to review the domestic availability of these medical devices keeping in the mind the Production Linked Incentive (PLI) scheme etc. and other relevant factors.

EXPIRED MEDICAL DEVICES PROPOSED TO BE TREATED AS E-WASTE FOR DISPOSAL PURPOSES

The Ministry of Environment, Forest and Climate change notified the draft E-Waste (Management) Rules on May 19, 2022 which upon notification will replace the existing E-Waste Management Rules, 2016[9] ("**Revised E-Waste Rules**"). The Revised E-waste Rules brings medical devices (with the exception of all implanted and infected products) within its ambit. As a result, all businesses involved in the manufacture, production, recycling, refurbishment, importers, etc. within the ambit of applicability of the Revised E-waste Rules, requiring registration for continuing business activities. The focus of Revised E-waste Rules is to encourage the stakeholders to recycle e-waste and to reduce use of hazardous substances by introducing the concept of 'extended producer's responsibility'. The extended producer's responsibility places a recycling target on the producer of electrical or electronic equipment to ensure environmentally sound e-waste management.

Additionally, the implanted or infected medical devices may be treated as biomedical or hazardous waste upon use/expiry, although more clarity regarding the same is yet to be provided by the Government.

DEVELOPMENTS IN MACHINE TO MACHINE LAWS

M2M communications covers any technology that enables networked devices or machines to exchange information and perform actions without or with minimal human intervention. In the recent past, M2M technology in the medical device industry has been gaining momentum given the surge shift in consumer preferences towards point of care diagnostics and treatment. Emerging trends such healthcare sensors, remote monitoring devices, point of care devices, precision medicine, nanomedicine etc. are some examples of M2M in healthcare.

In an effort to regulate the M2M industry, the Department of Telecommunications ("**DoT**") has amended the Unified License ("**UL**").[10] The amended UL now contains a new service authorisation for M2M. Accordingly, entities licensed by the DoT (such as internet service providers, telecom service providers etc.) are permitted to provide connectivity and related services to M2M service providers i.e. entities that collect and analyse data from M2M devices and platforms for a commercial purpose. The amended UL also imposes certain data-related obligations on licensed entities such as maintaining records of M2M devices, make, model, registration number etc. of the M2M devices, physical custodian's (end user) name and address etc.

The DoT has also published the Guidelines for Registration Process of M2M Service Providers[11] ("**M2M Guidelines**") which build upon the amended provisions of the UL. Specifically, the M2M Guidelines introduces registration requirements for M2M service providers and the obligate the M2M service providers to furnish data on custodians of the M2M device (end user) to the licensed entity on request. Further, all devices sold in India which have SIM inside them have to carry a declaration, "*This device is having SIM inside. e. At the time of re-sale/ loss/ transfer of this device, change of ownership details shall be shared with respective M2M Service provider/ Authorized Telecom Licensee.*"

All medical device importers and manufacturers dealing in medical devices operating on M2M technologies may be impacted and should assess compliance. Specifically, companies which sell medical devices that have an embedded SIM card or e-SIM may be regulated as a M2M service provider in India.

CONCLUSION

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Active regulation of the medical devices sector is underway with numerous compliance requirements being introduced with the phased-registration process of all devices. An interesting development seen in the first half of 2022 with regard to the medical devices industry is the proposed amendment to the Revised E-waste Rules which seek to treat expired medical devices as e-waste.

The passage of M2M regulation in India unravels the intent of the Government to regulate emerging technologies. Going forward, potentially healthcare applications involving emerging technologies would be cross-regulated and industry players will need to keep in mind these allied laws and developments to ensure compliance.

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You can direct your queries or comments to the authors

[1] Accessible at: https://egazette.nic.in/WriteReadData/2022/232729.pdf (Last accessed on June 27, 2022).

[2] Accessible at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzczMA== (Last accessed on June 27, 2022).

[3] Accessible at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODIyOA== (Last accessed on June 27, 2022).

[4] Notification issued by Ministry dated May 18, 2022. Accessible at:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODQ1OQ==(Last accessed on June 27, 2022).

[5] Accessible at: https://pharmaceuticals.gov.in/sites/default/files/Public%20Notice_BIS%20Standards.pdf (Last accessed on June 27, 2022).

[6] Accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2022/02/233003.pdf (Last accessed on June 27, 2022).

[7] Accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Notification-TMR-5-Medical-Devices.pdf (Last accessed on June 27, 2022).

[8] Accessible at: https://pharmaceuticals.gov.in/sites/default/files/OM%20No%204%201%202021%20dated%2006-01-2022.pdf (Last accessed on June 27, 2022).

[9] Accessible at: https://egazette.nic.in/WriteReadData/2022/235903.pdf (Last accessed on June 06, 2022)

[10] Accessible at: https://dot.gov.in/sites/default/files/UL%20VNO%20with%20M2M%20without%20INSAT%20MSSR%2017012022.pdf?download=1 (Last accessed on June 27, 2022).

[11] Accessible at: https://dot.gov.in/sites/default/files/M2MSP%20Guidelines%20.pdf?download=1 (Last accessed on June 27, 2022).