Pharma & Healthcare Update

January 23, 2025

REGULATORY WRAP 2024: PHARMACEUTICAL INDUSTRY IN INDIA

The most significant regulatory developments in the Indian pharmaceutical industry in 2024 are:

- The release of the Uniform Code of Pharmaceutical Marketing Practices 2024
- Issuance of revised guidance for post-approval changes in biological products
- There have been a slew of initiatives and proposed regulatory amendments aimed at improving the quality of drugs and integrity of the supply chain.

INTRODUCTION

The pharmaceutical industry in India is poised for significant growth with 2024 fuelling regulatory updates, government initiatives, and industry advancements. With a focus on enhancing safety, innovation, and global competitiveness, several key measures have been implemented to strengthen the sector. These updates align with India's ambitious goal of becoming a global leader in healthcare innovation, ensuring that the sector remains competitive and continues to serve the needs of both domestic and international markets.

CODE FOR PHARMACEUTICAL MARKETING PRACTICES RELEASED

On March 12, 2024, the Department of Pharmaceuticals ("**DoP**") released the revised Uniform Code of Pharmaceutical Marketing Practices ("**UCPMP**"), which introduces a set of guidelines designed to ensure integrity, transparency, and accountability in the marketing of pharmaceutical products (our detailed analysis of the UCPMP can be accessed here).

The UCPMP replaces the UCPMP 2014, which was a voluntary code. While the 2024 version of the UCPMP does not have statutory backing and remains enforceable primarily be industry associations, the intent of the DoP is for the UCPMP to be treated as binding. The executive head of the company is required to submit an undertaking certifying the company's compliance with the requirements of the UCPMP. Additionally, an annual return in respect of the UCPMP is to be submitted to the DoP, and misstatement or omission of information would attract liability under the Companies Act, 2013.

The UCPMP envisages a higher level of transparency, including disclosure on the company's website of expenditure incurred towards CME/CPD events. Further, the DoP has assumed a greater level of involvement under the UCPMP, and is directly involved in deciding appeals.

The UCPMP requires companies to closely examine their current marketing practices, and realign them with the requirements of the UCPMP.

REVISED GUIDELINES FOR POST-APPROVAL CHANGES IN BIOLOGICAL PRODUCTS

The CDSCO has issued revised Guidelines for Post-Approval Changes ("**PACs**") in Biological Products ("**PAC Guidelines**") to align with international standards.[2] The PAC Guidelines provides guidance for marketing authorization holders on the regulation of changes to the original marketing authorization dossier or product license for an approved biological product in terms of: (a) the procedures and criteria for the appropriate categorization and reporting of changes; and (b) the data required to enable NRAs to evaluate the potential impact of the change on the quality, safety and efficacy of the product.

The PAC Guidelines have classify PACs into four categories based on their impact on quality: Level I (major quality changes) which require prior approval; Level II (moderate quality changes) which require prior approval; Level III (minor quality changes) which must be notified to the CDSCO as part of an annual notification; and Level IV (quality-only changes) which should be retained recorded as part of the drug products' records at the manufacturing site, and must comply with the requirement of good manufacturing practice. Importers are required to submit data of Level IV changes once in thee years, as part of the re-registration of the registration certificate. The PAC Guidelines provide detailed guidance on the classification of specific PACs.

CDSCO CENTRALIZES EXPORT NOC PROCESS FOR UNAPPROVED, BANNED, AND NEW DRUGS

The CDSCO has centralized the process for obtaining an export No Objection Certificate ("**NOC**") for the manufacture of unapproved, banned, or new drugs exclusively for export.[1] Previously the SLAs were empowered to issue export NOCs and mandated that all applications be submitted online via the SUGAM Portal. These changes took effect on May 15, 2024. The CDSCO will now handle the issuance of NOCs through its zonal offices. This change is part of a

Research Papers

Mergers & Acquisitions
July 11, 2025

New Age of Franchising
June 20, 2025

Life Sciences 2025
June 11, 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

Reimagining CSR: From Grant Giving to Blended Finance & Outcome Based Funding
June 16, 2025

Courts vs Bankruptcy code: The

broader effort to streamline the process, as directed by the Union Health Ministry.

Pertinently, since the drugs are either unapproved or banned by the CDSCO – and therefore cannot be made available in the Indian market – the manufacturer is required to submit an undertaking stating that the drug is being manufactured solely for export purposes, and shall not be diverted for sale in India or used for any purpose in India. The undertaking also specifically mentions the quantity that is being manufactured for export, and requires that in the event of non-materialisation of export, the stocks must be physically destroyed in the presence of the SLA. The Drugs Consultative Committee ("**DCC**") has discussed the possibility of granting one-time export NOCs for certain categories of drugs, including unapproved new drugs, and is considering relaxing conditions on the destruction of excess quantities of drugs for export.[2]

REVISED GUIDELINES FOR SAMPLING BY DRUG INSPECTORS RELEASED

The Central Drugs Standards Control Organisation ("**CDSCO**") has issued regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by drug inspectors of both Central and State drug authorities ("**Sampling Guidelines**").[3]

Under the Drugs and Cosmetics Act, 1940 ("**DCA**"), State Licensing Authorities ("**SLAs**") regulate the manufacture and sale of drugs, granting licenses for manufacturing establishments and sale premises. State agencies appoint drug inspectors to conduct inspections to assess the quality of drugs at licensed facilities. The CDSCO guidelines serve as a model for SLAs ensuring uniform implementation of the provisions of the DCA and the associated rules.

Previously, 'Guidelines for taking action on samples of drugs declared spurious or not-of-standard-quality in the light of enhanced penalties under the Drugs and Cosmetics (Amendment) Act, 2008' had been issued as directions under the DCA. However, the revised Sampling Guidelines are significantly more detailed and granular, and provide guidance on procedural aspects such as where samples may be collected from, the number of samples to be taken, the quantity of samples, etc.

The Sampling Guidelines also formalise the requirements for a CDSCO-maintained NSQ Alert, which collates and publicises the data on not-of-standard-quality drugs that is forwarded by all state and central laboratories. Presently, the SLAs and CDSCO do publish data on their website about samples that were found to be of substandard quality. However, the Sampling Guidelines envisage a more robust, centralised NSQ Alert system.

While the Sampling Guidelines are applicable to the drug inspectors, they also provide valuable insights to the industry on the manner in which they would need to prepare themselves for inspections and could guide the internal processes and plans to be devised by companies for combatting drug quality-related issues.

CDSCO RELEASES GUIDANCE DOCUMENT ON GDP FOR PHARMACEUTICAL PRODUCTS

The CDSCO has released a draft guidance document on Good Distribution Practices ("**GDPs**") for pharmaceutical products, aligned with WHO standards, to prevent the introduction of spurious, adulterated, and NSQ products into the market.[4]

The guidelines outline the responsibilities of stakeholders involved in the storage and distribution of medical products. The key requirements under the guidelines include conducting self-inspections, maintaining records, and ensuring corrective actions are taken to maintain safety and quality of pharmaceutical products. The guidance document calls for cooperation among stakeholders to ensure quality of products is maintained at different stages of the supply chain. The distributors must establish a quality system with a documented policy, appoint a responsible person for each site, and ensure compliance with Good Storage Practices ("**GSP**") and quality risk management principles.

Reportedly, the GDP may be incorporated into the Drugs Rules – similar to Good Manufacturing Practices – upon their finalisation. The guidance document represents a positive step towards fostering cooperation and collaboration among stakeholders, with adherence to the guidelines enhancing the safety and quality of drugs in alignment with international standards.

PROPOSED AMENDMENT FOR INCLUSION OF EXCIPIENTS ON LABEL

The MoHFW has proposed changes to the labelling requirements for drugs vide a draft amendment to the Drugs Rules, 1945[5] mandating that "Details of excipients" also be declared on the label of drugs. Presently, the label of drugs is only required to bear details of the active ingredients that are used in the drug. The draft amendment is intended to enhance transparency and ensure that all necessary information is readily available to consumers and regulators, which leads to accountability and protection of consumer rights and public health. This comes against the backdrop of highly publicised quality related scandals, which were reportedly the result of substandard excipients being used for manufacturing the drug.

DRAFT DRUGS AND COSMETICS (COMPOUNDING OF OFFENCES) RULES, 2023

To give effect to the amendments to the DCA that were brought about by the Jan Vishwas (Amendment of Provisions) Act, 2023, which made certain offences under the DCA compoundable, the central government proposed the promulgation of the Drugs and Cosmetics (Compounding of Offences) Rules, 2023 ("**Proposed Rules**").

The Proposed Rules establish a structured framework for the settlement of offences through the payment of a compounding amount, coupled with the grant of immunity from prosecution for certain compoundable offences. The Proposed Rules are designed to provide stakeholders within the pharmaceutical sector with an expedient alternative to protracted litigation, thereby facilitating the swift resolution of disputes and enhancing regulatory compliance. Furthermore, these Rules may alleviate the strain on the overburdened judicial system, while concurrently streamlining enforcement procedures across the industry.

GUIDANCE DOCUMENT FOR RISK BASED INSPECTION OF DRUG MANUFACTURING SITES

With the revised Good Manufacturing Practices under Schedule M coming into effect, the CDSCO released a guidance document for risk-based inspection of drug manufacturing sites[6] in order to ensure consistency and

JSW-Bhushan Saga
June 04, 2025

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

uniformity in the implementation of the GMP standards across states.

The guidance document outlines the types of inspections, the identification of intrinsic and compliance-related risk of the site and the details of Quality Risk Management Tool for Risk Rating. The inspection officer must assess the site and draft a risk-based inspection report and score the facility on the parameters listed in the guidelines and record the observations on the building & premises, ancillary areas, security systems, water and compressed air systems, among aspects.

The guidelines for Risk Based Inspection ensures that the quality, safety, and efficacy of medicines is uniform across the country strengthening public health and global image of the industry. Additionally, the guidelines are a step in the right direction to bring the country's manufacturing sites at par with well-regulated countries such as USA and the EU which also follow such risk-based approach to inspections. Such countries identify facilities for inspection on the basis of history of inspection, risk associated with the product and finding of past inspections. Therefore, such risk-based inspections would optimise the resources of state agencies, allocation of resources and quality of products in the market.

CDSCO RELEASES DRAFT GUIDANCE DOCUMENT OF POLICY ON VACCINE APPROVAL AND PMS

The CDSCO has issued a guidance document outlining the pharmacovigilance requirements for vaccine manufacturers and importers in India. The guidance mandates that manufacturers and importers report Serious Adverse Events ("**SAEs**") in India and distributing countries to the CDSCO within 15 days.[7] The document addresses Post Market Surveillance ("**PMS**"), stipulating that Marketing Authorization Holders must implement a pharmacovigilance system to collect, process, and forward reports of Adverse Event Following Immunization ("**AEFI**") to the licensing authorities, enabling timely action to address safety concerns. The vaccine manufacturers are required to submit a detailed pharmacovigilance plan, which must include the methodology for pharmacovigilance, individual case safety reports, passive and active surveillance, and simulated reporting. The document also outlines the need for stringent follow-up after vaccine approval, through Phase IV-post marketing trials, PMS, observational studies, and non-interventional studies for active monitoring, including the assessment of AEFI and Adverse Events of Special Interest.

Vaccine manufacturers must conduct post-authorization safety studies and submit the final results to the CDSCO. The manufacturers must also report adverse events following immunization to AEFI and CDSCO within 15 days. Imported vaccines will require bridging studies in India. Special approvals may be expedited for vaccines addressing urgent health needs. After marketing, the holder must submit periodic safety updates, and the AEFI surveillance system will monitor vaccine safety. Both CDSCO and SLAs are responsible for ensuring the ongoing quality of vaccines through compliance with Good Manufacturing Practices ("**GMPs**") and lot release protocols.

CONCLUSION

India's pharmaceutical industry is undergoing transformative changes that aim to enhance quality, compliance, and global competitiveness. Regulatory developments, strategic initiatives, and collaborations position the industry for substantial growth. By adopting international standards and fostering innovation, India is on track to become a global healthcare powerhouse. These efforts will contribute to improving public health, expanding market access, and strengthening the country's manufacturing capabilities, making it a hub for both domestic and global healthcare solutions.

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://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE0MjA=

[2]Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MjIxMQ==

[3]Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTA5MzU=

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

[5]Accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE0NTI=

[6]Accessible at: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadCircularFile/Guidance%20document%20for%20risk%20based%20inspection.pdf

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