

Pharma & Healthcare Update

January 29, 2024

YEAR END REGULATORY UPDATE 2023: PHARMACEUTICAL AND MEDICAL DEVICES SECTOR IN INDIA

The most significant developments in the pharmaceutical and medical devices sector in the last quarter of 2023 are:

- Notification of revised Good Manufacturing Practices under the Drugs Rules.
- Amendment of the penalty provisions under the Legal Metrology Act, 2009.
- Release of the Approach Paper on the Draft National Pharmaceuticals Policy 2023 for encouraging innovation and research in the sector.
- Release of Policy Statement on the Ethical Conduct of Controlled Human Infection Studies.
- Transition from a registration to a compulsory licensing regime for Class C and D medical devices.
- Risk classification for in Vitro Diagnostic medical devices updated by the regulator.

INTRODUCTION

The landscape of the pharmaceutical and medical devices sector has continued to have a steady growth in the last quarter of 2023. The focus continues to be on encouraging domestic research and development and innovation in the sectors.

The most significant development in the final quarter of 2023 was the notification of the Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products to replace the existing Good Manufacturing Practices specified in Schedule M to the Drugs Rules, 1945 ("**Drugs Rules**"). Other notable developments include the enhancement of penalty provisions under the Legal Metrology Act, the release of the Approach Paper on the Draft National Pharmaceuticals Policy 2023 by the Department of Pharmaceuticals ("**DoP**") for stakeholder comments, and the Policy Statement on the Ethical Conduct of Controlled Human Infection Studies released by the Indian Council of Medical Research ("**ICMR**").

With respect to the developments in the medical devices industry, the transition from mandatory registration to a licensing regime for Class C and D medical devices stands out as a significant move by the Central Drugs Standards Control Organisation ("**CDSCO**"). This addresses concerns of industry stakeholders, ensuring business continuity. The clarity provided on deemed validity for license applications mitigates potential disruptions, offering a crucial extension to existing manufacturers and importers of medical devices. The CDSCO has also released an updated list of risk classification for In Vitro Diagnostic ("**IVD**") medical devices to guide the applicants seeking to obtain licenses to import or manufacture medical devices on the compliances to be undertaken.

In this update, we have discussed the key developments in the last quarter of 2023 in the Pharmaceutical and Medical Devices Sector.

REVISED GOOD MANUFACTURING PRACTICES STANDARDS RELEASED

The Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products¹ ("**GMP**") have been notified by the Ministry of Health and Family Welfare ("**MoHFW**") in the official gazette to replace the existing Good Manufacturing Practices provided in Schedule M of the Drugs Rules.

The GMP was brought under scrutiny amidst various risk-based inspections carried out by the regulatory authorities and the concerns raised over the existing quality management mechanisms being followed at various drug manufacturing plants in the country. Subsequently, the draft of the proposed revised GMP was published in late 2018 for inviting objections and suggestions from persons likely to be affected thereby and to bring Schedule M in consonance with international GMP standards introduced by the World Health Organization ("**WHO-GMP**").

The GMP comprise of mandatory requirements and standards to ensure quality of products, maintenance of facilities, personnel, storage and transport of material, etc. The GMP introduces a pharmaceutical quality system including a quality risk management system, self-inspection requirement, quality audit team, specific requirements for manufacture of pharmaceutical products containing hazardous substances, etc. The small and large manufacturers are required to comply with the revised GMP and obtain the WHO-GMP certifications within the timelines that have been prescribed.

PENALTY PROVISIONS UNDER THE LEGAL METROLOGY ACT ENHANCED

The Ministry of Law and Justice notified the Jan Vishwas (Amendment of Provisions) Act, 2023 on August 11, 2023

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("Jan Vishwas Act").² The Jan Vishwas Act amended various provisions pertaining to fines and penalties under the Legal Metrology Act, 2009 ("LM Act"). The amended provisions have been brought into effect upon publication of the Legal Metrology (Packaged Commodities)(Amendment) Rules, 2023 ("LM Amendment Rules") in the official gazette on August 31, 2023.³

The LM Act establishes standards of weights and measures to regulate trade and commerce in weights, measures and other goods which are sold or distributed by weight, measure or number. The LM Act establishes a uniform metric system based on the international system of units and prescribes declarations to be made on pre-packaged commodities meant for manufacture, packing, selling, importing, distributing etc. The LM Act also prescribes penalties for violation of the provisions of the act such as by use of non-standard weight or measure, manufacture or sale of non-standard weight or measure, alteration or tampering of any weight or measure, etc.

While imprisonment as a penalty has been done away with under the amended LM Act, the fine levied for the violation of the provisions of the LM Act have been enhanced by the Jan Vishwas Act significantly to ensure strict compliance.

DRAFT NATIONAL PHARMACEUTICALS POLICY 2023 RELEASED FOR STAKEHOLDER CONSULTATION

The DoP, under the Ministry of Chemicals and Fertilizers, released the Approach paper on Draft National Pharmaceuticals Policy 2023⁴ ("Approach Paper") on October 31, 2023, inviting suggestions from the stakeholders for the prospective National Pharmaceutical Policy, 2023 ("Proposed Policy"). The Proposed Policy seeks to serve as a comprehensive framework to address the challenges faced by the Indian pharmaceutical industries and to provide definitive policy interventions to enhance the collective ecosystem.

The Proposed Policy seeks to establish a collaborative framework to align India's regulatory standards with global best practices, by encouraging new technologies, harmonizing domestic regulatory practices, encouraging international collaboration, initiating capacity building, etc. to enhance global competence of the domestic manufacturing sector.

The Approach Paper provides an insight into the structure of the Proposed Policy and seeks stakeholder inputs on various policy interventions proposed to be addressed by the policy, which include:

- Support adoption of new pharmaceutical technologies through onboarding of stakeholders in the sector on the Ayushman Bharat Digital Mission ("ABDM") ecosystem to provide a platform for collaboration and exchange of knowledge and innovations.
- Encourage efficient coordination among various regulatory bodies within the sectors such as the CDSCO and DCGI and take continued efforts in promoting the use of its centralized portals- SUGAM and ONDLS to further the goal of regulatory harmonization.
- Streamlining of the licensing system to prevent duplication of efforts through a Single Window Clearance System for Licensing of Pharmaceuticals, incorporating stakeholders such as CDSCO, DCGI etc.
- Implementing a mandatory track and trace mechanism to ensure high-quality pharmaceuticals reach end-users, enhancing transparency and trust in the pharmaceutical supply chain.
- Create qualifications aligned with the Skill India Program to train professionals across the pharmaceutical value chain, to address the existing challenge of skill gaps in the sector.
- Strengthening the role of the Indian Patent Office in protecting intellectual property rights in the sector.

The DoP seeks to advance health equity and accessibility in the country by enhancing regulatory efficiency and to attract investments in the sector. There is ample scope for change to be reflected in the proposed policy by way of incentivizing adoption of the policy initiatives, highlighting the significance of the ABDM infrastructure, encouraging regulatory submissions to be made in line with international standards and encouraging the industry to engage with educational institutions to support the objective of skill building to aid the pharmaceutical industry.

The Approach Paper provides insight into the Proposed Policy and the importance being placed on collaborative efforts to be undertaken by the industry players to meet the broader initiatives of universal healthcare access, innovation-driven economic growth, and sustainable development. The final draft of the Proposed Policy is awaited which reflects the changes that have been proposed by the industry stakeholders.

POLICY STATEMENT FOR CONTROLLED HUMAN INFECTION STUDIES RELEASED BY ICMR

The Indian Council of Medical Research ("ICMR") has developed the Policy Statement on the Ethical Conduct of Controlled Human Infection Studies ("CHIS") in India in the second half of 2023.⁵ While the World Health Organisation ("WHO") has undertaken to guide developed as well as developing nations in carrying out CHIS studies, such studies are yet to begin in India.

The CHIS document seeks to guide researchers, sponsors, institutions and other stakeholders involved in reviewing or conducting CHIS. The unique research design of introducing infection in the human body to study diseases and treatment modalities warrants additional safeguards in order to ensure the protection of research participants. The CHIS document provides factors to conduct responsible research, ethical considerations for CHIS study as well as ethics committee considerations to guide the CHIS research.

The research model of intentionally exposing healthy individuals to pathogens in a controlled environment warrants for strict regulation given the nature of risk the individual is being exposed to. However, ICMR has recognized the potential benefits of undertaking such a study to enable detailed research for certain diseases like malaria, dengue fever, cholera, etc. to accelerate the pace of medical interventions as well as to make the treatment cost effective and efficient.

The independent ethics committee is empowered to monitor the CHIS studies and ensure ethical conduct of such research to address ethical concerns associated with CHIS, such as inducement and compensation, risk of disease transmission to third parties beyond the research participants, disproportionately involving patients from low-income communities, etc.

The ICMR's initiative emphasizes the importance of balancing scientific advancements with ethical considerations to ensure the responsible and ethical conduct of CHIS in India.

DRUG REGULATOR RELAXES COMPLIANCE WITH LICENSE REQUIREMENT FOR CLASS C & D MEDICAL DEVICES

Marking the conclusion of the class-wise implementation of the licensing requirements under the Medical Devices Rules, 2017, all Class C and D medical devices have been brought under the licensing regime effective October 1, 2023. Following representations from various stakeholders and associations and in order to minimise disruptions in supply of these lifesaving devices, the CDSCO issued a circular⁶ and clarification⁷ on October 12, 2023 (collectively, “**CDSCO Clarification**”).

The CDSCO Clarification provides a relaxation to manufacturers and importers of Class C and D devices who have applied for a license prior to September 30, 2023 but are yet to receive a final decision from the CDSCO or the State Licensing Authority, as applicable. Such manufacturers or importers may continue to manufacture or import the devices up to April 12, 2024 or until the CDSCO takes a decision on the application for the license.

The CDSCO Clarification further provides that only manufacturers and importers who have applied for a license prior to September 30, 2023 for Class C and D medical devices are eligible to continue to manufacture or import the devices up to April 12, 2024 in accordance with the CDSCO Clarification.

RISK CLASSIFICATION OF IVD MEDICAL DEVICES UPDATED BY CDSCO

The ambit of MDR was significantly broadened in 2020 by way of a notification issued by MoHFW. As a result of the said notification, all medical devices in India are regulated under the MDR from April 1, 2020. Consequently, the CDSCO 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. The risk classification notified by CDSCO 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 respect to the import, manufacture, clinical investigation, clinical performance evaluation, sale and distribution. For this purpose, dynamic risk classification notifications have been issued by the CDSCO.

The CDSCO issued a notice dated October 25, 2023,⁸ to update the risk classification for In-vitro Diagnostic Medical Devices (“**IVDs**”). The update encompasses various aspects, including intended use, associated risk, additional IVD categories, and other parameters and covers general intended use against each device for guidance to applicants while making applications for import or manufacture of the devices. Key updates to the IVD classification lists include changes to Annexure A for IVD analyzers, which now contains 72 total medical devices, and Annexure B for IVD instruments, now comprising 29 medical devices, all classified as Class A. Additionally, two new lists, Annexure D for IVD Specimen Receptacles and Annexure E for products falling under sub-rule (2) rule 4 of the MDR (e.g., COVID, DNA, and mRNA Extraction Kits), have been introduced. Despite these changes, Annexure C, covering IVD software, remains unchanged.

The updated list of risk classification for IVDs will assist applicants to assess the nature of compliances to be undertaken while submitting application for the import or manufacture of the medical devices in India under the MDR. The list released by CDSCO is dynamic and subject to revision from time to time given the evolving nature of medical devices in the country with fast paced adoption of technology in the medical devices sector.

CONCLUSION

The pharmaceutical and medical devices sectors are at the cusp of a transformative era, guided by strategic regulatory interventions. The collaborative policymaking approach, ethical considerations in research, digital transformation, and regulatory streamlining for medical devices collectively indicate an industry poised for innovation and growth. As we anticipate the new year, these regulatory milestones set the stage for a dynamic and progressive future in these sectors.

The adoption and implementation of new policies to encourage research and digital transformation of the regulatory landscape remains to be witnessed in the new year.

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You can direct your queries or comments to the authors.

¹ Accessible here: [https://egazette.gov.in/\(S\(tvaj4dhsli4rh0pqqcn3ou\)\)/ViewPDF.aspx](https://egazette.gov.in/(S(tvaj4dhsli4rh0pqqcn3ou))/ViewPDF.aspx)

² Accessible here: <https://egazette.gov.in/WriteReadData/2023/248047.pdf>

³ Accessible here: [https://egazette.gov.in/\(S\(h02ktwczsevmfoko4n3ruj\)\)/ViewPDF.aspx](https://egazette.gov.in/(S(h02ktwczsevmfoko4n3ruj))/ViewPDF.aspx)

⁴ Approach Paper on Draft National Pharmaceuticals Policy 2023 for stakeholder consultation, accessible at: <https://pharmaceuticals.gov.in/sites/default/files/31.10.23%20Draft%20National%20Pharmaceuticals%20Policy.pdf>

⁵ Accessible here: ICMR policy statement for Ethical Conduct of Controlled human Infection Studies in India 2023 - https://main.icmr.nic.in/sites/default/files/upload_documents/ICMR_CHIS%20_Policy_Document.pdf

⁶ Accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA1NzI=

⁷ Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA1NzU=

⁸ Accessible here: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA1ODc=

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