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Federation Of Pharma Entrepreneurs

NEWSLETTER

JUNE 2026 EDITION

Strengthening India's Pharmaceutical Industry through

- Policy Advocacy
- Collaboration
- Innovation
- Growth

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Events

Events

Professional Knowledge Sharing & Regulatory Awareness Initiatives

During June 2026, FOPE organized expert-led webinars focusing on regulatory compliance and recent legal developments affecting the pharmaceutical industry.

These sessions provided practical guidance to manufacturers, regulatory professionals, and industry stakeholders.

WEBINAR 1

Power & Procedures of Inspectors

Speaker: Mr. Narender Ahooja Vivek
(Ex-SDC, Haryana & Regulatory Consultant, FOPE)

Date: Tuesday, 16th June 2026

The webinar highlighted the legal powers, procedures, and jurisdiction of drug inspectors under the Drugs and Cosmetics Act, emphasizing statutory compliance, valid inspection practices, sample handling, documentation, and industry rights.

It also discussed the legal status of DCGI guidelines and recent regulatory developments affecting pharmaceutical inspections.

WEBINAR 2

Implications of Recent Himachal Pradesh High Court Judgements

Speaker: Adv. Sanjay Jain

Moderator: Shri Narender Kumar Ahooja
(Regulatory Consultant, FOPE)

Date: Saturday, 27th June 2026

The webinar discussed the implications of recent Himachal Pradesh High Court judgments, highlighting director liability, procedural compliance, Rule 45 timelines for government analyst reports, jurisdiction of regulatory authorities, and the importance of adhering to statutory provisions to ensure legally sustainable drug regulatory actions.

FOPE continues to organize knowedge sharing initiatives to strengthen regulatory awareness across the pharmaceutical industry.

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Circulars & Notifications

01. GOVERNMENT NOTIFICATION

DGFT Public Notice No. 14/2026-27 dated 1st June 2026 on Standard Input Output Norms (SIONs)

DGFT Notifies Six New SIONs for Chemical and Allied Products

The Directorate General of Foreign Trade (DGFT) has notified six new Standard Input Output Norms (SIONs), numbered A-3702 to A-3707, under the Chemical and Allied Product Group 'A'.

The new norms specify input-output requirements for products including Artemether, Artesunate, Dihydro Artemisinin and Doxycycline Hyclate tablets.

The notification enables Regional Authorities to issue Advance Authorisations directly without referring cases to the Norms Committee, thereby expediting approvals and ensuring greater uniformity in decision-making.

02. GOVERNMENT NOTIFICATION

DGFT Public Notice No. 16/2026-27 dated 2nd June 2026 on Amendment to Handbook of Procedures

DGFT Includes India–Oman CEPA under Certificate of Origin Framework

The Directorate General of Foreign Trade (DGFT) has amended Para 2.88(a) of the Handbook of Procedures, 2023 by including the India–Oman Comprehensive Economic Partnership Agreement (CEPA) in the list of Free Trade Agreements.

The amendment enables exporters to obtain Certificates of Origin under the India–Oman CEPA through the existing system of authorised issuing agencies, facilitating preferential trade benefits.

03. GOVERNMENT NOTIFICATION

DGFT Public Notice No. 15/2026-27 dated 2nd June 2026 on Amendment to Appendix 2B of the Foreign Trade Policy

DGFT Notifies Authorised Agencies for India–Oman CEPA Certificates of Origin

The Directorate General of Foreign Trade (DGFT) has amended Appendix 2B of the Foreign Trade Policy, 2023 by notifying the list of authorised agencies permitted to issue Preferential Certificates of Origin under the India–Oman Comprehensive Economic Partnership Agreement (CEPA).

The notification designates DGFT regional offices and other specified export promotion bodies and institutions to facilitate issuance of Certificates of Origin for eligible exports under the agreement.

04. GOVERNMENT NOTIFICATION

CDSCO Circular dated 3rd June 2026 on Implementation of Pharmacovigilance System

CDSCO Directs Licensees to Implement Pharmacovigilance Systems

The Central Drugs Standard Control Organization (CDSCO) has directed all stakeholders to establish and maintain an effective pharmacovigilance (PV) system in accordance with Schedule M of the Drugs and Cosmetics Act, 1940, the Rules made thereunder and the NDCT Rules, 2019.

The circular reiterates that licensees must collect, process and report adverse drug reactions to the licensing authorities, with compliance subject to verification during routine inspections by CDSCO and State Licensing Authorities.

05. GOVERNMENT NOTIFICATION

CDSCO Letter dated 3rd June 2026 on Enforcement of Ban on Chloramphenicol and Nitrofurans in Food-Producing Animals

CDSCO Seeks Strict Enforcement of Ban on Chloramphenicol and Nitrofurans

The Central Drugs Standard Control Organization (CDSCO) has directed all State and UT Drugs Controllers to strengthen enforcement of the prohibition on the import, manufacture, sale, distribution and use of Chloramphenicol and Nitrofurans in food-producing animals.

Citing continued detection of residues in export consignments, CDSCO has sought details on implementation, inspections and enforcement actions, while directing strict regulatory action against violations under the Drugs and Cosmetics Act, 1940.

06. GOVERNMENT NOTIFICATION

NPPA Letter dated 5th June 2026 on Availability of APIs/KSMs for Carboplatin and Cisplatin Formulations

NPPA Seeks Data to Address Shortage of Critical Anti-Cancer Drugs

The National Pharmaceutical Pricing Authority (NPPA) has sought information from the Drugs Controller General of India (DCGI) regarding the import and availability of Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs) for Carboplatin and Cisplatin formulations.

The initiative follows reports of nationwide shortages of these critical anti-cancer drugs and aims to assess supply constraints, facilitate policy intervention and ensure their continued availability in the country.

07. GOVERNMENT NOTIFICATION

Ministry of Health and Family Welfare Notification G.S.R. 477(E) dated 9th June 2026 on Amendment to the Drugs Rules, 1945

Government Amends Drug Classification under Drugs Rules

The Ministry of Health and Family Welfare has notified the Drugs (Fifth Amendment) Rules, 2026, amending the Drugs Rules, 1945.

The amendment removes the word "Syrups" from Item 7 under Serial Number 13 in the Schedule relating to the classification of drugs. The revised provisions came into force on the date of their publication in the Official Gazette.

FOPE Insight:
The notification primarily impacts retail sale and has no direct implication for manufacturers.

The amendment relates to the exemption available under Schedule K read with Rule 123 of the Drugs Rules, 1945.

It is pertinent to note that products covered under Schedule G or Schedule H were already excluded from the exemption available under Schedule K.

08. GOVERNMENT NOTIFICATION

CDSCO Circular dated 10th June 2026 on Compliance Requirements for Hair Color Cosmetic Products

CDSCO Directs Compliance with BIS Standards for Hair Color Cosmetics

The Central Drugs Standard Control Organization (CDSCO) has directed all importers and manufacturers of hair color cosmetic products to ensure compliance with the Cosmetics Rules, 2020 and applicable Bureau of Indian Standards (BIS) specifications.

The circular reiterates requirements relating to permitted ingredients, labelling, safety warnings and quality standards, and mandates that any changes to product labels, composition or quality specifications be reported to the appropriate licensing authority.

09. GOVERNMENT NOTIFICATION

NPPA Notification S.O. 3006(E) dated 11th June 2026 on Revision of Ceiling Prices of Vaccines

NPPA Revises Ceiling Prices of BCG, Measles and Measles-Rubella Vaccines

The National Pharmaceutical Pricing Authority (NPPA) has revised the ceiling prices of BCG Vaccine, Measles Vaccine and Measles-Rubella Vaccine under Paragraph 19 of the Drugs (Prices Control) Order, 2013.

The revision follows a review by the Department of Pharmaceuticals, which directed reconsideration of monopoly price reduction for these vaccines in view of their public health importance, ensuring their continued availability while incorporating the applicable Wholesale Price Index (WPI) adjustment for 2026.

10. GOVERNMENT NOTIFICATION

Government Notification S.O. 3068(E) dated 11th June 2026 on Fixed-Dose Combinations

Government Prohibits 16 Irrational Fixed-Dose Combinations

The Ministry of Health and Family Welfare has prohibited the manufacture, sale and distribution of 16 fixed-dose combinations for human use with immediate effect.

Issued under Section 26A of the Drugs and Cosmetics Act, 1940, the notifications follow reviews by expert committees and the Drugs Technical Advisory Board.

The combinations were found to lack adequate therapeutic justification, with available scientific evidence not supporting their rationality and safer alternatives being available. The action covers certain antibiotic–serratiopeptidase, antispasmodic and dermatological combinations.

11. GOVERNMENT NOTIFICATION

CDSCO Office Order dated 15th June 2026 on Constitution of Consultancy Committee for RTI Disclosures

CDSCO Constitutes Committee to Strengthen Proactive RTI Disclosures

The Central Drugs Standard Control Organization (CDSCO) has constituted a Consultancy Committee of key stakeholders to advise on proactive disclosures under Section 4 of the Right to Information Act, 2005.

The Committee will review compliance with RTI disclosure requirements, recommend measures to enhance transparency, oversee periodic updates of information on the CDSCO website and submit recommendations to the competent authority for improved public access to information.

12. GOVERNMENT NOTIFICATION

Ministry of Health and Family Welfare Notification G.S.R. 496(E) dated 18th June 2026 on Amendment to the Drugs Rules, 1945

Government Revises Testing Authority for Veterinary Vaccines

The Ministry of Health and Family Welfare has notified the Drugs (Sixth Amendment) Rules, 2026, amending Rule 3A of the Drugs Rules, 1945.

The amendment designates the Chaudhary Charan Singh National Institute of Animal Health, Baghpat, Uttar Pradesh, as the designated laboratory and its Director as the competent authority for testing and regulatory functions relating to 42 specified viral and bacterial veterinary vaccines, with immediate effect.and dermatological combinations.

13. GOVERNMENT NOTIFICATION

Ministry of Health and Family Welfare Notification G.S.R. 506(E) dated 22nd June 2026 on Amendment to the Drugs Rules, 1945

Government Expands Schedule H2 to Cover Key Drug Categories

The Ministry of Health and Family Welfare has notified the Drugs (Seventh Amendment) Rules, 2026, amending Schedule H2 of the Drugs Rules, 1945.

The amendment introduces a new table covering therapeutic categories including all vaccines, antimicrobials, narcotic and psychotropic substances, and anticancer drugs. The revised provisions will come into effect from 1st July 2027, with the antimicrobial category becoming effective from 1st July 2028.

14. GOVERNMENT NOTIFICATION

Ministry of Health and Family Welfare Notification S.O. 3286(E) dated 22nd June 2026 on Commencement of Jan Vishwas (Amendment of Provisions) Act, 2026

Government Notifies Effective Date for Jan Vishwas Amendments to Drugs and Cosmetics Act

The Ministry of Health and Family Welfare has notified 30th June 2027 as the date on which the provisions of the Jan Vishwas (Amendment of Provisions) Act, 2026 relating to the Drugs and Cosmetics Act, 1940 will come into force.

The notification brings into effect the amendments corresponding to Serial Number 8 of the Act's Schedule, marking the implementation timeline for the related regulatory reforms.

15. GOVERNMENT NOTIFICATION

NPPA Retail Price Computation Sheet dated 22nd June 2026 under DPCO, 2013

NPPA Revises Retail Price of Paracetamol Combination Suspension

The National Pharmaceutical Pricing Authority (NPPA) has revised the retail price of a Paracetamol-based combination suspension containing Phenylephrine Hydrochloride, Chlorpheniramine Maleate, Ammonium Chloride, Sodium Citrate and Menthol under Paragraph 5 of the Drugs (Prices Control) Order, 2013.

Based on a review order dated 21st May 2026, the retail price has been fixed at ₹0.68 per ml (excluding GST) for the formulation manufactured by Windlas Biotech Ltd. and marketed by Biological E. Ltd.

16. GOVERNMENT NOTIFICATION

NPPA Office Memorandum dated 23rd June 2026 on Integration of Pharma Jan Samadhan Portal with Pharma Sahi Daam Portal

NPPA Integrates Citizen Portals for Medicine Price Information and Grievance Redressal

The National Pharmaceutical Pricing Authority (NPPA) has integrated the Pharma Jan Samadhan Portal with the Pharma Sahi Daam Portal to provide a unified digital platform for medicine price information and grievance redressal.

The integration aims to improve citizen convenience, enhance transparency, reduce duplication of services and provide a more efficient, user-friendly interface for accessing pricing information and lodging complaints.

17. GOVERNMENT NOTIFICATION

CDSCO Circular dated 24th June 2026 on Regulation of Formulation Intermediates

CDSCO Clarifies Regulatory Requirements for Formulation Intermediates

The Central Drugs Standard Control Organization (CDSCO) has issued a clarification on the regulation of formulation intermediates such as directly compressible granules, taste-masked granules and modified-release granules/pellets.

The circular specifies the approval requirements under the New Drugs and Clinical Trials Rules, 2019, clarifying that formulation intermediates containing only approved drug substances may be licensed by State Licensing Authorities, while those containing new or novel excipients require prior approval from CDSCO.

18. GOVERNMENT NOTIFICATION

CDSCO Circular dated 24th June 2026 on Online Submission of Post Approval Change Applications for Human Vaccines and Anti-sera

CDSCO Mandates Online Submission of Post Approval Change Applications through SUGAM Portal

The Central Drugs Standard Control Organization (CDSCO) has mandated that applications for Post Approval Changes (PACs) relating to Registration Certificates and Import Licences of Human Vaccines and Anti-sera be submitted exclusively through the SUGAM Portal.

Effective 1st July 2026, hard copy submissions through CRU or by email will no longer be accepted, streamlining the regulatory process and facilitating online processing of PAC applications.

19. GOVERNMENT NOTIFICATION

Ministry of Chemicals and Fertilizers Notification S.O. 3516(E) dated 30th June 2026 on Amendment to the Drugs (Prices Control) Order, 2013

Government Amends DPCO to Streamline Drug Pricing and Compliance Framework

The Ministry of Chemicals and Fertilizers has notified the Drugs (Prices Control) Amendment Order, 2026, introducing significant amendments to the Drugs (Prices Control) Order, 2013.

The changes provide for separate pricing of therapeutically justified drug variants, simplify procedures for launching new drugs, strengthen compliance and record-keeping requirements, clarify liability for overcharging, and introduce a new reporting format for notifying the launch of new drugs, thereby enhancing transparency and regulatory efficiency.

FOPE Insight:
A significant amendment has been made to Paragraph 14(2) of the DPCO, 2013. Earlier, manufacturers were liable for the entire quantity of overcharged stock available in the market.

Under the amended provision, liability is restricted only to the actual quantity traded by distributors or retailers found to have overcharged, provided the manufacturer has complied with the price dissemination requirements under Paragraph 24.

Benefits for the Industry:

Reduced financial burden on manufacturers. Greater transparency and fairness in the price control mechanism.

Smoother implementation of regulatory provisions. Balanced enforcement that reflects practical supply chain realities.

This amendment is a welcome and progressive step that protects consumer interests while ensuring that compliant manufacturers are not unfairly penalized.

The pharmaceutical manufacturing industry has been advocating for this change for a considerable period.

Additionally:
The definition of "New Drug" under the DPCO differs from that under the NDCT Rules.

The definition under the NDCT Rules contains additional provisions compared to the earlier definition under Rule 122E of the Drugs Rules.

The summaries above provide only the key highlights. For complete notifications and detailed regulatory provisions, visit our website.

Read all official notifications here →

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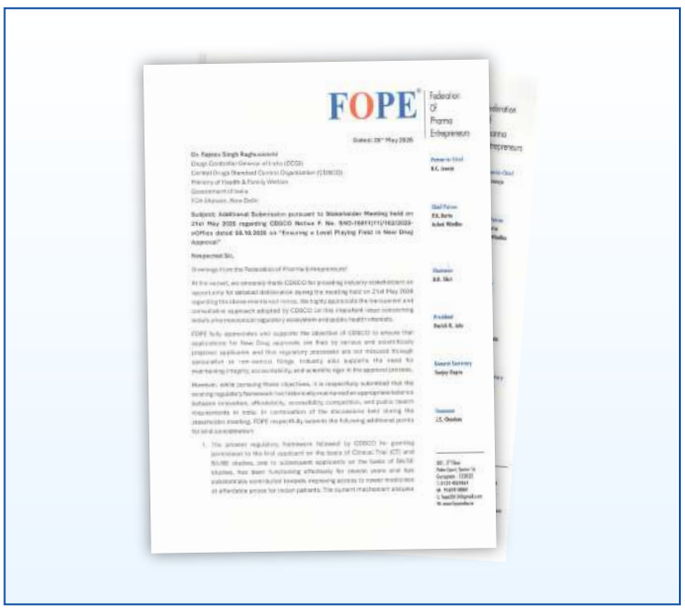
Representations

FOPE REPRESENTATIONS

FOPE SUBMISSION ON NEW DRUG APPROVAL FRAMEWORK



FOPE Advocates Balanced and Competitive Approval Pathway

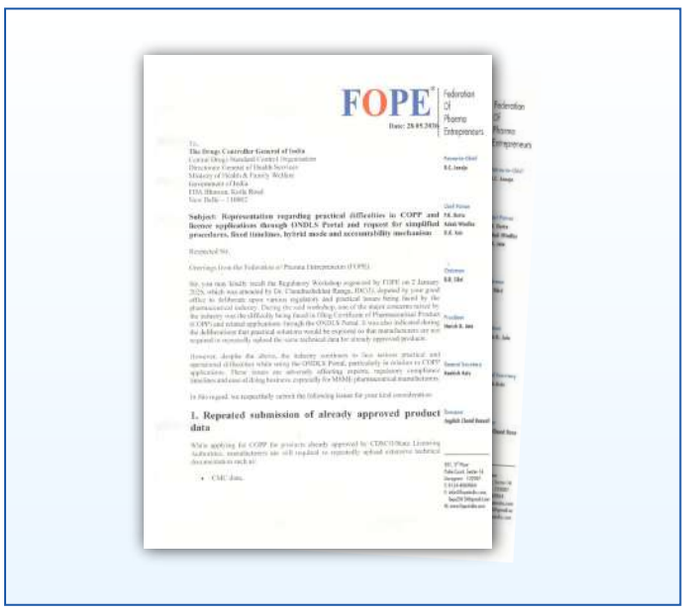
Following the CDSCO stakeholder meeting held on 21 May 2026, the Federation of Pharma Entrepreneurs submitted additional recommendations on maintaining a level playing field in new drug approvals.

FOPE supported stronger scrutiny of non-serious applications but cautioned against requiring subsequent applicants to repeat clinical trials where adequate safety and efficacy data already exist.

It highlighted that such requirements could delay access, increase medicine prices, affect MSMEs and weaken supply continuity.

FOPE recommended a reasonable time-bound lead advantage or administrative incentives for the first clinical-trial applicant while retaining the established BA/BE-based pathway for subsequent applicants.

FOPE REPRESENTATION ON COPP & ONDLS PORTAL REFORMS



FOPE Calls for Simplified and Time-Bound COPP Approval Process

FOPE has submitted a representation to CDSCO highlighting the practical challenges faced by pharmaceutical manufacturers while applying for Certificates of Pharmaceutical Product (COPP) and licence-related services through the ONDLS portal.

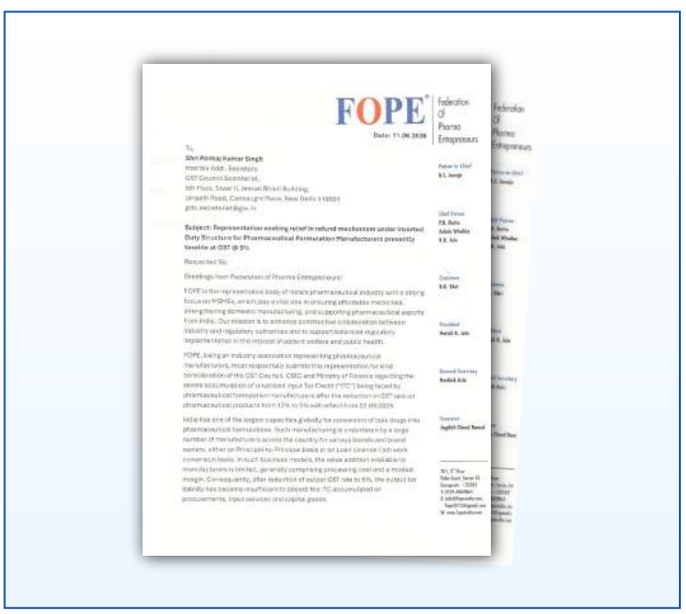
The federation identified issues such as repeated submission of already approved product data, portal performance limitations, file upload restrictions, approval delays and inconsistent query management, all of which increase compliance burden and affect export timelines.

FOPE recommended simplified filing for previously approved products, fixed approval timelines, a hybrid online-offline submission mechanism during the portal stabilization phase, and a Right to Service–style accountability framework with improved transparency and digital tracking.

FOPE REPRESENTATIONS

The recommendations aim to strengthen ease of doing business, support MSMEs, and enhance India's pharmaceutical export competitiveness.

FOPE REPRESENTATION ON INVERTED DUTY STRUCTURE & ITC REFUND RELIEF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FOPE Seeks GST Relief for Pharmaceutical Formulation Manufacturers

FOPE has submitted a representation to the GST Council, CBIC and the Ministry of Finance seeking relief from the growing accumulation of unutilized Input Tax Credit (ITC) under the inverted duty structure following the reduction of GST on pharmaceutical formulations to 5%.

The federation highlighted that the existing refund mechanism excludes ITC on input services and capital goods, resulting in blocked working capital, increased production costs and reduced competitiveness, particularly for MSME manufacturers.

FOPE recommended expanding ITC refund eligibility, introducing a dedicated refund mechanism for the pharmaceutical sector, enabling flexible utilization or transfer of accumulated credit, and issuing suitable policy clarifications to address persistent credit accumulation.

The proposed measures aim to improve liquidity, preserve tax neutrality and strengthen the competitiveness of India's pharmaceutical manufacturing sector.

The summaries above present the key highlights of FOPE's representations. To read the complete representations and detailed recommendations submitted to the concerned authorities, visit our website.

Read all representations here →

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Landmark Judgements

LANDMARK JUDGMENT

Petitions Covered:

Cr.MMO No.127 of 2022 – M/s SBS Biotech & Ors. vs. Union of India

Cr.MMO No.504 of 2022 – Deepak Kumar vs. Union of India

Cr.MMO No.762 of 2022 – Deepak Kumar vs. Union of India

High Court of Himachal Pradesh | Decided on: 22 June 2026

The High Court of Himachal Pradesh delivered a common judgment disposing of the above three connected petitions, all arising from prosecutions initiated under the Drugs and Cosmetics Act, 1940 in respect of drugs declared "Not of Standard Quality (NSQ)."

The petitioners challenged the criminal complaints and summoning orders primarily on the grounds that they were neither responsible for the day-to-day affairs of the companies/firms nor could they be held vicariously liable merely because they were partners or directors.

They also questioned the jurisdiction of the Central Drugs Inspector and raised procedural objections regarding investigation and testing.

After examining the statutory provisions and several Supreme Court precedents, the Court reiterated that criminal liability under Section 34 of the Drugs and Cosmetics Act cannot be imposed solely on the basis of a person's designation as a partner or director.

To prosecute such persons, the complaint must contain specific averments establishing that they were in charge of and responsible for the conduct of the business at the time of the alleged offence.

Mere bald or omnibus allegations are insufficient to attract vicarious liability.

Finding that the complaints lacked the necessary factual assertions regarding the petitioners' role in the day-to-day management of the companies/firms, the Court held that continuation of the criminal proceedings would amount to an abuse of the process of law.

Accordingly, the High Court allowed all three petitions, quashed Complaint Nos. COMA 09/2021, COMA 04/2022 and COMA 10/2022, along with the corresponding cognizance and summoning orders, while reaffirming the settled legal principle that criminal prosecution of company officials must be supported by clear and specific allegations demonstrating their actual responsibility for the conduct of the business.

The summary above is intended to provide a concise overview of the judgment. For the complete judgment and detailed legal findings, visit our website.

Read the complete judgment here →

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Articles

Article

Strengthening Coordination between State and Central Drugs Regulators

By Mr. Narender Ahooja Vivek
Ex-State Drugs Controller, Haryana | Regulatory Consultant, FOPE

India's drug regulatory framework operates through shared responsibilities between the Central Government and State Governments under the Drugs and Cosmetics Act, 1940.

Effective coordination between these authorities is essential not only for protecting public health but also for ensuring consistency, legal certainty and ease of compliance for pharmaceutical stakeholders.

The Drugs Consultative Committee, constituted under Section 7 of the Act, should be strengthened as the principal statutory platform for consultation and coordination between the Centre and States.

Its composition and functioning must remain aligned with the Act, ensuring appropriate representation of the Central Government and every State Government.

Regular deliberations through the Committee can help promote uniform interpretation and implementation of the Act and Rules across the country.

Section 33P empowers the Central Government to issue directions to State Governments for carrying out the provisions of the Act. This provision may be effectively utilised to issue harmonised guidance, model procedures and implementation frameworks after due consultation with State regulators.

The objective should be cooperative federalism rather than centralisation, with both levels of government discharging their respective statutory responsibilities in a coordinated manner.

A national regulatory information-sharing mechanism is also necessary. Central and State Licensing Authorities should be able to promptly exchange information relating to licences, inspections, prosecutions, recalls, quality alerts and enforcement actions.

A rapid communication system for spurious, adulterated, misbranded and Not of Standard Quality drugs would enable coordinated action across State borders and reduce risks to patients.

Joint inspections and enforcement actions should be encouraged in matters involving inter-State operations, imports or significant public-health concerns.

Coordination between Central and State Drug Testing Laboratories must similarly be strengthened through uniform testing standards, harmonised reporting formats and timely sharing of analytical reports.

Regular training and capacity-building programmes for Drug Inspectors, Government Analysts and Licensing Authorities would further support consistent enforcement.

Uniform Standard Operating Procedures should be developed for inspections, sampling, seizure, prosecution, recall and licensing.

Periodic meetings between CDSCO and State Drug Controllers can provide an effective forum to review implementation challenges, resolve jurisdictional issues and share good regulatory practices.

There must also be greater clarity regarding the division of powers and duties between Central and State regulators.

Manufacturers, marketers, wholesalers and retailers should not be placed in a situation where they receive conflicting directions from different authorities. Regulatory agencies should coordinate internally and communicate a clear and consolidated position to stakeholders.

Products lawfully approved by competent State Licensing Authorities should not automatically be treated as unapproved drugs or unapproved fixed-dose combinations without a clear legal basis, scientific examination and due process.

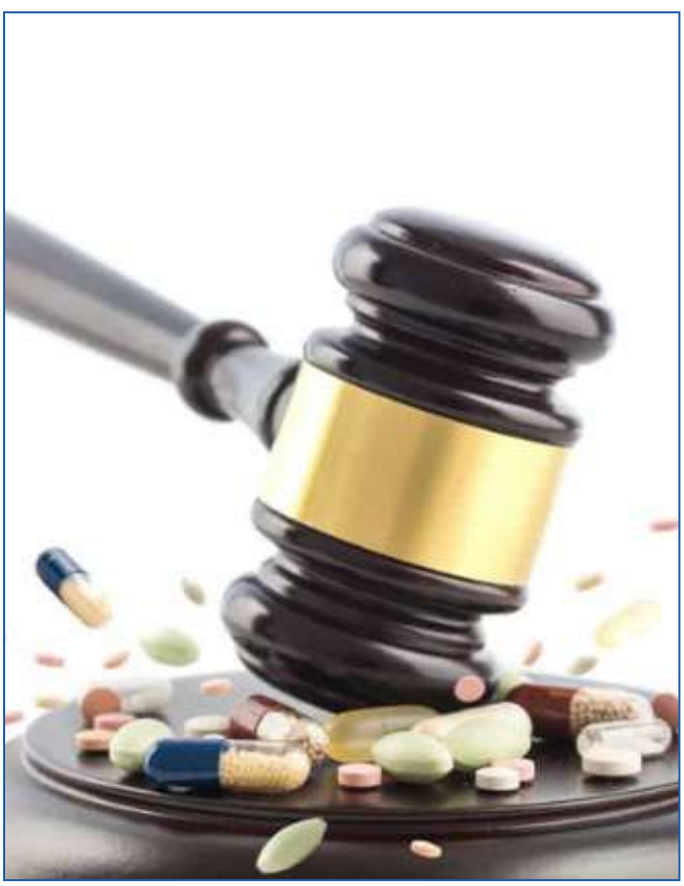
Regulatory decisions should take into account the legal provisions and practices prevailing at the time the approvals were granted.

As a general principle of law and fairness, new regulatory requirements should operate prospectively unless retrospective application is expressly provided. The bioavailability and bioequivalence requirements introduced through the 2017 amendment should, therefore, not ordinarily be imposed retrospectively on formulations approved by State Licensing Authorities before the amendment.

Similarly, products already approved and marketed should not be categorised as “new drugs” merely because regulatory requirements or interpretations have subsequently changed.

A coordinated, transparent and predictable regulatory framework will strengthen public-health protection while supporting responsible pharmaceutical development.

Central and State regulators must function as partners, ensuring that enforcement remains scientifically sound, legally sustainable and fair to all stakeholders.



Disclaimer: The views and opinions expressed in this article are solely those of the author and do not necessarily reflect the views, policies, or position of FOPE.

About FOPE

Established in 2006, the Federation of Pharma Entrepreneurs (FOPE) is a national body dedicated to representing and addressing the common concerns of the Indian pharmaceutical industry.

FOPE actively engages with the Government of India, regulatory authorities, and key stakeholders on policy, regulatory, and industry-related matters impacting the pharma sector.

With a strong presence through its five regional chapters, FOPE connects pharmaceutical entrepreneurs across the country and serves as a unified platform for advocacy, collaboration, and knowledge sharing.

Through consistent engagement in meetings, seminars, conferences, and workshops, and by fostering interactions with organizations like the CDSCO, MoHFW, Department of Pharmaceuticals, and NPPA, FOPE remains instrumental in amplifying the voice of the Indian Pharmaceutical Industry, especially the MSME sector.

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