FOPE®

Federation Of Pharma Entrepreneurs

NEWSLETTER

SEPTEMBER 2026 EDITION

Strengthening India's Pharmaceutical Industry through

Policy Advocacy | Collaboration | Innovation | Growth



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CONTENTS

Section	Page
FOPE Office Bearers	02
FOPE Women Forum	03–04
FOPE Editorial Board	05
Events & Activities	08–09
Circulars & Notifications	11–12
Representations	14–16
Landmark Judgements	18–21
Articles	23–26
About FOPE	27

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FOPE Women Forum



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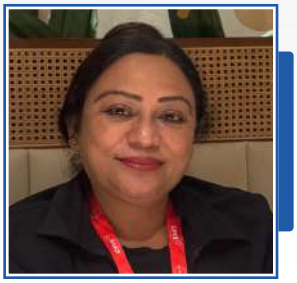
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Smt. Meenakshi Gupta
Convener
FOPE Women Forum



Dr. Aprajita Takiar
Working President, FOPE



Dr. Kashish Aziz
General secretary, FOPE



Sh. Narendra Kumar Ahooja
Ex-SDC Haryana
Regulatory Consultant, FOPE

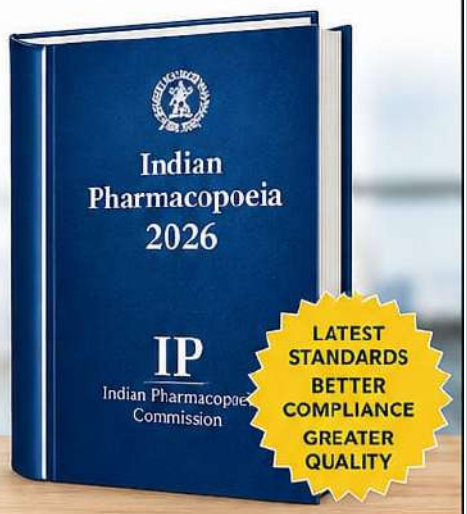


Sh. Yogesh Vats
Executive Secretary, FOPE

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Stronger Together...
For a Quality India



SPECIAL DISCOUNT
ON
INDIAN PHARMACOPOEIA
2026

EXCLUSIVELY FOR FOPE MEMBERS

The Indian Pharmacopoeia Commission (IPC) appreciates FOPE and is pleased to offer a **special discounted rate** on **Indian Pharmacopoeia 2026** to all member organizations of FOPE, in support of regulatory compliance, quality assurance and harmonized pharmaceutical practices.

WHY AVAIL THIS OFFER?

- Access to latest official standards
- Ensure regulatory compliance
- Improve quality assurance
- Strengthen pharma ecosystem

DISCOUNT OFFER DETAILS

Name & Details of Publication	Current Price per copy/user excl GST	Discount %	Effective Price per copy/user excl GST
IP-2026, 4 Volume set + 01 user Free online subscription	Rs. 60,000/-	5%	Rs. 57,000/-
IP online subscription only	Rs. 50,000/-	10%	Rs. 45,000/-

CONDITIONS OF OFFER

- FOPE has to pay full advance amount for the bulk purchase members in account of IPC in lumpsum.
- Complete details of subscriber have to be given by FOPE.
- The participation of MSME under bulk purchase will be encouraged.
- The offer is for a limited time period.

OFFER VALID TILL RELEASE OF NEXT EDITION OF IP

Let's join hands to promote quality, compliance and excellence in the pharmaceutical sector.

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For more details, please contact FOPE Secretariat

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Events & Activities



1. WEBINAR

Dissolution Science & Bioavailability for Complex Molecules



Speaker: Dr. Gaurav Kumar Jain
Associate Professor,
Pharmaceutics & Coordinator,
DSIR-DPSRU-CRTDH

Moderator: Shri Narender Kumar Ahooja
Ex-SDC Haryana
Regulatory Consultant, FOPE

Date: Monday, 12th September 2026

A webinar focused on Dissolution Science & Bioavailability for Complex Molecules, exploring how drug dissolution and absorption influence pharmaceutical performance and development.

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

2. WEBINAR

FOOD & NUTRACEUTICAL LABELLING



Speaker: Smt. Deepika Chauhan
Former DC, FDCA, Gujarat

Moderator: Shri Narender Kumar Ahooja
Ex-SDC Haryana
Regulatory Consultant, FOPE

Date: Monday, 21st September 2026

The webinar focuses on food and nutraceutical labelling requirements, helping participants understand the key regulatory standards, compliance rules, and labelling practices for these products.

FOPE PARTICIPATION IN REGULATORY MEETINGS

Key EoDB initiatives, FTA opportunities and obligations, and ongoing reforms aimed at simplifying and streamlining trade- related processes and procedures", being organised by the Department for Promotion of Industry and Internal Trade (DPIIT) under the chairmanship of Shri Piyush Goyal, Hon'ble Minister of Commerce & Industry, Shri Jitin Prasada, Hon'ble Minister of State

Date: Tuesday, 22nd September 2026

Attended by:
Shri Narender Kumar Ahooja
Ex-SDC Haryana
Regulatory Consultant, FOPE

Dr. Kashish Aziz
Gen. Secretary, FOPE

FOPE Inputs: These points were discussed FOPE representative Sh. Narender Kumar Ahooja & Dr Kashish Aziz and brought in the knowledge for consideration of Hon'ble Minister Sh. Piyush Goyal.

1. All the Services Provided by CDSCO should be brought under Right to Service Act with Auto Appeal System Deemed Approvals if Service not delivered in prescribed Time Lines and auto appeal system for accountability of service provider.

2. Non-Functioning of ONDLS Portal not working properly and delay occur.

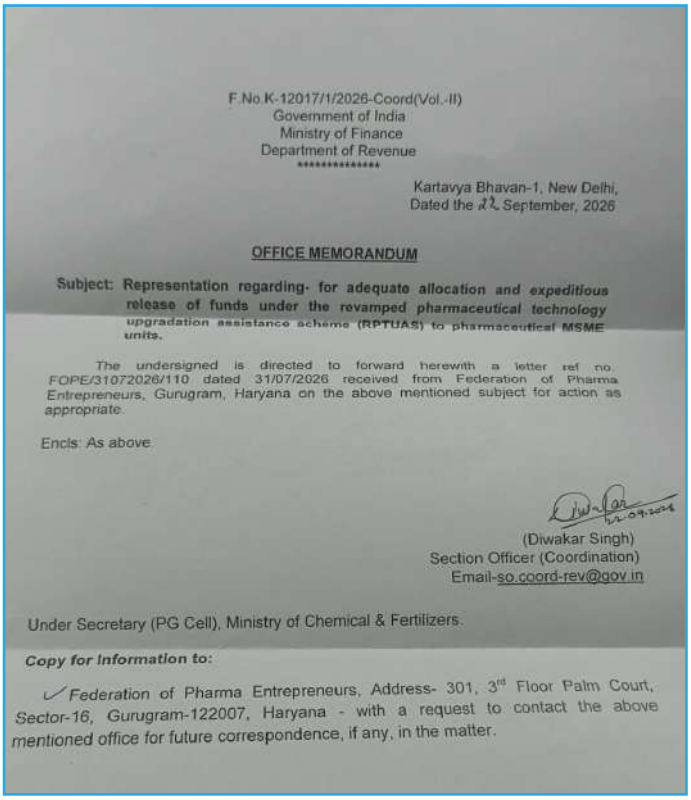
3. For Export NOC - All the products which are already approved in India, included in IP Declared Rational by Kokate Committee NOC should not be demanded. Export NOC should be limited only to Habit Forming Drugs.

4. BA / BE studies for already approved Drugs should not be demanded.

5. Retrospective Application of Rules made specially New Drug and Clinical Trial Rules 2019 should not be done.

FOPE'S RPTUAS REPRESENTATION FORWARDED FOR APPROPRIATE ACTION

Date: Tuesday, 22nd September 2026



F.No.K-12017/1/2026-Coord(Vol.-II)
Government of India
Ministry of Finance
Department of Revenue

Kartavya Bhavan-1, New Delhi,
Dated the 22 September, 2026

OFFICE MEMORANDUM

Subject: Representation regarding- for adequate allocation and expeditious release of funds under the revamped pharmaceutical technology upgradation assistance scheme (RPTUAS) to pharmaceutical MSME units.

The undersigned is directed to forward herewith a letter ref no. FOPE/31072026/110 dated 31/07/2026 received from Federation of Pharma Entrepreneurs, Gurugram, Haryana on the above mentioned subject for action as appropriate.

Encls: As above

(Diwakar Singh)
Section Officer (Coordination)
Email-so.coord-rev@gov.in

Under Secretary (PG Cell), Ministry of Chemical & Fertilizers.

Copy for information to:

Federation of Pharma Entrepreneurs, Address- 301, 3rd Floor Palm Court, Sector-16, Gurugram-122007, Haryana - with a request to contact the above mentioned office for future correspondence, if any, in the matter.

FOPE Inputs: Your voice is loud and clear and the Government is listening

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Circulars & Notifications



01. GOVERNMENT NOTIFICATION

Draft Notification S.O. 4996(E) dated 3rd September 2026 on Restriction of Antimicrobials for Animal Use

Government Proposes Restrictions on Certain Antimicrobials for Animal Use

The Ministry of Health and Family Welfare has proposed restricting the import, manufacture, sale and distribution of certain antimicrobial medicinal products for animal use due to potential risks to human health and the availability of safer alternatives.

The draft notification, issued under Section 26A of the Drugs and Cosmetics Act, 1940, proposes restrictions on Carboxypenicillins and Phosphonic Acid Derivatives, including their formulations for animal use.

Stakeholders have been invited to submit objections and suggestions within 30 days from the date the Gazette is made available to the public.

02. GOVERNMENT NOTIFICATION

CDSCO Public Notice dated 5th September 2026 on Misbranded and Spurious Drugs

Drug Regulators Intensify Action Against Illegal Drug Supply Networks

The CDSCO and drug enforcement agencies have intensified coordinated surveillance against the illegal manufacture and distribution of misbranded and spurious drugs.

Following a search by Delhi Police and Drugs Control officials, Rabies Vaccine (Abhayrab), Batch No. KE25012, was seized from an unlicensed premises in Delhi and subsequently reported as misbranded and Not of Standard Quality by the Central Drugs Laboratory, Kasauli.

CDSCO has alerted State Drugs Controllers to maintain vigilance and take appropriate regulatory action.

Four persons have been arrested, with further investigation and legal action underway.

FOPE Insight:
FOPE Committed for Quality of Drugs appreciate the efforts of Apex Regulators / DCGI and request such comparative chart between Original / Genuine Drug Product and Counterfeit Drugs Sampled Drugs from Market should be issued as Alerts to save the public health at large and for easy detection of Counterfeit Drugs and Save the Brands from Counterfeiting.

03. GOVERNMENT NOTIFICATION

Minutes of the 94th DTAB Meeting held on 27th August 2026 on Drug and Medical Device Regulatory Reforms

DTAB Recommends Key Reforms to Strengthen Drug and Medical Device Regulation

The Drugs Technical Advisory Board (DTAB), in its 94th meeting, recommended several regulatory changes covering drug imports, clinical trials, GMP requirements, wholesale licensing and medical devices.

Key recommendations include adding more ports/ICDs/SEZs for faster drug and medical device clearance, introducing prior intimation for certain new-drug imports and reducing Form CT-17 processing time to 45 working days, and requiring wholesale licence competent persons to be registered pharmacists.

The Board also recommended that no new nicotine formulations be approved, mandatory e-RaktKosh registration and donor authentication for blood centres, and several medical device rule amendments.

Circulars & Notifications

DTAB further recommended prohibition of manufacture, sale and import of Lindane.

FOPE Insight:
FOPE advocated for inclusion of FOPE, ie. MSME representative in DTAB

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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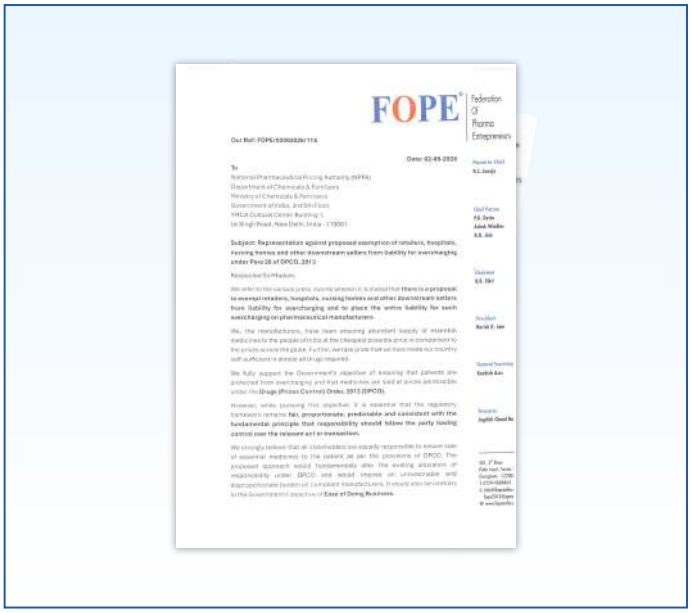
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Representations



FOPE Representations

FOPE REPRESENTATION ON DPCO LIABILITY FOR DOWNSTREAM-SELLERS



FOPE Urges NPPA to Retain Balanced Responsibility for Overcharging

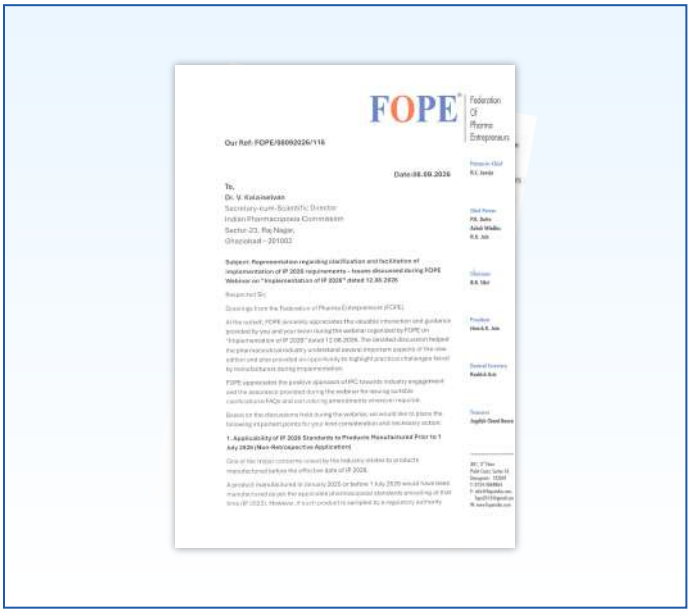
FOPE has submitted a representation to the National Pharmaceutical Pricing Authority (NPPA) opposing the proposed exemption of retailers, hospitals, nursing homes and other downstream sellers from liability for overcharging under Para 26 of the DPCO, 2013.

FOPE highlighted that the existing framework already assigns responsibilities across different stages of the pharmaceutical supply chain and that overcharging at the retail level occurs at the point of sale, which is generally beyond the manufacturer's control.

The federation urged NPPA to retain a proportionate, risk-based responsibility framework, with accountability linked to the stakeholder controlling the transaction.

FOPE also suggested strengthening the PHARMA SAHI DAAM (PSD) system and updating manufacturer-submitted prices to ensure clarity, compliance and ease of doing business.

FOPE REPRESENTATION ON IMPLEMENTATION OF IP 2026



FOPE Seeks Clarifications and Practical Guidance on IP 2026 Requirements

Following FOPE's webinar on "Implementation of IP 2026", the federation submitted a representation to the Indian Pharmacopoeia Commission (IPC) highlighting practical implementation challenges faced by pharmaceutical manufacturers.

FOPE sought clarification that IP 2026 requirements should not apply retrospectively to products manufactured before its effective date and requested reconsideration of newly introduced upper limits for sensitive vitamins.

It also called for clear guidance on alternative analytical methods, reference standards, equivalent HPLC columns, controlled substances used for testing, and availability of impurities specified in IP 2026 monographs.

FOPE further urged IPC to develop consolidated FAQs and practical guidance to ensure uniform interpretation, smoother regulatory implementation and a seamless transition to IP 2026.

FOPE Representations

FOPE REPRESENTATION ON FDC NOTIFICATION FOR CHLORPHENI-RAMINE–PHENYLEPHRINE COMBINATIONS

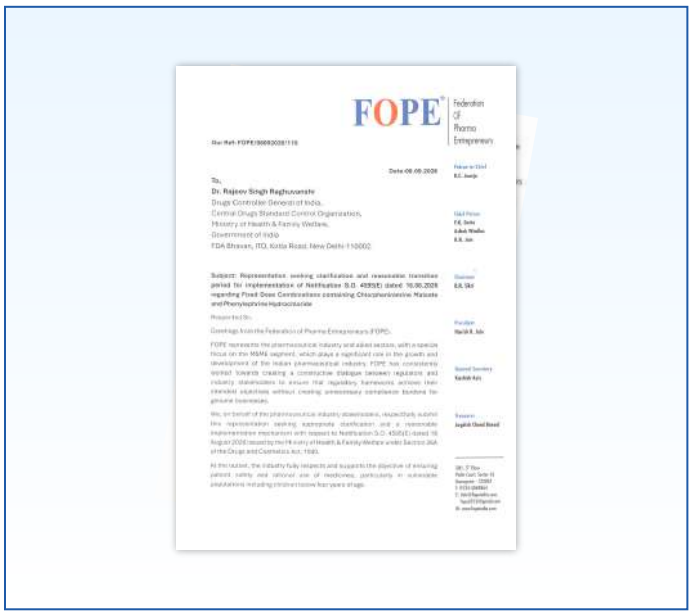


FOPE Seeks Transition Period and Clarification on New FDC Warning Requirements

FOPE has submitted a representation seeking clarification and a reasonable transition period for implementation of Notification S.O. 4595(E) dated 18 August 2026 concerning fixed-dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride. FOPE highlighted concerns over the treatment of existing stocks manufactured before the notification and urged that the new warning requirement be applied prospectively, without penalising products manufactured and marketed under the earlier applicable requirements.

The federation also requested a practical compliance mechanism, including permission to use warning stickers or stamps on existing stock, and clear guidance on the precise formulations and dosage forms covered. FOPE urged uniform implementation across stakeholders while ensuring patient safety and avoiding unnecessary disruption to compliant businesses.

FOPE REPRESENTATION ON FDC NOTIFICATION FOR CHLORPHENI-RAMINE–PHENYLEPHRINE COMBINATIONS



FOPE Seeks Clarification and Transition Period for New FDC Warning

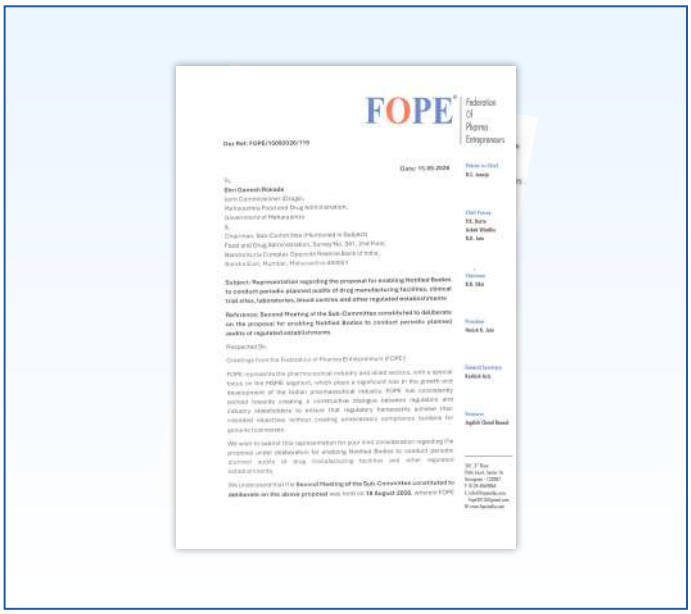
FOPE has submitted a representation seeking clarification and a reasonable transition period for implementing Notification S.O. 4595(E) dated 18 August 2026 concerning fixed-dose combinations containing Chlorpheniramine Maleate and Phenylephrine Hydrochloride.

FOPE requested that the new warning requirement stating that such combinations should not be used in children below four years be applied prospectively and not retrospectively to products manufactured and marketed under earlier requirements.

The federation also sought adequate time for existing stocks to move through the supply chain and proposed practical compliance measures, including permission to affix warning stickers or stamps and modify package inserts. FOPE further urged clear guidance on the precise formulations and dosage forms covered to ensure uniform implementation without unnecessary disruption to compliant businesses.

FOPE Representations

FOPE REPRESENTATION ON NOTIFIED BODIES FOR DRUG MANUFACTURING AUDITS

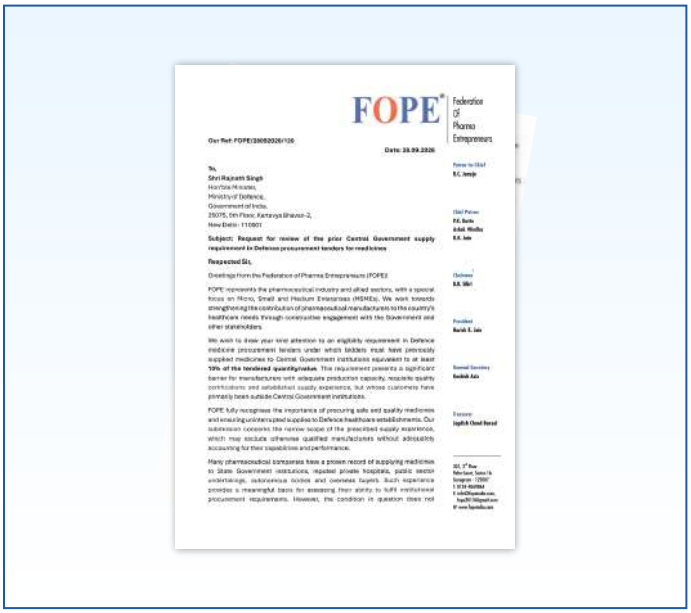


FOPE Seeks Review of Proposed Notified Body Audit Mechanism

FOPE has submitted a representation regarding the proposal to enable Notified Bodies to conduct periodic planned audits of drug manufacturing facilities, clinical trial sites, laboratories and other regulated establishments. FOPE called for a detailed assessment of the need and regulatory value of introducing an additional inspection mechanism alongside existing State FDA and CDSCO inspections. It also sought clarity on auditor qualifications, administrative control, accountability, the role of Licensing Authorities and the financial impact on manufacturers, particularly MSMEs.

FOPE urged the Government to consult pharmaceutical manufacturers and State Licensing Authorities before implementation and ensure that any new framework strengthens regulatory oversight without creating duplication, additional costs or unnecessary compliance burdens.

FOPE REPRESENTATION ON DEFENCE PROCUREMENT ELIGIBILITY FOR MEDICINES



FOPE Seeks Review of 10% Prior Supply Requirement in Defence Tenders

FOPE has submitted a representation to the Ministry of Defence seeking review of the requirement that pharmaceutical bidders must have previously supplied medicines to Central Government institutions equivalent to at least 10% of the tendered quantity. FOPE highlighted that the condition may exclude capable manufacturers, particularly MSMEs, whose experience is primarily with State Government institutions, public hospitals, PSUs, autonomous bodies and overseas buyers. It also noted that restricting eligible bidders could reduce competition and affect procurement costs.

FOPE proposed removing the mandatory 10% Central Government supply requirement or broadening eligible supply experience and accepting alternative criteria such as GMP certification, statutory licences, turnover, quality compliance and institutional supply performance.

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 Judgements

01. LANDMARK JUDGMENT

Case: Cipla Pharma and Life Sciences Limited vs State of Maharashtra & Ors.

Case No.: Writ Petition No. 11376 of 2026

Court: Bombay High Court, Civil Appellate Jurisdiction

Order Date: 29 August 2026

The Bombay High Court considered Cipla's challenge to an action taken by the Maharashtra FDA/State Department. During the proceedings, the State informed the Court that the impugned order would be withdrawn forthwith. The Department agreed to issue a fresh, specific show-cause notice while considering Cipla's earlier notice and its interim and final replies dated 20 August and 25 August 2026.

The Court recorded that the Department would serve the fresh notice, along with relevant documents, by email by 04 S eptember 2026, and Cipla would submit its detailed reply by 11 September 2026. If a personal hearing was considered necessary, the Department could schedule it with at least five days' notice. The Court also directed that a reasoned order be passed and served on Cipla within 24 hours.

Accordingly, the Writ Petition was disposed of in view of the State's undertaking to withdraw the impugned action and follow the fresh show-cause and hearing process.

FOPE Insight:
The Maharashtra FDA had cancelled the wholesale and carrying/forwarding drug licences for Cipla's Wadki facility in Pune over alleged packaging and recall irregularities concerning Reactin Plus tablets-Following the court's strict rap, the Maharashtra FDA agreed to withdraw the cancellation order.

The authority must now issue a fresh show-cause notice and conduct a proper hearing on a regular working day before passing any reasoned order

02. LANDMARK JUDGMENT

Case: Indira IVF Hospital Limited Medical Store Thr. Dondhiram Dattabuwa Bharati vs. State of Maharashtra & Others

Case No.: Writ Petition No. 11482 of 2026

Court: Bombay High Court, Aurangabad Bench

Decided on: 01 September 2026

The Bombay High Court considered a petition challenging an order passed by the Assistant Commissioner, Drugs and License Authority, Food and Drugs Administration Department, Chhatrapati Sambhajinagar, suspending the licence of the medical store attached to the petitioner's hospital. The suspension order was passed on 28 August 2026 under the Drugs and Cosmetics Act, 1940, but was served on the petitioner only on 31 August 2026, with the suspension scheduled to take effect from 1 September 2026.

The petitioner contended that the extremely short period between service of the order and its effective date deprived him of sufficient time to approach the competent appellate authority. The Court noted that Section 66(2) of the Drugs and Cosmetics Act, 1940 provides 90 days to approach the competent authority against such an order. Although the State opposed the petition citing serious lapses and irregularities found during inspection and raised the availability of an alternate remedy, the Court held that sufficient time had not been provided to the petitioner to exercise the statutory remedy.

Accordingly, the High Court stayed the effect and operation of the suspension order dated 28 August 2026 for two weeks from 1 September 2026, solely to enable the petitioner to approach the competent

authority under the Act. The Court expressly clarified that it had not expressed any opinion on the merits of the case, and that all contentions of the parties remained open. The writ petition was thereafter disposed of.

FOPE Insight:
This Judgement made this very clear that Sufficient Time should be given to person / firm to file Appeal against the Suspension Order.

Although not given in order but means that Order of STOP PRODUCTION without giving opportunity of being show caused and without giving sufficient time for Appeal is bad in eye of law. Law of Natural Justice prevails

03. LANDMARK JUDGMENT

Case: M/s Super Cardio Devices Private Limited & Others vs State of Haryana

Case No.: CRM-M-11321-2015 (O&M)

Court: High Court for the States of Punjab and Haryana at Chandigarh

Decided: 14 September 2026

The High Court considered a petition seeking quashing of criminal proceedings against the petitioners for allegedly manufacturing "Heart Lung Pack" without a valid drug manufacturing licence. The prosecution treated the product as a "drug" under Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940. The petitioners contended that Heart Lung Pack had never been specifically notified as a drug through an Official Gazette notification, as required by Section 3(b)(iv).

The Court held that merely being a medical device used for medical purposes does not make a product a "drug" under Section 3(b)(iv). A device must be specifically brought within the statutory definition through a Central Government notification in the Official Gazette, after consultation with the Board. The 06.10.2005 notification mentioned "Catheters" but not Heart Lung Pack; the 20.03.2009 clarification and 07.09.2012 departmental communication were only administrative documents and could not substitute for the required statutory notification. The Court also noted that the subsequent clarification could not retrospectively create criminal liability for manufacture in 2010.

Accordingly, the Court found that the prosecution lacked the foundational statutory basis to treat Heart Lung Pack as a "drug" on the date of the alleged manufacture. Continuing the proceedings would amount to an abuse of the process of law. The complaint, summoning order and consequential criminal proceedings were quashed.

FOPE Insight:
Prosecution has failed to establish the necessary statutory foundation for treating the product manufactured by the petitioners on the relevant date as a "drug" under Section 3(b)(iv) of the Act, 1940. The subsequent administrative communications, including the letter dated 07.09.2012, cannot retrospectively supply the requirement of a statutory notification so as to sustain criminal liability for the alleged manufacture in the year 2010.

This Judgement in a way provide that Administrative Order cannot have retrospective effect.

04. LANDMARK JUDGMENT

Case: Union of India vs M/s Salus Pharmaceuticals & Ors.

Case No.: Special Leave Petition (Criminal) Diary No. 50645/2026

Court: Supreme Court of India

Order Date: 15 September 2026

The Union of India challenged the final judgment and order dated 07 May 2026 passed by the High Court of Himachal Pradesh in CRMMO No. 929/2023 concerning M/s Salus Pharmaceuticals & Others. The matter came before the Supreme Court as a Special Leave Petition under Article 136 of the Constitution.

The Supreme Court condoned the delay in filing the petition, but found no sufficient ground to interfere with the impugned judgment/order in exercise of its jurisdiction under Article 136. The Court therefore declined to examine the High Court's decision further at the SLP stage.

Accordingly, the Special Leave Petition was dismissed, and all pending applications were disposed of. Thus, the High Court's order dated 07 May 2026 remained undisturbed.

FOPE Insight:
Judgement of hon,ble Himachal high court in Salus pharmaceutical -vs- UOI. Upheld , SLP of Union of Indian (DCG(I)) dismissed This has clarified the Jurisdiction Issue between state and Center Drugs Inspectors Expert opinion Chapter III of the Drugs Act enforcement by CDSCO Inspectors and Chapter IV of the Drugs Act enforcement by State Drugs Inspectors / Regulators.

05. LANDMARK JUDGMENT

Case: M/s. Pharmed Limited & Anr. vs Union of India & Ors.

Case No.: Writ Petition No. 595 of 2017 with Chamber Summons No. 135 of 2017

Court: Bombay High Court, Ordinary Original Civil Jurisdiction

Decided: 22 September 2026

The Bombay High Court considered a challenge to notifications and demand notices issued by the National Pharmaceutical Pricing Authority (NPPA) alleging overcharging on Cartigen Forte Tablets, a formulation used for osteoarthritis, under the Drugs (Prices Control) Order, 1995 (DPCO 1995). The petitioners contended that no ceiling price had been validly fixed for the formulation and that the impugned notifications could not be applied to it.

The Court noted that the formulation's active ingredients included Glucosamine Sulfate Potassium Chloride, Chondroitin Sulfate Sodium and Methyl Sulfonyl Methane. The Court held that even where a formulation qualifies as a scheduled formulation, ceiling price fixation under paragraphs 9 and 11 of DPCO 1995 had to follow the specific price-calculation formula under paragraph 7 and be notified in the Official Gazette. Since this exercise was never undertaken for Cartigen Forte, the 27.09.2007 notification concerning multivitamin and mineral formulations could not be applied to it. The Court further held that the 30.01.2009 NPPA notification was overly broad and ultra vires DPCO 1995, as it effectively bypassed the prescribed price-fixation mechanism.

Accordingly, the Court allowed the writ petition. The notification dated 27.09.2007 was quashed insofar as it applied to the petitioners' formulation, while the notification dated 30.01.2009 was quashed in its entirety. Consequently, the related demand notices for alleged overcharging, including recovery proceedings under the Maharashtra Land Revenue Code, were also set aside, and the respondents were directed not to act upon those demands.

FOPE Insight:
NPPA Cannot Apply Blanket Drug Price Ceiling Without Following DPCO Formula: Bombay HC Quashes Notifications and ₹13-Crore-Plus Demand. NPPA Notifications on ceiling prices should have legal basis and based on Formula given in DPCO and Demand Notice should not be arbitrary and should be based on Law of Natural Justice

06. LANDMARK JUDGMENT

Case: Shri Deepak Kumar & Others vs The State of Meghalaya & Others

Case No.: Crl. Petn. Nos. 53/2025, 54/2025 & 56/2025

Court: High Court of Meghalaya, Shillong

Order Date: 23 September 2026

The High Court considered three petitions arising from criminal complaints under the Drugs and Cosmetics Act, 1940 and Rules, 1945, involving Directors and employees of a company. The complaints alleged offences under Sections 18(a)(i), 17(b), Rule 96 and Schedule P, punishable under Section 27(d). The central issue was whether prosecution could continue against the Directors and employees when the company itself had not been made an accused.

Relying on the Constitution Bench judgment in Aneeta Hada v. Godfather Travels & Tours Pvt. Ltd., the Court held that arraigning the company as an accused is a condition precedent for fastening vicarious liability on its Directors or other responsible officers. The Court found Section 34 of the Drugs and Cosmetics Act to be pari materia with Section 141 of the Negotiable Instruments Act and held that the principle in Aneeta Hada squarely applies to prosecutions under the Drugs and Cosmetics Act.

Accordingly, the Court held that the Magistrate could not have taken cognizance against the petitioners without the company being arrayed as an accused. The orders issuing process in C.R. Case Nos. 04/2025 and 08/2024, along with the consequential criminal proceedings, were quashed and set aside.

FOPE Insight:
Learned Magistrate could not have taken cognizance of the two complaints filed by the Inspector qua the petitioners, without the company being arrayed as an accused.

In view of the aforesaid legal position, the petitions deserve to be allowed. Accordingly, the orders issuing process passed by the learned Chief Judicial Magistrate, South Garo Hills District, Baghmara and consequently, the proceedings pending before the learned Chief Judicial Magistrate, South Garo Hills District, Baghmara, are quashed and set aside.

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



Counterfeit Drugs Problem & Solution



By: Shri Narender Kumar Ahooja
Ex-SDC, Haryana,
Regulatory Consultant, FOPE

Counterfeit Drugs in India: The Growing Problem and the Way Forward

The increasing detection of counterfeit drugs in India is a matter of serious concern—not only for drug regulators and the pharmaceutical industry, but, most importantly, for the patient, who is the ultimate consumer of medicines.

Almost every day, reports appear in print and electronic media about counterfeit medicines being detected during investigations, raids, inspections and market surveillance. The situation becomes particularly alarming when counterfeit versions of well-known and trusted brands are detected in the market.

When a patient hears that a counterfeit version of a familiar medicine has been found, an obvious question arises:

"How can I be sure that the medicine I am taking is genuine?"
This directly affects public confidence in the Indian pharmaceutical supply chain.

Why is counterfeiting increasing?

An analysis of cases detected by State Drug Regulatory Authorities suggests that the problem needs to be examined from the entire ecosystem of manufacturing, employment, licensing and distribution.

One category that deserves attention is manufacturing establishments that have been ordered to stop production or whose licences have been cancelled, particularly following the implementation and enforcement of revised Schedule M requirements.

Some such establishments may continue to possess manufacturing infrastructure, machinery and technical manpower but no longer legally permitted to manufacture medicines. A second category consists of establishments operating in the nutraceutical/food-product space under FSSAI regulation and Ayurvedic Drug Manufacturing Units.

The regulatory boundary between food/ nutraceutical products and drugs can sometimes create enforcement gaps. Where regulatory responsibility is unclear or inspections are inadequate.

Unscrupulous operators may exploit that gap to manufacture or introduce counterfeit medicines. Thus, counterfeiting should not be viewed merely as a question of criminal intent. Regulatory gaps, abandoned manufacturing infrastructure, unemployed technical manpower and weaknesses in the distribution chain can collectively create an ecosystem in which counterfeiting becomes easier.

Stop-production orders alone may not solve the problem

Whenever a legitimate manufacturing unit is found non-compliant, regulatory action is obviously necessary. However, merely shutting down a facility may sometimes create another unintended problem.

A closed factory may still have:

- manufacturing machinery;
- premises capable of pharmaceutical
- production;
- technical staff possessing manufacturing expertise; and
- an established local supply and distribution network.

If these resources move into an illegal ecosystem, the problem can become more difficult for regulators. Therefore, wherever feasible and legally permissible, regulatory authorities should combine enforcement with a structured upgradation and hand-holding mechanism.

Instead of immediately pushing every non-compliant unit outside the regulated system, authorities could consider a graded approach:

Identify → Correct → Upgrade → Inspect → License → Monitor.

The objective should be to bring as many genuine manufacturing facilities as possible into compliance rather than allowing their infrastructure and manpower to migrate into an illegal market.

What should happen to machinery after closure?

Where a manufacturing licence is permanently cancelled or a stop-production order cannot be reversed, there should be a formal mechanism for securing, disabling, transferring or disposing of pharmaceutical manufacturing machinery.

This was discussed in DCC as agenda brought by Rajasthan and referred to the subcommittee.

Otherwise, machinery belonging to a closed unit can potentially be diverted to clandestine manufacturing.

A regulatory framework could therefore provide for:

- inventory of major manufacturing equipment;
- sealing or disabling of critical equipment where appropriate;
- documented disposal or authorised transfer;
- verification that the premises are no longer being used for unauthorised pharmaceutical production; and
- periodic surveillance in high-risk cases.

The technical manpower issue

There is another dimension that deserves serious consideration.

A compliant pharmaceutical manufacturing unit employs, production personnel, quality-control professionals, other technically trained workers. When a facility is closed, these people can suddenly become unemployed. Their technical knowledge, however, remains.

Therefore, the regulatory system should also consider the rehabilitation and redeployment of skilled technical manpower.

Industry associations and State Drug Authorities could facilitate employment in compliant manufacturing facilities rather than allowing technical expertise to be absorbed by an illicit manufacturing network.

The nutraceutical and Ayurvedic Drug Manufacturing regulatory grey area

One of the most important areas requiring coordinated action is the interface between FSSAI and CDSCO/State Drug Regulatory Authorities.

Nutraceuticals and related products can fall into a regulatory space where the distinction between food, health supplements and medicinal products becomes particularly important.

This should not become a "tug of war" between two regulators.

The principle should be:
FSSAI + CDSCO + State Drug Regulators = stronger enforcement

rather than:
FSSAI – CDSCO = regulatory gap.

Where a suspected facility is manufacturing products under an FSSAI framework but there are indications that it is also manufacturing drugs illegally, the matter should trigger coordinated action by the relevant authorities.

Allowing licensed drug manufacturers to manufacture nutraceuticals

There is also a case for reconsidering the policy concerning manufacture of nutraceuticals by licensed pharmaceutical manufacturing units, subject of course to the prevailing legal position and court orders.

Specially Karnataka high court under A pharmaceutical manufacturing unit is already subject to substantial regulatory oversight, including inspections, documentation, quality systems and compliance requirements.

If suitably licensed pharmaceutical manufacturers are permitted to manufacture nutraceutical products under an appropriate regulatory framework, it could potentially reduce the number of isolated and i nadequately monitored facilities operating in this space.

Such a policy would need to be accompanied by clear product classification, licensing conditions, separate records, appropriate GMP requirements and effective regulatory surveillance.

The supply chain is another critical weak point

They become a public-health problem when they enter the legitimate-looking supply chain.

Therefore, enforcement must move beyond manufacturing premises and address:

Manufacturer → Distributor → Stockist → Retailer → Patient

At every stage, regulators should be able to establish:

- who manufactured the product;
- who purchased it;
- who distributed it;
- where it was stocked;
- where it was sold; and
- ultimately, how it reached the patient.

Digital traceability, batch-level verification, inspections and stronger market surveillance can play an important role here.

Need for a national anti-counterfeit strategy

India needs a coordinated National Strategy for Prevention and Detection of Counterfeit Medicines, involving:

CDSCO + State Drug Regulators + FSSAI + Customs + Police/Economic Offences Units + GST authorities + Industry + Digital Supply-Chain Stakeholders.

The strategy should include:

- Risk-based market surveillance
- Joint inspections of high-risk premises
- Intelligence sharing between regulators
- Monitoring of closed/cancelled manufacturing units
- Tracking and disposal of abandoned pharmaceutical machinery
- Monitoring of technical manpower migration where appropriate
- Stronger scrutiny of suspicious nutraceutical establishments
- Digital verification and traceability of medicines

- Stronger action against counterfeit manufacturers and distributors
- Public awareness regarding purchase of medicines only from authorised channels

Conclusion

Counterfeit drugs are not merely a regulatory violation.

They are a direct threat to patient safety and public confidence in the pharmaceutical system. India has a strong pharmaceutical manufacturing base and a generally well-developed regulatory framework.

The challenge is to ensure that regulatory gaps between different jurisdictions do not become opportunities for criminals.

The solution therefore cannot be only "close the factory and prosecute the offender."

The broader approach should be:

Regulate + Upgrade + Monitor + Trace + Coordinate + Enforce.

The objective should be to ensure that every legitimate manufacturing facility remains within the regulated system, every closed facility is prevented from becoming a source of illicit manufacturing, every regulatory grey area is jointly monitored, and every counterfeit medicine is traced back through the supply chain.

Most importantly, the patient should never have to wonder:

"Is the medicine in my hand genuine?"

Restoring and maintaining that confidence must be the ultimate objective of India's anti-counterfeit drug strategy.



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.

FOPE®

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