Pharma & Healthcare Update

January 22, 2025

REGULATORY WRAP 2024: MEDICAL DEVICES

The most significant developments from 2024 for the medical devices industry in India are:

- The release of a separate code to govern marketing and promotion of medical devices.
- Government strengthens Materiovigilance Programme of India.
- The Bureau of Indian Standards is in the process of developing standards for critical medical devices and assistive technologies.

INTRODUCTION

The past year has seen significant developments in the medical device industry, driven by various regulatory and strategic initiatives aimed at enhancing safety, transparency, and global competitiveness.

Notably the Department of Pharmaceuticals introduced a Uniform Code for Marketing Practices in Medical Devices, which provides clear guidelines for the operational mechanisms and execution of marketing activities within the sector. The Materiovigilance Programme of India has been launched by the regulator to monitor, record and analyse the root cause of adverse events or risks associated with the use of medical devices and in vitro devices in India. To further strengthen the sector, the Bureau of Indian Standards announced the development of additional standards for critical medical devices and assistive technologies. The Union Minister of Chemicals and Fertilizers also unveiled a strategic scheme with a total outlay of Rs. 500 crores, aimed at providing substantial support to the medical device industry in India. The Central Drugs Standard Control Organization became an Affiliate Member of the International Medical Device Regulators Forum, underscoring its commitment to fostering growth, innovation, and aligning the domestic industry with global standards.

These initiatives reflect the ongoing efforts to enhance the medical device sector in India, improving safety, compliance, and global competitiveness. The key developments of 2024 highlighting the industry's focus on aligning with international best practices while fostering continued growth are discussed in the update below:

SEPARATE MARKETING CODE FOR MEDICAL DEVICES RELEASED

On September 6, 2024, the Department of Pharmaceuticals ("**DoP**") issued the Uniform Code for Marketing Practices in Medical Devices ("**UCMPMD**")[1] to govern the marketing and promotional activities of the medical device industry (our detailed hotline providing our analysis of the UCMPMD may be accessed here). Previously, medical devices companies were also bound by the Uniform Code for Pharmaceutical Marketing Practices ("**UCPMP**"), which resulted in operational challenges while executing marketing activities.

The UCMPMD contains provisions which are more conducive to the practical requirements of medical devices companies. The UCMPMD broadens the scope of medical representatives to include not only sales representatives but also medical affairs professionals, marketing specialists, and clinical experts. The guidelines allow for the provision of evaluation and demonstration samples to Healthcare Professionals ("**HCPs**"), subject to strict record-keeping requirements to ensure traceability. The UCMPMD also distinguishes between evaluation samples, which are intended for hands-on experience with medical devices, and demonstration products, which are used by medical representatives to explain the device's features to HCPs. Most significantly, the UCPMPD permits overseas clinical training under specific conditions, requiring prior approval from the DoP.

The UCMPMD provides clearer guidelines for the medical device sector, marking a significant step towards a distinct regulatory framework. It emphasizes the ethical engagement of medical device companies with HCPs, prioritizing education and patient welfare while ensuring that promotional practices do not influence clinical decisions.

REGULATOR ATTEMPS TO STRENGHTEN MATERIOVIGILANCE PROGRAMME OF INDIA

The Materiovigilance Programme of India ("**MvPI**") was launched by the Ministry of Health and Family Welfare with the objective of monitoring, recording and analysing the root cause of adverse events or risks associated with the use of medical devices and in vitro devices that are being marketed in India. At present, there is no statutory requirement that healthcare professionals or companies report adverse events.

However, in a bid to strengthen the MvPI, the Drugs Controller General of India issued a circular[2] requesting healthcare professionals, general public, users and patients to actively report any adverse events and serious adverse events to the Indian Pharmacopoeia Commission ("**IPC**") – the designated authority for coordination of the MvPI.

Research Papers

New Age of Franchising
June 20, 2025

Life Sciences 2025
June 11, 2025

The Tour d'Horizon of Data Law Implications of Digital Twins
May 29, 2025

Research Articles

2025 Watchlist: Life Sciences Sector India
April 04, 2025

Re-Evaluating Press Note 3 Of 2020: Should India's Land Borders Still Define Foreign Investment Boundaries?
February 04, 2025

INDIA 2025: The Emerging Powerhouse for Private Equity and M&A Deals
January 15, 2025

Audio

CCI's Deal Value Test
February 22, 2025

Securities Market Regulator's Continued Quest Against "Unfiltered" Financial Advice
December 18, 2024

Digital Lending - Part 1 - What's New with NBFC P2Ps
November 19, 2024

NDA Connect

Connect with us at events, conferences and seminars.

NDA Hotline

Click here to view Hotline archives.

Video

Vyapak Desai speaking on the danger of deepfakes | Legally Speaking with Tarun Nangia | NewsX
April 01, 2025

Subsequently, in October 2024, the IPC released a revised version[3] of the 'Medical Device Adverse Event Reporting Form' which is intended to collect information on medical devices adverse event in India. The form is designed to be used by Manufacturer/Importer/ Distributor of medical devices and HCPs with direct/indirect knowledge of adverse events relating to medical devices.

BIS DEVELOPING ADDITIONAL STANDARDS FOR CRITICAL MEDICAL DEVICES AND ASSISTIVE TECHNOLOGY

The Bureau of Indian Standards ("**BIS**") has announced that it aims to develop standards for critical medical devices and assistive technologies in line with the National Medical Device Policy 2023 ("**NMDP**"). The NMDP seeks to accelerate the growth of the medical device sector both domestically and globally. To foster innovation, growth, and accessibility —key objectives of the NMDP— it is crucial that the regulatory framework is standardized.

In line with this, the BIS has prioritized the development of standards for 214 critical medical devices identified in consultation with the DoP. As on date, the BIS has already published over 1700 standards for the medical devices sector.[4] Pertinently, the Medical Devices Rules, 2017 ("**MDR**") have made it mandatory for manufacturers and importers to ensure adherence with the BIS standards, if any, that are applicable to the device in question. Failure to conform to the standards would render the medical device not-of-standard-quality and would expose the manufacturer to liability under the medical devices framework.

NEW SCHEME FOR STRENGTHENING MEDICAL DEVICE INDUSTRY

The Union Minister of Chemicals & Fertilizers has formally unveiled a strategic scheme with a total outlay of Rs. 500 crores, aimed at providing a substantial impetus to the medical device industry in India. Despite the rapid growth of the sector, it continues to face significant challenges, including supply chain disruptions, procurement issues related to raw materials, and a deficiency in specialized training. The scheme seeks to address these critical issues by targeting key areas within the medical device industry, including the manufacturing of essential accessories and components, skill development, and infrastructure enhancement.

The financial outlay is allocated across five distinct sub-schemes designed to: (a) fortify common facilities within medical device clusters; (b) promote investment to mitigate import dependence; (c) advance skill development initiatives; (d) support clinical studies; and (e) facilitate the promotion of medical devices. The successful implementation of these sub-schemes, along with the development of requisite infrastructure, is poised to stimulate further growth in the medical device sector, fostering innovation and enhancing the global competitiveness of the Indian medical industry in the areas of research and development, infrastructure, and technical proficiency.[5]

CDSCO BECOMES AFFILIATE MEMBER OF IMDRF

The Indian medical device regulatory framework aims at aligning its framework governing medical devices with globally accepted standards to promote growth and innovation in the medical device sector. With an agenda to boost global prominence, enhance competitiveness of the domestic industry and align the medical device sector with global standards the CDSCO, under the Ministry of Health and Family Welfare applied for Affiliate Membership in the International Medical Device Regulators Forum ("**IMDRF**") in 2024.

The IMDRF is a collaborative group of global medical device regulators dedicated to accelerating the harmonization and convergence of international medical device regulations. With countries such as the United States, Australia and Canada as members of the IMDRF, India will get significant opportunities to collaborate and exchange technical know-how and rely on the established regulatory frameworks and sophisticated systems of such developed countries.

The membership will benefit the medical device manufacturers by harmonizing regulatory standards across domestic and global markets and promoting convergence, thereby positively affecting the innovation and timely access to medical devices.

The information exchange, collaboration and discussions on the medical device regulatory strategies and trends will help bolster India's efforts to standardize their regulatory framework and align the same with countries across the globe, encouraging innovation and accessibility to new medical devices and strengthening India's position as a leader in the global medical device sector.[6]

CONCLUSION

The regulatory updates in 2024 demonstrate the government's unwavering commitment to enhancing the safety and quality of medical devices in India while aligning industry standards with global best practices. As the sector continues to evolve with stronger regulations and adherence to international norms, it is poised for substantial growth, offering significant opportunities and a strengthened foundation for all stakeholders involved. These developments will not only ensure greater safety and transparency but also drive innovation, making India a more competitive player in the global medical device market.

Authors

- Uttara Jhaveri, Tanya Kukade, Eshika Phadke and Dr. Milind Antani

You can direct your queries or comments to the relevant member.

[1] Accessible at: https://pharmaceuticals.gov.in/sites/default/files/UCMPMD_0.pdf

[2] Accessible at: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Circular%20dated%2015%2005%202024.pdf

[3] Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTIwNDU=

[4] Accessible at: https://pharmaceuticals.gov.in/sites/default/files/Public%20Notice_BIS%20Standards.pdf

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

[5]Accessible at: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2071850

[6]Accessible at: https://pib.gov.in/PressReleasePage.aspx?PRID=2061397