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E-Newsletter

DCOIWA News

Drugs Control Officers (I) Welfare Association (Regd)

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Monthly Newsletter

For circulation among DCOIWA members only

In collaboration with The Health Master

Published on 1st day of every month

5 Northern State SDCs Unite Against Counterfeit Drugs

As the threat of counterfeit drugs and psychotropic substances looms increasingly large, a meeting of minds and policies has forged a united front.

Regulators across five northern states **Jammu and Kashmir, Himachal Pradesh, Haryana, Uttarakhand,** and **Punjab** have come together to formulate a strategy to overcome the menace.

The meeting was held at **Himachal Bhavan** under the guidance of the Drug Control Administration of Himachal Pradesh **(DCA HP)** to ensure a strong and united front against the malpractice that has crippled the northern pharmaceutical market for years.

Led by Dr. Manish Kapoor, the **State Drug Controller** (**SDC**) of **DCA HP**, the meeting aimed to bolster inter-state coordination to crack down on inter-state drug rackets.

Regulators Come Together to Protect Public Health

The increased frequency of counterfeit drugs and illicit psychotropic drug regulations is an emergency risk to public health for residents across North India.

However, drug regulators met to strategize an outline to combat the growing malpractices firmly.

The five northern states, **Jammu & Kashmir, Himachal Pradesh, Haryana, Uttarakhand,** and **Punjab** have come together to formulate a strategy to overcome the menace.

This meeting was headed by **Drug Controller** of DCA HP **Dr. Manish Kapoor**.

Meeting of the Minds

The meeting took place in **Chandigarh** and welcomed regulators from across the region to attend in person or virtually.

Besides **DCA HP** head **Dr. Manish Kapoor**, the other **SDCs** included **Lotika**

(Continued on page 14)

Editorial Board

D C O I W A N E W S

Rakesh Dahiya

Editor-in-Chief
DCOIWA Newsletter

Celebrating Our 20th Edition

It's hard to believe, but this very issue marks our **20th Edition** of the DCOIWA Newsletter. Two years! Twenty months of sharing, learning, and strengthening the bonds that connect every single Drugs Control Officer across this great nation. Twenty times we've gathered the crucial threads of our profession into one place, and with each edition, the energy of our association, the **DCOIWA**, only seems to grow stronger.

This isn't just a newsletter; it's a mirror reflecting the tireless, often unseen, work we all do—work that touches the lives of millions.

The Power of Being United

This edition is packed with stories that highlight our collective strength. Just look at the news of **Five Northern State SDCs Uniting Against Counterfeit Drugs**. This isn't just a headline; it's a testament to the fact that counterfeiters don't respect state lines, and neither should we. When we stand shoulder-to-shoulder, the wall we build against fake medicines becomes impenetrable. This spirit of cooperation is the very heart of effective drug regulation in India.

And speaking of heart, we've dedicated significant space to celebrating **World Pharmacists Day 2025**. From Rajasthan to West Bengal, the celebrations remind us that our colleagues—the pharmacists—are the final link in the chain, the professionals who ensure the right medicine gets to the right patient. Their expertise is a pillar of public health, and their day deserves every bit of the recognition we've given it.

Digging into the Details

The beauty of our work lies in the **detailed procedures** that keep the system honest and safe. This month, our exclusive articles pull back the curtain on some of the most critical aspects of our jobs. For anyone involved in ensuring quality, the **Procedure to Obtain a License for Manufacturing of Drugs** and the **Standard Operating Procedure for Inspection of Manufacturing Units** are must-reads. These aren't just dry legal documents; they are the blueprints for keeping quality control a non-negotiable standard.

(Continued on page 4)

(Continued from page 3)

The coverage of the **Overview of current statutory provisions related to MTP Kits** is incredibly timely and important. The work of our colleagues in **FDA Haryana** taking strong action against illegal selling is a stark reminder of the vigilance required to protect vulnerable people. Our duty extends far beyond just checking labels; it's about upholding ethical and legal access to crucial health services.

A New Era of Regulation

The regulatory landscape is constantly evolving, and this issue captures that perfectly. The news that **Indian Drug Regulation is Going 97% Digital** is huge. This shift, driven by **CDSCO**, promises to simplify our processes and make the entire system more transparent and efficient. We are also seeing important, human-centric changes, like the push for **Braille Labeling on Medicine Strips**. This small but mighty change ensures medicine safety for our visually impaired citizens a truly compassionate move that brings regulation into the service of all.

Celebrating Our People

Ultimately, the most valuable asset in our field is the **human element**. This edition is full of well-deserved recognition:

- We send a huge congratulations to **Sh. Rakesh Dahiya** on his promotion to Asstt. State Drugs Controller an inspiring example of dedication being rewarded.

- We warmly welcome the **49 New Drug Inspectors joining CDSCO**—the next generation of regulators ready to take up the mantle.

We pause to honor our colleagues in the **President's Note on the retirements**. Their years of service have built the foundation we now stand on.

The work we do from banning key antimicrobials for animal use to redefining cocrystals, from tracking NSQ samples to fighting fake drugs in Puducherry is complex, challenging, and profoundly important.

As we turn the page to the 20th time, let's recommit to the core values of integrity, vigilance, and cooperation. Thank you for being the human face of drug control. Your efforts truly make India a safer place, one license, one inspection, one decision at a time.

We hope you enjoy this detailed and dedicated edition!

———

President Note

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(Regd.No. 634 of 2022)
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Mr. Tapan Ch
Cell: 9[illegible]

Date: 1st October 2025
Place: Hyderabad.

President's Note

Dear Members,
Greetings to all of you.

As we step into October 2025, I find it an opportune moment to reflect on our shared journey and the pressing matters that demand our attention in the field of drug control and regulation. Our role—ensuring public health, curbing misuse, maintaining drug quality, and protecting consumers—is as vital as ever, and the recent developments across India underscore both our challenges and opportunities.

Recent Highlights & Challenges

1. Regulatory Oversight and the Outsourcing Debate

One of the most discussed issues in recent months has been the proposal by the Karnataka Government to outsource regulatory compliance monitoring to a third-party agency (the Quality Council of India). Our Association, and fellow bodies like the All India Drug Control Officers Confederation, have raised serious concerns. Regulatory oversight of drug quality is a statutory function under the Drugs & Cosmetics Act, which requires government officials with legal authority and accountability. Delegating this to external agencies risks diluting accountability, undermining technical expertise, and could compromise transparency. Our collective stance must remain firm: functions critical to public safety should reside with empowered, trained, and accountable drug control officers.

2. Actions Against Illegal Sale & Adulteration

We are seeing active enforcement in many states. For example, Utharpradesh, Telangana's Drugs Control Administrations have carried out several successful raids recently—on quack clinics, unlicensed premises, and outlets illegally stockpiling or distributing drugs without proper licences. These raids are vital reminders of what concerted action can achieve.

3. Antimicrobial Resistance (AMR) and Misuse of Antibiotics

The threat posed by AMR is increasing, and with it, the need for tighter regulation of antibiotic dispensing. Measures being planned, such as restricting over-the-counter sales of certain antibiotics and strengthening prescription tracking, are steps in the right direction. These will require not only regulatory backing but also cooperation from medical practitioners, pharmacists, public awareness campaigns, and interdepartmental coordination.

4. Drug Abuse, Treatment, and Preventive Infrastructure

States like Punjab are spearheading efforts to expand access to standardized substance use disorder treatments, creating model centers, and integrating legal, clinical, and communitycentric approaches. Meanwhile, other regions are beginning to recognize that enforcement alone is insufficient if not coupled with treatment, rehabilitation, and public health measures.

President Note

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Our Call to Action

Strengthen Statutory Authority: We must advocate for clarity in law that reinforces that core regulatory functions rest with government drug control officers—not third parties.

Continuous Training & Capacity Building: As laws, drug markets, and illicit practices evolve, our technical competency must keep pace. Workshops, webinars, and handson enforcement training are essential.

Better InterState and Central Coordination: Many illicit networks and regulatory challenges cross borders. Sharing intelligence, harmonizing processes, and having unified standards across states will improve efficiency and efficacy.

Engaging Stakeholders & Public Awareness: From pharmacists to medical practitioners, and from communityleaders to lay citizens, awareness about proper use, drug safety, and how to report or resist misuse is crucial.

Balancing Enforcement with Compassion: For drug abuse, our approach must not only punish but also treat—promoting more facilities, evidencebased treatment regimens, and minimizing social stigma.

Looking Ahead

As your President, I am committed to steering the Drugs Control Officers India Welfare Association to be not just a professional body but also a force for progressive and principled drug regulation and welfare. In the coming months, we plan to:

- Convene a national committee to draft policy recommendations on the outsourcing issue.
- Organize refresher training programs (both regulatory & legal) in multiple regions.
- Partner with NGOs/academic institutions on AMR awareness initiatives.
- Propose framework guidelines for best practices in deaddiction centres and public health partnerships.

I wish to express my deepest appreciation for your dedication, often in difficult circumstances. Your vigilance, professionalism, and integrity are the backbone of a safer, healthier India. Let us continue working together, with resolve and empathy, to uphold our mandate and serve the public good.

Warm regards,

G. Koteshwar Rao
President
Drugs Control Officers (India) Welfare Association

President Note on Promotion

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Date: 19th September 2025
Place: Hyderabad

To
Shri Rakesh Dahiya Ji,
Editor-in-Chief, DCOIWA Newsletter
Organizing Secretary, DCOIWA
& Trust Board Member, DCOIWT

Subject: Congratulations on Your New Appointment

Dear Shri Rakesh Dahiya ji,

On behalf of the entire Central Executive Committee members and the Trust Board members of DCOIWT, I extend our heartfelt congratulations to you on your appointment as Assistant Drugs Controller, FDA Haryana.

Your dedication, hard work, and commitment to the profession have been truly commendable, and this achievement is a proud moment for all of us. We are confident that in your new role, you will continue to serve with the same zeal and uphold the values of our profession.

With best wishes for your continued success.

Regards,

G. Koteshwar Rao
National President, DCOIWA

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Kukatpally, Hyderabad (T.S), INDIA.
Phone : 8121296397, 8094357800,9977177574.

President Note on Superannuation

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Date: 30 September 2025
Place: Hyderabad.

To
Shri K.G. Gadewar
Assistant Commissioner,
Food & Drugs Administration, Maharashtra.

Respected Sir,

On behalf of the Drugs Control Officers India Welfare Association (DCOIWA) and on my personal behalf, I extend my warm greetings and heartfelt felicitations to you on the occasion of your retirement from Government service.

Your distinguished career in the Food & Drugs Administration, Maharashtra, has been marked by integrity, dedication, and a deep sense of responsibility in safeguarding public health. Your valuable contributions to the regulatory system, professional guidance to colleagues, and commitment to enforcement of drug laws have left an indelible mark and will be remembered with respect.

As you step into a new phase of life, we convey our sincere gratitude for your service and wish you good health, happiness, and a peaceful retired life filled with joy and fulfillment.

With high regards,

Yours sincerely,

(G. Koteshwar Rao)
National President,
Drugs Control Officers India Welfare Association (DCOIWA)

H.Q. 15-21-150/6, New Balaji Nagar,
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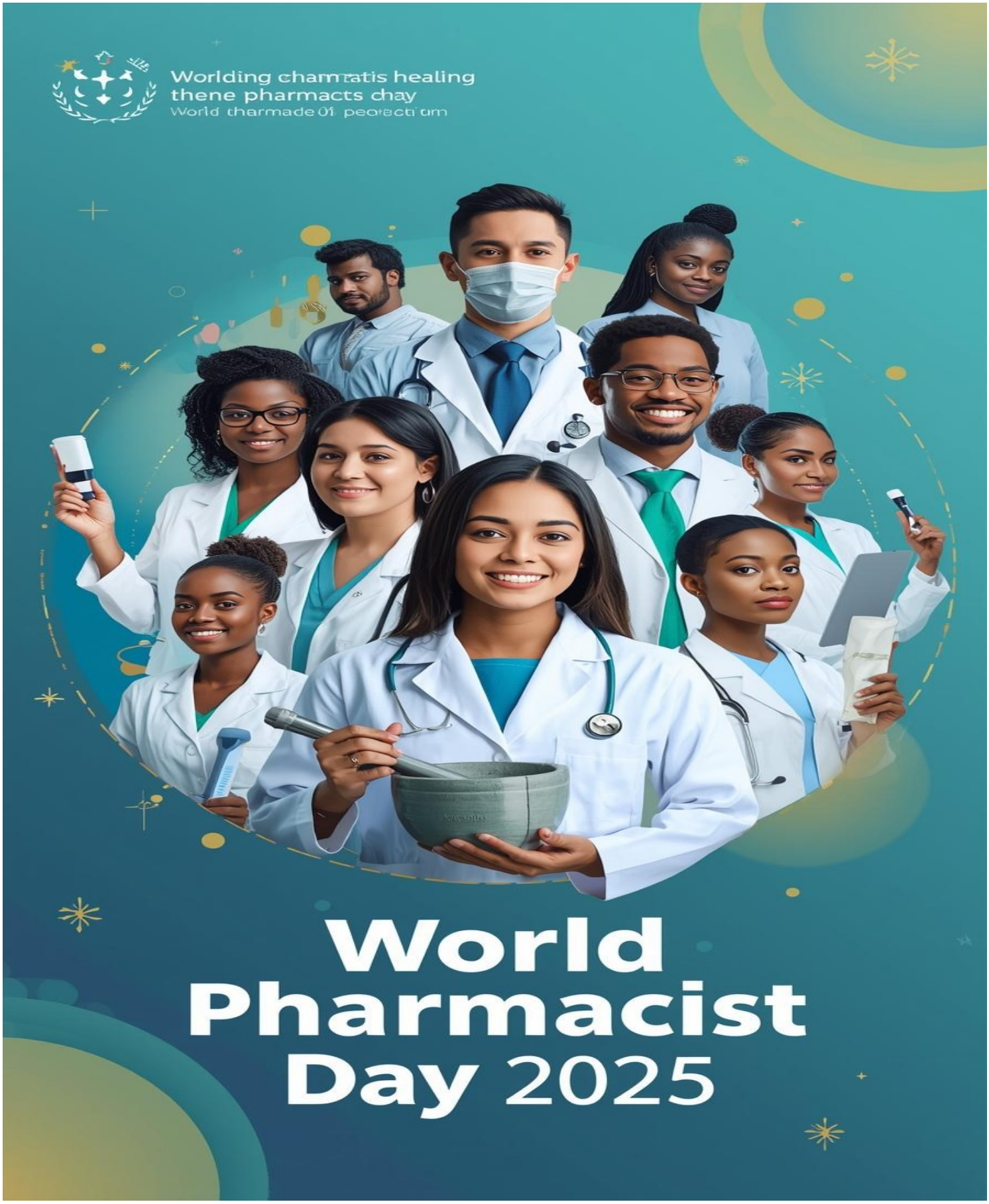
World Pharmacists Day 2025



Message from IPGA President, Telangana on World Pharmacists Day 2025

INDIAN PHARMACY GRADUATES' ASSOCIATION TELANGANA

IPGA - TELANGANA

(Affiliated to IPGA New Delhi - Regn.No. S/8255 of 1976)

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Dr. V. ASHA JYOTHI
Dr. V. KIRAN KUMAR

Date: 25th Sep.2025
Place: Hyderabad

Message on the Occasion of World Pharmacists Day – 25th September 2025

On this World Pharmacists Day, with the inspiring theme "Think Health, Think Pharmacist", we proudly acknowledge the pivotal role pharmacists play in safeguarding public health and ensuring access to quality medicines.

Pharmacists are not only dispensers of medicines but also trusted healthcare professionals who guide patients towards safe, effective, and rational use of drugs. Our profession bridges science and service, ensuring that every individual receives the right medicine, in the right dose, at the right time.

As we celebrate this special day, let us reaffirm our commitment to advancing pharmacy practice, promoting patient well-being, and contributing to a healthier India. Together, let us continue to strengthen public trust in our profession and live up to the belief that when you "Think Health, Think Pharmacist."

On behalf of the Indian Pharmacy Graduates Association, Telangana Branch, I extend my heartfelt greetings to all pharmacists, students, and healthcare professionals who dedicate their lives to this noble cause.

G. Koteshwar Rao
President, Indian Pharmacy Graduates Association
Telangana , Hyderabad.

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World Pharmacists Day 2025 celebration Rajasthan

16th World Pharmacist Day Celebration Mahatma Gandhi Medical College & Hospital, A Unit of Mahatma Gandhi University of Science & Technology (MGUMST), Jaipur on 25th September, 2025

The 16th World Pharmacist Day was celebrated with great zeal & enthusiasm by Pharmacy Wing of Mahatma Gandhi Medical College & Hospital, A Unit of Mahatma Gandhi University of Science & Technology (MGUMST), Jaipur on 25th September after gaining the status of First Academic Medical Centre in India to secure Joint Commission International (JCI) accreditation in June 2025. The institute is already having to its credit NABH, NABL accreditation with NAAC A+ ranking. All the departments of the institution have to put their hundred percent efforts in achieving all these quality milestones in the 1450 bedded hospitals for which unwavering support and driving force of the management key to grand success.

In the back drop of these achievements World Pharmacist Day was celebrated ceremoniously by Pharmacy Wing of the institution which is one of the most important wings of the academic medical centre & hospital.

Mr. R. S. Thakur, former Assistant Drugs Controller, Rajasthan is instrumental in managing the affairs of the Hospital Pharmacy & Clinical Pharmacy of the hospital.

Mr. Thakur, while addressing to the strong team of about two hundred hospital pharmacy personnel (including 73 hospital pharmacists and 11 clinical pharmacists which is largest number for any hospital); highlighted the important roles of pharmacists played in attaining the public health while maintaining patients safety goals. Undisputedly the drugs are indispensible for diagnosis, treatment, mitigation or prevention of diseases or disorders and personnel who are involved in manufacturing, research & development, formulation development and quality control at plant site and those who are involved in distribution, procurement, inventory management, preservation of quality, dispensing & counseling are known as PHARMACISTS. Additionally in hospital IPD set up CLINICAL PHARMACISTS plays role in review of reconciliation of drugs, medication appropriateness review, preventing medication errors, carrying out prescription audits, reporting adverse events due to drugs and medical devices, enforcement of antimicrobial stewardship program to minimize their resistance and coordinate with all healthcare team members viz. doctors, nurses and other paramedical staff etc. All these activities of pharmacists are not only to ensure their availability but also ensure safe & effective usage of drugs with minimal effects. FOR ALL THESE ACTIVITIES PHARMACISTS ARE INDISPENSIBLE. Hence this year's theme "THINK HEALH: THINK PHARMACISTS" has been very aptly assigned by the International Pharmaceuticals Federation (FIP) ..... and we are to justify the same.

Celebration ended with distribution of awards to the best performers. Later Pharmacists donated 25 units of blood voluntarily for needy patient in Hospital Blood Centre.

R. S. Thakur, Former ADC, Rajasthan

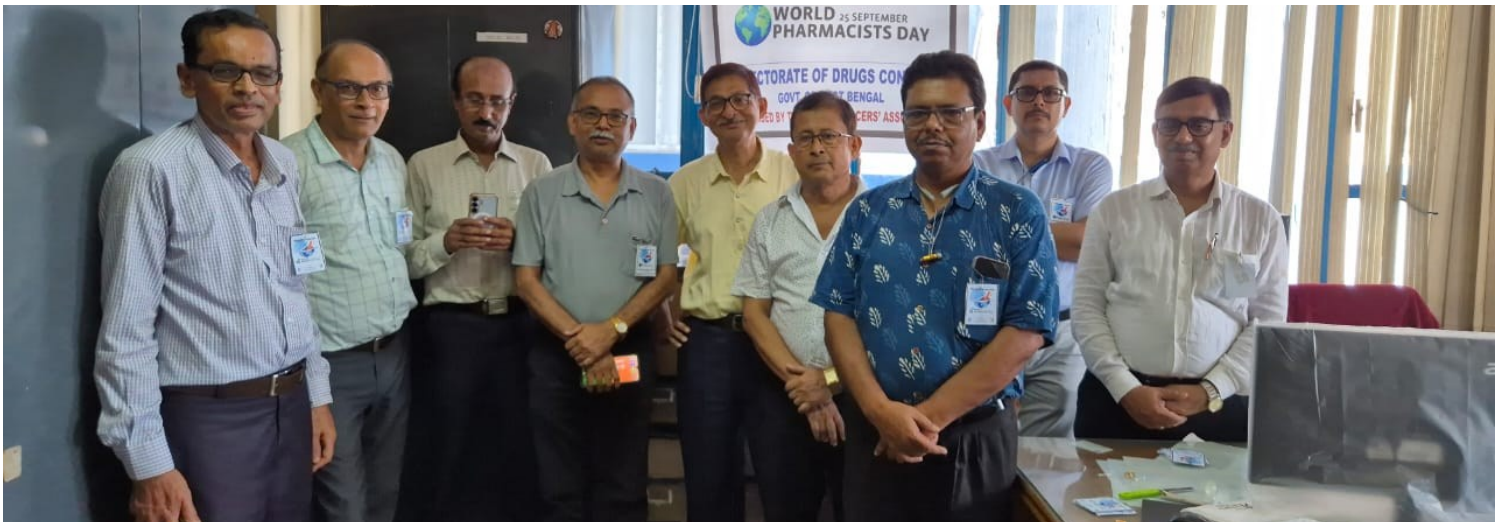
World Pharmacists Day 2025 celebration Rajasthan

25th SEPTEMBER 2025

WORLD PHARMACISTS DAY

CELEBRATION PROGRAMME

World Pharmacists Day 2025 celebration West Bengal



5 Northern State SDCs Unite …….

(Continued from page 1)

Khajuria (Jammu & Kashmir), **Sanjeev Garg** (Punjab), **Lalit Kumar Goel** (Haryana), **Tajber Singh** (Uttarakhand), as well as a representative from Uttar Pradesh.

The intervention and involvement of senior government officials of various departments (health, safety, CID, and NCB) virtually indicate that this challenge is widespread and requires multi-agency intervention.

Objective of the Meeting

The key takeaway from this coalition summit is a primary plan to keep drug lords on their toes and make trading and diversion more challenging.

As recommended by **Lalit Kumar Goel**, SDC from Haryana, an **interstate coordination committee** should be established to promote information/ intelligence exchange between drug controllers, facilitate joint raids, and hold swift investigations.

This initiative will allow cross-border offenders to be more easily apprehended instead of evading arrests simply because they crossed state lines.

One significant resolution is a unanimous appeal to the central government for a **"One Nation–One Dedicated Portal".**

This portal will facilitate real-time tracking of **psychotropic drugs** from manufacturing to users.

Regulators deem this essential for detecting breaches that can lead to exploitation and addiction among vulnerable youth populations.

Finally, these states will improve internal measures, including formulating a seamless **Standard Operating Procedure (SOP)** for swift communication of malpractices as they arise.

Any company found diverting drugs illegally will face more robust legal action.

Future Expectations

Dr. Kapoor confirmed that joint surprise inspections of drug manufacturing companies are here to stay.

Such inspections go hand-in-hand with the activities of anti-narcotics task forces focusing on drug manufacturing and wholesale activity and retail pharmacy practices.

Thus, if any citizen has intel regarding wrongdoings at any level of pharmacy operation, the drug regulators urge them to come forward immediately.

Lalit Kr. Goel believes this can be **a new example for other regions in India.**

With a concentrated focus on interstate collaboration, leveraging technology with frequent adjustments, and compliance investigation tasks forced by intelligence, a more effective and efficient regulatory mechanism will simplify efforts for all in charge and increase safety for civilians.

Source: The Health Master

Procedure to obtain license for Manufacturing of Drugs

Rakesh Dahiya

Editor-in-Chief,
DCOIWA News
Organising Secretary,
DCOIWA
Asstt. State Drugs Controller,
FDA Haryana

How to obtain manufacturing license for drugs

Documents required

For obtaining drug manufacturing license (DML), the list of documents required is provided below. Download the pdf file and prepare the documents accordingly.

Documents-required-for-obtaining-DML

Procedure

Procedure for obtaining manufacturing license for drugs. Download the pdf file for more detail and prepare the documents accordingly.

Procedure-for-obtaining-DML

Forms

List of Forms & Fee for obtaining the said license is provided below.

Download the below pdf files for various Forms which suits your requirement

Form-24

Form-24A

Form-24F

Form-27

Form-27A

Form-27B

Form-30

Click below link to download the fee structure of all types of drug licenses

License fee structure for all licenses

Click below link to download the Area requirement for the manufacturing of Drugs, Cosmetics, Homoeopathic and Blood Centre

Area requirement for manufacturing

Schedule M

Download Schedule M dated 28-12-2023

Gist of 31 Chapters on schedule M

License conditions

Conditions of licenses is to be maintained after obtaining the required manufacturing license for drugs. Download the pdf file for ready reference.

License-conditions-for-manufacturing-of-Allopathic-drugs

Form-51

Form-51: Form of undertaking to the licensing authority for marketing a drug under a brand name or trade name — to be submitted by the manufacturer or on behalf of the manufacturer

FORM-51

(Continued on page 16)

Procedure to obtain license for Manufacturing of Drugs

(Continued from page 15)

Retention Fee

Procedure for submission of license retention fee. Download the pdf file for more detail and prepare the documents accordingly.

Procedure-for-License-retention-fee

List of colors permitted

List of colours permitted in manufacturing of disinfectants, click below link

GSR-623E-dt-10-08-2022-To-include-colour-of-disinfectants-in-rule-127-of-Drugs-Rules-1945

List of Colours Permitted in manufacturing of drug, click below link:

List-of-colours-permitted-to-be-used-in-drugs

Also read the following notification regarding the use of color in Gelatin capsule:

GSR-1186-E-dt-07-12-2018-Rule-1272-Approved-or-permitted-color-in-Gelatin-capsule

Life period of Drugs

Click below link for Life period of drugs:

Life-period-of-Drugs

Pack size of Drugs

Click below link for Pack size of drugs:

Pack-Size-of-Drugs

WHO GMP: Guidelines

Read or download following WHO GMP guidelines:

WHO Guidelines TRS 986 Annexure 2

WHO Guidelines TRS 986 Annexure 2

WHO Guidelines TRS 1044 Annexure 2

WHO Guidelines TRS 1044 Annexure 2

Compiled by:

Rakesh Dahiya

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Click here for more articles of the Author

Standard Operating Procedure for Inspection of Manufacturing Units

Dr. Arvind H Zala
Assistant Commissioner
FDCA Gujarat

Standard Operating Procedure for Inspection Of Manufacturing Units

1.0 Objectives: To describe the detailed procedures before, during the inspection of drugs manufacturing firm.

2.0 Scope: This standard operating procedure is applicable for inspections of drugs manufacturing firms to the Inspectors of Food and Drugs control administration.

3.0 Responsibilities:

3.1 Initiating department: Senior drugs inspectors'/ Drugs inspectors/ Such designee.

3.1.1 To follow the standard operating procedure during inspections.

3.1.2 To ensure that the records of inspection and reports are maintained.

3.2 **Initiating department: Head of office/Assistant Commissioners/ADC or Such Designee**.

3.2.1 To impart training to all officers involving in the inspection of the drugs manufacturing firm.

3.2.2 To ensure that standard operating procedure is followed.

3.3 **Initiating department: Head of Zone/Deputy Commissioners or DDC or Such Designee**.

3.3.1 To approve the stand operating procedure.

3.4 **Initiating department: Commissioner/ Joint Commissioners or Such Designee**.

3.4.1 To authorize the approved standard operating procedure.

4.0 Type of inspections:

4.1 Pre-approval inspections
4.2 Routine GMP Inspections
4.3 GMP certification inspections
4.4 WHO certification inspections
4.5 Not of standard quality/ OOS inspections
4.6 Complaint investigational inspections
4.7 Technical person pre-approval inspection
4.8 Document verification inspections

5.0 Mandatory duties of inspector

5.1 The Inspector or Inspectors shall examine all portions of the premises, plant and appliances and also inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for standardizing and testing the substances to be manufactured and inquire into the professional qualifications of the technical staff to be employed.

5.2 He shall also examine and verify the statements made in the application in regards to their correctness, and the capability of the applicant to comply with the requirements of competent technical staff, manufacturing plants, testing equipment and the requirements of plant and equipment as laid down in provisions of Drugs and cosmetics act and rules.

5.3 Subject to the instructions of the controlling authority it shall be the duty of an Inspector authorized to inspect the manufacture of drugs:

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Assistant Commissioner
FDCA Gujarat

5.3.1 To inspect not less than once a year, all premises licensed for manufacture of drugs or cosmetics within the area allotted to him to satisfy himself that the conditions of the license and provisions of the Act and Rules there-under are being observed;

5.3.2 In the case of establishments licensed to manufacture products specified in Schedule C and C(1) to inspect the plant and the process of manufacture, the means employed for standardizing and testing the drugs or cosmetics, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to affect the potency or purity of the product;

5.3.3 To send forthwith the controlling authority after each inspection a detailed report indicating the conditions of the license and provisions of the Act and Rules there-under which are being observed and the conditions and provisions, if any, which are not being observed.

5.3.4 To take samples of the drugs or cosmetics manufactured on the premises and send them for test or analysis in accordance with these Rules;

5.3.5 To institute prosecutions in respect of breaches of the Act and Rules there-under.

5.4 Prohibition of disclosure of information

5.4.1 Except for the purposes of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any information acquired by him in the course of his official duties.

5.5 Form of order not to dispose of stock

5.5.1 An order in writing by an Inspector under clause *(c)* of Section 22 of the Act requiring a person not to dispose of any stock in his possession shall be in Form 15.

5.6 Forms of receipts for seized drug, cosmetic, record register, document or any other material object.

5.6.1 A receipt by an Inspector for the stock of any drug or cosmetic or for any record, register, document or any other material object seized by him under clause (c) or clause (cc) of sub-section (1) of Section 22 of the Act shall be in Form 16.

5.7 Form of intimation of purpose of taking samples.

5.7.1 When an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in Form 17 to the person from whom he takes it.

5.8 **Form or receipt for samples of drugs where fair price tendered is refused.**

5.8.1 Where the fair price, for the samples of drugs taken for the purpose of test or analysis, tendered under sub-section (1) of section 23 has been refused, the Inspector shall tender a receipt thereof to the person from whom the samples have been taken as specified in Form 17-A.

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Assistant Commissioner
FDCA Gujarat

6.0 Procedures

6.1 Pre-approval inspections, Routine GMP Inspections and GMP certification inspections

6.1.1 Read the application and the maps, designs, documents submitted with application, before startup of inspection.

6.1.2 Follow the standard operating procedures of the firm's for entry in and exist from the respective inspection area.

6.1.3 Do not ask the confusing questions to the responsible technical persons of the firm during inspection.

6.1.4 Take the round of the premises. All rooms shall be visited. Ask the firm to unlock the locked rooms.

6.1.5 Start the inspection from raw material area like, raw material receipt area, sampling area, raw material under test storage, approved raw material area, dispensing area, and dispensed raw material storage area. Inspect the facility and premises as per the material movement flow.

6.1.6 **In case of tablets, hard gelatin capsules and soft gelatin capsules manufacturing processing area**: inspect the operations facility like mixing, granulation, compression, coating, capsulations /bottling /stripping / blistering, labeling, packing, etc. The premises, equipment, materials, facilities, procedures etc. shall be complied with part-1 and part -1B of schedule- M covered under rules 71, 74, 76 and 78.

6.1.7 **In case of oral liquid manufacturing processing area**: inspect the operations like syrup base preparations, mixing, filtration, filling, visual inspection, labeling, packing, etc. The premises, equipment, materials, facilities, procedures etc. shall be complied with part-1 and part -1C of schedule- M covered under rules 71, 74, 76 and 78.

6.1.8 **In case of sterile products, parenteral preparations, small volume injectables, large volume parenterals and sterile ophthalmic preparations manufacturing processing area**: inspect the operations facility like bulk preparations, mixing, filtration, filling, visual inspection, labeling, packing, etc. The premises, equipment, materials, facilities, procedures etc. shall be complied with part-1 and part -1A of schedule- M covered under rules 71, 74, 76 and 78.

6.1.9 **In case of manufacturing of medical devices, disinfectant fluid, diagnostic reagents:** The premises, equipment, materials, facilities and procedures etc. shall be complied with schedule- M-III covered under rules 76 and 78.

6.1.10 **In case of manufacturing of topical products (Creams, Ointments, Pastes, Emulsions, Lotions, solutions, dusting powders and Identical products):** The premises, equipment, materials, facilities and procedures etc. shall be complied with part-1 and part -1D of schedule-M covered under rules 71, 74, 76 and 78.

6.1.11 **In case of manufacturing of Ayurvedic, Siddha And Unani Medicines:** The premises, equipment, materials, facilities and

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procedures etc. shall be complied with schedule- T covered under rules 157.

6.1.12 **In case of manufacturing of Homoeopathic Preparation:** The premises, equipment, materials, facilities and procedures etc. shall be complied with schedule- M-1 covered under rules 85-E (2).

6.1.13 Check the room area, carpet area, height, wall covering paints, flooring quality, flushed doors, flushed windows, concealed wirings, pipeline coverings etc.

6.1.14 Check the equipment, instruments kept for manufacturing and testing operations. Check the calibration and status labels. Check design qualification, installation qualification, operational qualification and performance qualifications.

6.1.15 In case of manufacturing premises, manufacturing allopathic drug preparations, Check the water system requirement, air handling units and filtered air supply requirements, raw material receipt area, mentioned in Schedule-M for manufacturing section and schedule L-1 under rule 74, 78 and 150-E, requirements for testing sections. Check the preparations to maintain records of the drugs manufacturing and testing as per the Schedule-U.

6.2 WHO certification inspections:

6.2.1 In addition to all above requirements, mentioned in drugs and cosmetic act and rules there-under, manufacturing firm shall be inspected for compliance of WHO TECHNICAL REPORT SERIES NO: 902, 929, 948, 953, 957, 961, 970, 981, 992, 986, 1010, 1019, 1033, 1044, 1052, 1060, and other TRS timely published by WHO.

6.3 Not of standard quality/ OOS inspections

6.3.1 Observe and read the test report of testing laboratory in detail with respect to sampling and testing results mentioned in it.

6.3.2 Inspect the firm for respected batch numbered drug product. Observe the records of active and supporting raw materials used in the manufacturing of the said batch. Observe the water testing records if it is used in processing of the batch. Observe the environment control records of the days on which the questioned batch was manufactured. Observe the records of manufacturing and testing of the said batch. Observe the sale and distribution records and recall procedures, carried / to be carried out, by firm. Inspect and investigate the firm to find out the root cause of the OOS results. Extend the inspection for other previous or past manufactured batched for all above mentioned facts.

6.4 Complaint investigational inspections:

6.4.1 Check the complaint details, like who is complainant, where it is received, what are the basics of complaint, etc.

6.4.2 On basis of complaint details, decide what type of operations of the firm shall be inspected in detail. List out the critical steps involving in the manufacturing operations for the said drugs complaint investigation.

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Inspect the premises for each respective points mentioned in the complaint.

6.4.3 Inspect and investigate the firm to find out the root cause of the failure mentioned in complaint. Extend the inspection for other previous or past manufactured batched for all above mentioned facts.

6.5 Technical person pre approval inspection

6.5.1 Check the presence of the technical person applied for approval. Observe salary sleeps and attendance register for his/her regular presence.

6.5.2 Observe the records of manufacturing or testing where he/she involved in. Check the signatures and entries made in the said records.

6.6 Document verification inspections

6.6.1 List out and demand the documents to be observed before premises inspection startup.

6.6.2 Demand additional documents related to the compliance or Non-compliance of the provisions.

6.6.3 Check the preparations to maintain records of the allopathic drugs manufacturing and testing as per the Schedule-U.

7.0 Communications during inspections

7.1 Verbal communications shall be soft. The communication shall not be such that it hurt personal/cast/religious emotions of the opponents. Use technical words. Ask the questions related to the technical matters. Ask the question short and understandable. Ask the questions step by step. So many questions on single sentence make the opponent in confusion. Ask the questions to appropriate responsible personals.

7.2 Allow a reasonable time for the answer. Don't make a confirmatory statement without hearing the complete answer. The questioned communications shall be related on specific system.

7.3 Make observation entry in the Inspection Book in Form 35 as a record his impressions and the defects noticed.

8.0 Reports and recordings of the inspection

8.1 **Primary details:** prepare a detailed report stating the time and date of inspection, inspecting officers, firm's detail, firm's license, constitutional details, premises possession details, reason for inspection,

8.2 **Premises details:** premises situations details, air handling system and environment control details, water system details,

8.3 **Quality assurance system details**: personals, self-inspection audits details, validation and process validation details, product recall and complaint investigation and adverse drugs reaction details, etc.

8.4 **Records details:** Site master file, standard operating procedures, master formula records, product permission records, batch manufacturing records, batch testing records, batch distribution records, etc.

8.5 Report related to Personnel's, clothing, sanitation, and hygiene.

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FDCA Gujarat

8.6 **Production details:** environment control details, equipment and instrument details, manufacturing and control details, precautions against prevent the mix-ups and contaminations, sanitation in manufacturing premises,

8.7 **Quality control details:** specifications and methods of testing, raw material testing, water testing, environment specification testing, in-process product testing, finished product testing, stability testing, microbiological and sterility testing, etc.

8.8 Approved technical staff details.

8.9 Details of Drugs samples taken for Government testing laboratory.

8.10 Non-compliance observation details with contravening Para or rules of the statutory provision like drugs and cosmetic act or Technical review reports.

8.11 Conclusion and clear-cut recommendations.

9.0 Penalty vexatious search or seizure.

9.1 As per section 34AA of the drugs and cosmetic act-1940, Any Inspector exercising powers who,

9.1.1 without reasonable ground of suspicion searches any place, vehicle, vessel or other conveyance; or

9.1.2 vexatious and unnecessarily searches any person; or

9.1.3 vexatious and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object; or

9.1.4 commits, as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty, shall be punishable.

10.0 Distribution of list of SOP

10.1 Master copy at the Commissionerate office

10.2 One copy each to all circle office

10.3 One copy each to drugs inspector inspecting the manufacturing firms

11.0 Reference:

11.1 Drugs and cosmetic act 1940 and rules there-under.

11.2 WHO-Technical report series.

12.0 Abbreviations

12.1 SOP= Standard operating procedure

12.2 GMP= Good manufacturing practice

12.3 OOS= out of specification.

12.4 TRS = Technical report series published by WHO-Geneva

13.0 History of revision and change

Revision no.	supersedes	Effective date	C.C. No.	Reason for revision or change.

End of the article

Overview of current statutory provisions related to MTP Kits

Chirag

Drugs Inspector
Himachal Pradesh

The medical termination of pregnancy (MTP) Kits contain 1 tablet of mifepristone 200mg + 4 tablets of misoprostol 200mg. As per current provisions of Drugs and Cosmetics Act 1940 and Drug Rules 1945 the MTP kits comes under Schedule H of Drug Rules 1945. The labelling of Schedule H Drugs As per rule 97 (b) of Drug rules 1945 is as below:

"if it contains a drug substance specified in Schedule H, be labeled with symbol Rx and

conspicuously displayed on the left top comer of the label and shall also be labeled with the

following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG - CAUTION: Not to be sold by retail without the prescription of a Registered Medical Practitioner.

In addition to this as per advisory issued by Drugs Controller General (I) dated 09.08.2019 that the MTP Kits are approved with following warning:

"Warning: product is to be used only under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 & MTP Rules 2003"

Hence as per current provisions of Drugs and Cosmetics Act 1940 and Drug Rules 1945 the MTP kit can be sold in retail only on the prescription of Registered Medical Practitioner (as per rule 2(ee) of Drug Rules 1945).

The medical termination of pregnancy is also regulated in India through Medical Termination of Pregnancy Act,1971 and Medical Termination of Pregnancy Rules, 2003.The definition of Registered Medical Practitioner varied across Drugs and Cosmetics Act 1940, Drug Rules 1945 and Medical Termination of Pregnancy Act 1971, Medical Termination of Pregnancy Rules, 2003. The overview of definition of Registered Medical Practitioner is as below:

Rule 2(ee) of Drugs Rules 1945

Registered medical practitioner" means a person:

(i) holding a qualification granted by an authority specified or notified under section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916), or

specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

(ii) registered or eligible for registration in a medical register of a State

(Continued on page 24)

Overview provisions related to MTP Kits .....

meant for the registration of persons practicing the modern scientific system of medicine [excluding the Homoeopathic system of medicine]; or

(iii) registered in a medical register [other than a register for the registration of Homoeopathic practitioners] of a State, who although not falling within sub-clause (i) or sub-clause (ii) is declared by a general or

special order made by the State Government in this behalf as a person practicing the modern scientific system of medicine for the purposes of this Act; or

(iv) registered or eligible for registration in the register of dentists for a State under the Dentists Act, 1948 (16 of 1948); or

(v) who is engaged in the practice of veterinary medicine and who possesses qualifications approved by the State Government;

MTP Act 1971 Section 2(d) read with Rule 4 of MTP Rules 2003

MTP Act 1971 Section 2(d): "registered medical practitioner" means a medical practitioner who possesses any recognized medical qualification as defined in Cl.(h) of Sec. 2 of the Indian Medical Council Act, 1956 (102 of 1956), whose name has been entered in a State Medical Register and who has such experience or training in gynecology and obstetrics as may be prescribed by rules made under this Act.

MTP Act

Rule 4 of MTP rules 2003: For the purpose of clause (d) of section (2), a registered medical practitioner shall have one or more of the following experience or training in gynaecology and obstetrics, namely;

(a) In the case of a medical practitioner, who was registered in a State Medical Register immediately before the commencement of the Act, experience in the practice of gynaecology and obstetrics fora period of not less than three years;

(b) In the case of a medical practitioner, who is registered in a State Medical Register:- (i) if he has completed six months of house surgency in gynaecology and obstetrics; or (ii) unless the following facilities are provided therein, if he had experience at any hospital for a period of not less than one year in the practice of obstetrics and gynaecology ; or

(c) if he has assisted a registered medical practitioner in the performance of twenty-five cases of medical termination of pregnancy of which at least five have been performed independently, in a hospital established or maintained or a training institute approved for this purpose by the government.

(i) This training would enable the Registered Medical Practitioner (RMP) to do only

(Continued on page 25)

Overview provisions related to MTP Kits .....

(Continued from page 24)

1stTrimester terminations (up to 12 weeks of gestation).

(ii) For terminations up to twenty weeks the experience or training as prescribed under sub rules (a), (b) and (d) shall apply .

(d) In case of a medical practitioner who has been registered in a State Medical Register and who holds a post-graduate degree or diploma in gynaecology and obstetrics, the experience or training gained during the course of such degree or diploma.

As per the definition of Registered Medical Practitioner in MTP Act 1971 and MTP rules 2003 the experience or training of gynaecology and obstetrics as specified in rule 4 of MTP rules 2003 is mandatory. Additionally, the termination of pregnancy shall be carried out in the place as specified under section 4 of MTP Act 1971 read with rule 5,6,7 of MTP rules 2003.

The Drugs Controller General (I) advisory dated 09.08.2019 also specified that MTP kits be used supervision of a service provider and in a medical facility as specified under MTP Act 1971 (amendment 2002) & MTP Rules 2003.

Key Takeaways

1. MTP Kits contains contains 1 tablet of mifepristone 200mg + 4 tablets of misoprostol 200mg and comes under the Schedule H of Drug Rules 1945 and can be sold in retail only on the prescription of Registered Medical Practitioner (as per rule 2(ee) of Drug Rules 1945)

2. As per advisory issued by Drugs Controller General (I) dated 09.08.2019 MTP kits should be used under supervision of a service provider and in a medical facility as specified under MTP Act 1971 (amendment 2002) & MTP Rules 2003.

3. The definition of Registered Medical Practitioner varied across Drugs and Cosmetics Act 1940 and Medical Termination of Pregnancy Act,1971

4. More stringent provisions in Drug and Cosmetics Act 1940 and Drug rules 1945 which are in line with Medical Termination of Pregnancy Act,1971 and Medical Termination of Pregnancy Rules, 2003 are required

Source: Chirag Thakur, DI, HP

India Bans 34 Key Antimicrobials for Animal Use

In an unprecedented move for animal and public health, the **import, manufacture, sale, and distribution** of major classes of critical antimicrobials (antiviral and antibiotics) for animal use has officially been **banned in India**, encompassing a great many of the drug types that serve as last-resort medications for humans.

The notification by Health Ministry, which was made official on **September 23, 2025** comes in light of the growing national and international need for **antimicrobial resistance (AMR)** prevention, infection control and mitigation of the danger posed by resistant pathogens.

Download the notification

Why Address Antimicrobial Resistance (AMR)?

Antimicrobial resistance is a silent pandemic. When microbes no longer respond to the drugs designed to kill them, we find ourselves left with 'superbugs.'

If powerful, last-resort antibiotics are used in animal husbandry, **antimicrobials** and resistance only increase.

In addition, these resistant microbes can pass through the human food chain or environment to humans, rendering human antibiotics and antivirals useless.

Antimicrobial Resistance (AMR) and Ban Release

Following a **draft notification** in **May 2025**, the **Ministry of Health and Family Welfare** decided on swift release.

In addition, it was noted that "safer alternatives to the said drugs for animal use

are available."

Thus, there will be no impact on animal well-being; veterinarians and the agriculture industry will be supported in this transition.

The decision was made in consultation with the Drugs Technical Advisory Board **(DTAB)**, ensuring a scientifically supported determination that serves the best interests of public health.

What Life-Saving Medications Are Banned?

While exact articles or numbers were not published, the new notification released banned classes of drugs that are otherwise life-saving for serious infections in humans.

As such, India seeks to preserve their usefulness in humans but absolves their need in animals.

The following antibiotics, antivirals, and antiprotozoals are banned:

- **Last-Resort Antibiotics:** These include entire classes based on their utility in resistant bacteria situations
- **Carbapenems** (Doripenem)

(Continued on page 27)

India Bans 34 Key Antimicrobials ……continue

(Continued from page 26)

and **Penems** (Imipenem—last resort penicillins)

- **Glycopeptides** (Vancomycin) and **Lipopeptides** (Daptomycin)—associated with MRSA infections
- **Oxazolidinones** (Linezolid-like antibiotics)
- Some **Cefazolin** (Cephalosporins)
- **Ceftobiprole** (5th generation Cephalosporin)
- **Ceftaroline** (for skin infections)
- Various forms of **Penicillin**
- Essential Antivirals: These include a range of antivirals to treat viral infection in humans.
- Oseltamivir (Tamiflu), Ribavirin, Molnupiravir (current COVID treatment)—now prohibited from use in animals for any reason.
- Specific Antiprotozoals: Any anti-parasitic that also works as an antiviral will not be permitted.

Nitazoxanide

1 List of Antimicrobials Banned:

2 Antibiotics (15 classes/drugs):

1. **Ureidopenicillins**
2. **Ceftobiprole**
3. **Ceftaroline**
4. **Siderophore cephalosporins**
5. **Carbapenems**
6. **Penems**
7. **Monobactams**
8. **Glycopeptides**
9. **Lipopeptides**
10. **Oxazolidinones**
11. **Fidaxomicin**
12. **Plazomicin**
13. **Glycylcyclines**
14. **Eravacycline**

Omadacycline

1 Antivirals (18 drugs):

1. **Amantadine**
2. **Baloxavir marboxil**
3. **Celgosivir**
4. **Favipiravir**
5. **Galidesivir**
6. **Lactimidomycin**
7. **Laninamivir**
8. **Methisazone/Metisazone**
9. **Molnupiravir**
10. **Oseltamivir**
11. **Peramivir**
12. **Ribavirin**
13. **Rimantadine**
14. **Tizoxanide**
15. **Triazavirin**
16. **Umifenovir**
17. **Zanamivir**
18. **Nitazoxanide**

1 Antiprotozoal (1 drug):

Nitazoxanide

Source: The Health Master

ANTIBIOTICS

49 new Drug Inspectors join in CDSCO

Drug Inspectors:

The Central Drugs Standard Control Organisation (CDSCO) is set to receive **49** new drug inspectors as the **Ministry of Health and Family Welfare** has moved forward with plans to hire these candidates under the **Drugs and Cosmetics Act of 1940** and establish a watchful eye over one of the largest pharmaceutical and drug markets in the world.

Download the list

Why This Matters

This is not merely a hiring spree for an administrative backup.

The candidates that become drug inspectors will be granted certain powers under the **Drugs and Cosmetics Act of 1940** to ensure that Indians receive safe and effective medications.

The following list comprises all roles and responsibilities that come with drug inspector recruitment:

- **Manufacturing Establishments Inspections:** To manufacture drugs and cosmetics.
- **Premises Inspections:** Where drugs are sold or stored; such premises are monitored to avoid malpractices.
- **Samples Collection:** Of drugs are taken for necessary analysis.
- **Searches:** Searches and inspections to prevent mala fides.

At least half of the candidates for this new hiring batch are women, bringing a breath of fresh and diverse air to this much-needed regulatory force.

The total Strength of the of Drug Inspectors

The CDSCO has been working for years with a **drug inspector** shortage.

According to a seniority list dated **November 2024**, **419 posts** of **drug inspectors** are sanctioned under the central level, but **230 positions** are vacant.

Therefore, while 49 have been recruited recently, many more need to be adjusted.

The same situation applies to the **Medical Devices** under the **CDSCO**, where **85 posts** were sanctioned, and by the end of **2024**, nearly **80%** were vacant.

This has also been taken up by parliamentary committees in the last few years.

Increasing the strength of the Drug Inspectors

Over the years, the sanctioned strength of **drug inspectors** has increased from **62** in **2008** to **504** as of now.

The number of inspections needed has greatly increased, and thus, intervention has become necessary

Each state has its own cadre of **drug inspectors** linked to the **CDSCO** for licensing and enforcement issues at the state level.

Source: The Health Master

Haryana: ₹5,000 Crore investment Plan for Pharma and Medical Device

Pharma and Medical Device

Haryana has identified its next growth area becoming a global hub for **pharma** and **medical device** manufacturing.

The state government has instituted a new policy that aims to create a comprehensive, sustainable ecosystem for the sector generating an expected investment of **₹5,000 crore** Yes, that's a billion with the following benefits.

Policy Focused on Elevating the Manufacturer's Experience

The **Haryana Pharma and Medical Device Manufacturing Policy** is filled with fiscal incentives to support the manufacturer experience straight from government to investment.

The following gives a comprehensive overview of what's on the table for potential manufacturers:

Capital Expenditure Support:

From a government's perspective, billion/₹ crores projects are not uncommon, as they stem from aspirations of great growth.

To offset new development costs for units, the policy allows for capital expenditure support for projects up to **₹200 crore**.

The allowance lowers the threshold burden of startup capital at such high prices.

Operational Expenditure Support:

The government doesn't stop financing major projects; it continues through their operation.

Once established, units are eligible for operational expenditure support up to **₹20 crore**.

This helps facilitate units in their day-to-day endeavors once they're part of the fabric of **Haryana**.

Prototype Funding for Startups:

For those innovative entrepreneurs out there, special considerations can help those newcomers get off the ground.

Eligible startups those that are **Haryana based** and working within the pharma or **medical device** sector can get **50% reimbursement** on expenses incurred when creating a prototype product with an annual cap of **₹10 lakh**.

This provides entrepreneurs the assistance needed to take their bright ideas and make them functional realities.

Foundational Considerations for a Sustainable Future

While financial incentives are in play, the government has other goals in mind to ensure a sustainable future for the state and country:

Infrastructure and R&D:

For real estate developers looking to build new industrial opportunities, there are incentives for creating specific **pharma and medical device clusters and parks**.

These areas will house shared incubation centers and **research and development facilities** to promote communal efforts toward individual goals.

Reduced Import Reliance:

Another goal is to ensure, at some point, that **Haryana** does not have to import **pharma and medical device**, as it will produce enough quality goods on its own.

Encouraging **domestic manufacturing** efforts along the entire healthcare value chain will allow **Haryana** to have its inventory of equipment and medicines while promoting national support for quality goods.

Export Opportunities:

While companies may want to focus solely on state-side efforts, the policy helps businesses gain international certifications and access global markets.

Therefore, if companies would like to export their products, assistance is available.

Skilled Development:

Ultimately, the policy aims to create a sustainable ecosystem through skill development.

Therefore, a trained workforce will ensure that educational institutions develop talent for years to come.

Source: The Health Master

CDSCO Redefines Cocrystals as 'New Drugs'

In a significant twist to the Indian drug development scenario, the **Central Drugs Standard Control Organization (CDSCO)** has provided a **crucial clarification** about **Cocrystals** that is bound to affect the future of drug development in the country.

In a recent notification, effective **September 15, 2025**, the **CDSCO** has clarified that **pharmaceutical cocrystals** made from approved active pharmaceutical ingredients (APIs) shall be considered "**new drugs**", therefore requiring companies to follow a more extensive **regulatory pathway** to ensure approval.

This crucial clarification about **Cocrystals** comes after representations were made from stakeholders in the industry for a clarified approval route for these substances.

The notification impacts any drug manufacturer practicing formulation and crystal engineering and requires compliance with the more extensive **New Drugs and Clinical Trials Rules, 2019**.

What are Cocrystals?

Pharmaceutical cocrystals are **solid crystalline materials** made up of two or more different molecules and are generally defined as having an active pharmaceutical ingredient (API) complex with a coformer or another molecule held together in a ratio through a non-covalent bond.

This non-covalent bond allows an excellent approach to modifying the physical properties of a drug without potentially changing its chemistry.

Pharmaceutical Cocrystals Provide the Following Benefits:

- **Drug Bioavailability Enhancements:** This means that the dissolved state of the cocrystal can enhance how well the drug works once absorbed.
- **Improved API Stability:** Should help to keep drugs safe from environmental effects.

Better Processability: It generally makes processes easier.

What Changes in the Approval Process for Pharmaceutical Cocrystals?

Thus far, if companies were to incorporate an existing drug in pharmaceutical cocrystals, they would not have to assess this as a new drug.

However, now, the **New Drugs and Clinical Trials Rules** stipulate that an application for a pharmaceutical cocrystal must be treated as a new drug application.

This includes submissions to see if the following studies prove to show:

- **Manufacturing Process Validation Studies**—consistent methods of repeatability must show acceptance.
- **Stability Studies**—shelf life under varying degrees of temperature and environments must be reported.
- **Additional Clinical and Non-clinical Studies**—more than just simple indications must prove established safety and efficacy.
- **Bioavailability/Bioequivalence (BA/BE) Studies**—studies in the bioavailable/bioequivalent field must prove this form is superior to just an equally proportioned compound of components.

This clarification applies to state-appointed drug controllers and union territories on **September 15, 2025**, so all **CDSCO** zonal and port offices should also comply.

Source: The Health Master

Stickers on Medicines and Medical Devices: GST

Stickers on Medicines

Ever notice those pricing labels and **stickers on medicines**? While they may seem unnecessary, they're an integral part of the government's price management system.

But soon, it'll all get a lot clearer and less expensive for us all!

The Indian government has officially announced a reduction in taxes on drugs and medical devices, meaning the prices will come down for you!

And to ensure a swift transition, the government's **Central Drugs Standard Control Organisation (CDSCO)** is connecting with manufacturers to apply new price **stickers on medicines and medical devices**.

This is an important initiative because it implies that the benefit of the new reduced **Goods and Services Tax (GST)** will actually trickle down to the end consumer instead of just remaining with the manufacturers.

A move to make medicine cheaper

The **CDSCO** has issued a communication to all state and central drug authorities asking them to fast track something called "**no objection**" approvals.

Manufacturers require a no-objection approval process to enact label changes pertaining to their products, and inclusion of revised pricing is part of this.

In simple terms, if a manufacturer produces thousands of bottles of a specific drug but already packaged them with the older pricing, to avoid wastage and losing business, they'll essentially slap a new sticker on the bottle indicating the new price.

Fast-tracking such approvals will reduce the time taken for consumers to benefit from reduced pricing.

Read or download CDSCO dt 11-09-2025 Stickering on Medical Products due to reduction in Goods Service Tax (GST) rate

Special circumstances for Medical Devices

Drugs aren't the only products benefiting from price cuts.

Many **medical devices** are also experiencing changes in pricing.

(Continued on page 32)

Stickers on Medicines ……continue

(Continued from page 31)

In fact, for select important devices, the government has an exclusive allowance.

For more important medical devices (like blood glucose monitors), known as **Class C** and **Class D** medical devices, the manufacturers have three months' time to update their prices via **stickers**.

- **Class A & B medical devices:** These are low-risk medical devices; their pricing adjustments will be applied by the state authority.
- **Class C & D medical devices:** These are more complicated and critical medical devices; these FDA approvals will be governed by a central authority.

  Thus, all medical equipment gets a price adjustment with relative ease.

The big deal: Why this is happening now

So why are these price changes being implemented now? It's all thanks to the **GST Council**, a committee focused on tax rate assessment that recently convened and proposed some drastic recommendations that benefit us all.

- **GST imposed on all drugs and medical devices reduced:** The tax has been reduced to 5%!
- **GST waived on life-saving drugs:** For 36 life-saving drugs, no taxation will be applied.
- **Lower tax on varied medical apparatus:** Items like surgical implements and diagnostic kits were reduced from 18% to 5% and 12% to 5%, respectively.

This is great news for families who need access to these important health products because it makes them more affordable and accessible.

What's next?

While this is all great news, the industry is concerned about logistics.

How can one effectively **sticker**-relabel millions of products in a short time frame?

The worry is valid.

Yet government officials have long been in contact with manufacturers to ensure no disruption occurs.

Keep in mind, the availability of these medications and supplies should remain standard so that you receive them as you always have.

Source: The Health Master

Braille labeling on Medicine Strips: A New Era

Recently, India's top drug regulator, the **Central Drugs Standard Control Organization (CDSCO)**, has welcomed comments from **stakeholders** across the pharmaceutical arena and advocacy sectors regarding a proposal of **Braille labeling** on medicine strips that would allow the **blind** and **visually impaired** to access critical information on medicine strips.

Download CDSCO Notice dt 09-09-2025 regarding the proposal regarding problem faced by the blind or visually impaired people to read medicines tablets and capsules strips

This means that companies have the chance to provide feedback on a plan that will change the lives of blind and partially sighted individuals significantly.

This is not the first announcement regarding this change.

Back in **July 2020**, during the **58th Drugs Consultative Committee (DCC)** meeting, the proposal for such a change was put on the table, leading to a sub-committee specially designed to explore the depths of need and implementation for this project over time.

Phased Suggestions Include:

The sub-committee has made several suggestions that are quite specific to implementation over time.

Some of the following will potentially take effect:

- **Braille labeling** will be implemented voluntarily on medicine packaging for single or mono packs. This would be a phased process where companies could test things out at their level while not being locked into a contract.
- **Braille labeling** will be considered for medicines most frequently used by blind and impaired persons, including eye drops, as they need specific details for proper administration.
- Proposed exemptions will apply to **Braille labeling** needs for injections, vaccines, etc., as these are provided directly by professionals who can educate the patient without the need for **Braille labeling**.
- Registered agencies like **Braille Council of India** or any other government-specified body must clear any design for branded packaging to ensure accuracy.

In subsequent meetings, new ideas were provided that can expand upon the original concept. During the 66th DCC meeting held on June 17, 2025, these suggestions were also made:

1. For bigger packs (more than ten tablets/ capsules), separate **Braille cards** should accompany the medicines.

2. **QR codes** will be utilized on larger packaging to provide voice assistance once scanned for medicine identification, dosage, and expiration information.

What's Next?

This opportunity is a clear indication that India's pharmaceutical and regulatory industry is responsive and accountable to its stakeholders and vulnerable populations.

The public comment period is a chance for pharmaceutical giants, consumer interest groups, and the visually impaired community to unite under a proposal that can significantly enhance quality of life for millions.

This is more than just a packaging change; it's a health sector initiative to embrace empathy and inclusivity where blind persons can now learn about their medicine with the same accessibility as sighted persons.

With the implementation of voice assistance via **QR codes** additionally championed at new meetings, India could set the standard internationally for accessible healthcare.

Source: The Health Master

Indian Drug Regulation Goes 97% Digital: CDSCO

CDSCO

The regulatory landscape is evolving rapidly, and one of the leaders in this transformation is India's drug regulatory authority, the **Central Drugs Standard Control Organisation (CDSCO)**.

Following a significant digitization of operations, the **CDSCO** is on the path to faster, smarter regulation with greater transparency.

It is beyond just de-bureaucratization; it's a matter of ensuring drug safety and international competitiveness.

Digitization Leap: Statistical Evidence

When **97%** of operations are digitized, it's no wonder the world is going digital.

CDSCO's transition to almost all online functioning has decreased inefficiency by 25%, according to **Dr. Rajeev Singh Raghuvanshi**, the current **Drugs Controller General of India (DCGI)**.

This digitization also means that every team member has access to a personalized dashboard to see what files are up on their end and where they are in the turnaround process.

Simple but effective, this advancement fosters accountability and rapid response, which is critical for approvals that may otherwise sit unattended at administrative levels.

- **Export Approvals:** Export NOCs (No Objection Certificates) took ages to achieve; now, it takes fewer than seven days to secure one digitally. –

Drug Safety Assurance: By digitizing functions and controlling what goes in and out of the country more stringently, only the approved drugs leave the nation, ensuring safety for all in India and abroad.

Easier Regulations to Help Us All

Of course, technology cannot do it all; therefore, the **CDSCO** has examined its practices and begun simplifying drug-related regulations to cut unnecessary red tape.

This allows experts to focus on where they are needed most determining whether new drugs meet innovation and safety standards rather than wasting time on superfluous tasks.

"By simplifying regulations operationally, we are paving the way to revisit and revise them to be more flexible and aligned with global healthcare needs," **Dr. Raghuvanshi** notes.

(Continued on page 35)

97% Digital: CDSCO …….

(Continued from page 34)

The effort toward flexibility also inspires India's domestic pharmaceutical companies to do better.

For example, revisions to **Schedule M notification** encourage Indian pharmaceutical companies to adopt stricter **WHO-GMP** (World Health Organization – Good Manufacturing Practices) compliance; this only increases the desirability of Indian drugs for regulated international markets and strengthens India's presence as a vendor quality supplier for **LMICs** (low and middle-income countries), of which more than 90% of quality-assured India medicines are supplied.

International Best Practices for Brand Building

India wants to become a part of the world's drug inspection team; thus, it's attempting to align with **PIC/S** (Pharmaceutical Inspection Co-operation Scheme).

Joining this global cooperative body will require all state-level drug regulators to comply with good and best practices.

Thus, the **CDSCO** created the **State Regulatory Index** to gauge state performance for regulatory compliance with an accompanying ranking.

Friendly competition will encourage states to improve systems and collaboration with other states.

Thus far, it's working; over **17 nations recognize the Indian Pharmacopoeia**

(IP) as applicable regulations at home and abroad; more than 20 nations have entered Memorandum of Agreements (MoUs) with **CDSCO** for cooperative efforts.

A Shift from Generics to Innovation

For years, India was recognized as the "**pharmacy of the world**" for its generic options; now, it has transitioned to its focus on innovation (for biosimilar development, specifically) and simultaneous reliance on a regulatory system as a respectable global player.

Furthermore, India's endeavors in drug safety perpetuate its acclaim. In this regard, the **Pharmacovigilance Programme of India (PvPI)** observes any issues that may arise.

The PvPI actively reports adverse drug reactions (**ADRs**) to the **Uppsala Monitoring Centre (UMC)**, a leading pharmacoepidemiology platform.

Through information sharing with the broader public health community, India's regulators also gain access to ADR data to make informed decisions within their borders.

Source: The Health Master

Govt. amends Uniform Code for Marketing Medical Devices

Recently, some significant amendments were made by the Department of Pharmaceuticals (DoP), Govt. of India to the **Uniform Code for Marketing Practices for Medical Devices (UCMPMD 2024)**.

The amendments concern everyone, from the manufacturers/traders of **medical devices** to the healthcare professionals using them. Here are the changes in layman's terms.

The Summary: Why it Was Amended

The **UCMPMD 2024** is a code of control exerted upon those looking to manufacture devices. Essentially, it prevents unethical and non-transparent marketing efforts.

The DoP's amendments were made after stringent representations from many eminent associations in the **medical devices** industry.

Essentially, the DoP has allowed for clarity of reporting without diminishing the code's primary purpose.

Such considerations make compliance easy for those manufacturers and traders who would otherwise comply.

Free Samples

One of the largest amendments concerns the value attributable to free samples provided by **medical device** companies.

Companies providing free samples do not provide free samples as an attempt to hide the value or implement any unethical movements; thus, this provides clarity as to the value rendered per annum for such "**brand reminders**" and "**evaluation samples**."

From a manufacturer's perspective:

The value realized is equal to what the company charges its principal customers, inclusive of stockists for that product, when the company manufactures products as "**free samples**."

This figure shall be per item; this means that if a company has provided one free vial, the value realized would be that of a free vial price charged to the client.

From a purchaser's perspective:

If the companies acquire "**samples**" from other companies, it will be assessed at the value that assessed its exchange of purchase.

Ultimately, this creates a paper trail of identity for a fleeting but effective promotional endeavor.

Where Disclosure is Now Easier

Previously, if any complaint was raised via industry associations, the government portal would require the associations to lodge a complaint first and then decide upon a resolution, which had to be uploaded. This was seen as redundant.

A final authority:

Now, associations need only upload their findings to their association portals. The government assumes that ethical associations can resolve their own complaints and maintain information for public viewing.

Less oversight, more faith:

This provides less government oversight and more faith that the industry can self-govern while still maintaining ethical practices and transparent accounting.

Self-Disclosure and Reporting

The new code clarifies how companies disclose their marketing expenses and how associations view such information.

The consolidated report goes to one place:

Where this was confusing before, now companies must go to one entity for their annual requirements.

If one company belongs to many assured associations, they must go to one assured association for disclosure while noting the others.

It eliminates redundancy.

Data holding is strict:

Associations must hold data in securely heightened precautions.

All data held must be retained for five years minimum unless a pending inquiry necessitates additional time for evidence in court.

Source: The Health Master

Govt to amend Clinical Trials Rules to speed up approvals

Clinical Trials

A draft published by the Union Health Ministry could change the drug approval game in the country, for it includes newly proposed guidelines that will create easier pathways to manufacturing and clinical trials for lifesaving drugs.

This could be beneficial for large pharmaceutical companies as well as small private research hospitals.

Why Update the System?

The current process is tedious and requires extensive documentation; questions and answers and subsequent approvals take so long that precious research time is lost.

Therefore, the Ministry of Health wants to establish a **50% reduced** approval timeline for licensing to manufacture drugs as well as **clinical trials.**

- **Present approval timeline:** Up to 90 working days
- **Proposed approval timeline:** 45 working days

Such changes to the **clinical trials** process would render India a much more accessible and available country for large pharmaceutical company trials, as some approvals take less time than in other nations—and India is a diverse nation, bringing new potential to international firms while offering India new capital infusions.

Finding Easier Access

Perhaps the most intriguing aspect of this proposal states that stakeholders can now **notify authorities** (virtually) without seeking prior formal approval for products that are made strictly for testing/preclinical assessment purposes.

This is critical for basic science, as findings must be tested almost immediately.

However, some caveats exist. The draft simplifies the traditional pathway for the **majority** of new drugs sourced and manufactured, excluding:

- Sex hormones
- Cytotoxic drugs
- Beta-lactam drugs
- Biologics with live microorganisms
- Narcotics & psychotropic drugs

For these selected substances, the longer pathways of approval will remain in place for safety and compliance reasons.

When Will The Draft Be Approved/ Disapproved?

As it stands, this is all subject to change. There is a **30-day window** for any corporation, researcher, or layperson to comment on the draft proposal.

Such efforts show the government's desire to work with industry professionals and voices to create a streamlined, cohesive process as India's manufacturing abilities grow stronger and more necessary in international healthcare efforts.

Source: The Health Master

FDA Haryana

MTP Action

Panipat: 29-09-2025

A team of Dr. Abhai Vats, Nodal Officer PC & PNDT Panipat, Dr. Lalit, Dr. Shakhi and Vijay Raje DCO Panipat -1 raided at House situated in Gali No. 11, Vikas Nager, Panipat on the basis of secrete information regarding illegal MTP practice.

A decoy operation was carried out by team. Decoy was sent to the house and the present lady i.e Dai Sudesh Kumari agreed to do MTP of the decoy.

After getting signal form the decoy, team entered in the house and recover the instruments used in MTP.

Spot memo and Seizure Memo was prepared on the spot. Registration of FiR is under process.

Source: Vijay Raje, DCO, FDA Haryana

Hisar: 22-09-2025

Medical Store sealed in Hansi selling Tramadol Tablets

Hansi, Hisar: In a significant crackdown on drug trafficking, a joint team of the Food and Drugs Administration Haryana (FDA) and the Haryana State Narcotics Control Bureau (HSNCB) has taken action against a chemist shop in Hisar.

The raid, which occurred on September 22, 2025, targeted Vikram Singh, who was found to be involved in the illegal sale of a large quantity of Tramadol tablets.

The operation was initiated after it was discovered that Vikram Singh had sold 2,500 tablets of Tramadol HCI SR Tablet 100mg to an individual, who then sold them to another person from whom the drugs were recovered.

The joint team, comprising of Ritu Mehla, Drugs Control Officer of Hisar-3, Ajay Bishnoi, DCO Hisar-2 and SI Tarsem Singh of the HSNCB inspected the premises of M/s Vijender Singh Medical Store in Hansi, Hisar.

Upon inspection, Vikram Singh, who runs the chemist shop, admitted that he was on bail in a previous case under the NDPS Act and that his sister-in-law, Kajal, was acting as a proxy for the shop's operations. He also stated that his brother, Sachin, is also out on bail in a separate NDPS Act case.

The team found that the firm was illegally selling the intoxicating drug without issuing cash memos and in the absence of a registered pharmacist. To prevent the illegal sale of drugs, the shop was sealed under the Drugs & Cosmetic Act.

Source: Ritu Mehla, DCO, FDA Haryana

FDA Haryana

Drugs seized from Karnal

Karnal: 11-09-2025

On the basis of CM window complaint regarding illegal , team of Vikas Rathi DCO Karnal-2 and Dr. Vandana SMO Nilokheri visited at Clinic (Name not mentioned), Near Shiv Mandir, Village Butana, Tehsil Nilokheri, Distt Karnal.

On telephonically message to CM window complainant, he also joined the team. Akram S/O Sh. Ikbal was found present and introduce himself as owner of clinic.

Team disclosed the identity and purpose to him.

A huge quantity of allopathic drugs were stocked for sale or for distribution in the premises. Akram did not show any Drugs Licenses, Purchase invoice and sale invoices.

DCO, Karnal seized twenty seven different types of allopathic drugs vide Form-16 and also withdrawn six drugs samples for test and analysis.

CM window disposed off with satisfaction of the complainant.

Source: Vikas Rathee, DCO, FDA Haryana

Medical Store sealed selling MTP Kit

Jhajjar: 05-09-2025

A raid was conducted by Dr Suresh Kumar, DCO Gurugram II along with MTP Nodal Officer, Jajjhar, MO, PHC, Majra, Jajjhar at Kapil Medicose, Tumbaheri, Distt Jajjhar.

The firm sold MTP kit to a patient who is admitted in Civil Hospital, Jajjhar after her abortion with various other complications discloses that she has purchased MTP kit from this Firm.

The team submitted Complaint for FIR under MTP Act to the concerned PS by following reverse tracking.

Some other contraventions was also found in the shop.

So the shop was being sealed to stop furtherance of offence under section 22(1)d of D&C Act.

Source: Dr. Suresh Kumar DCO, FDA Haryana

FDA Haryana

Drugs seized in Mewat

Mewat: 04-09-2025

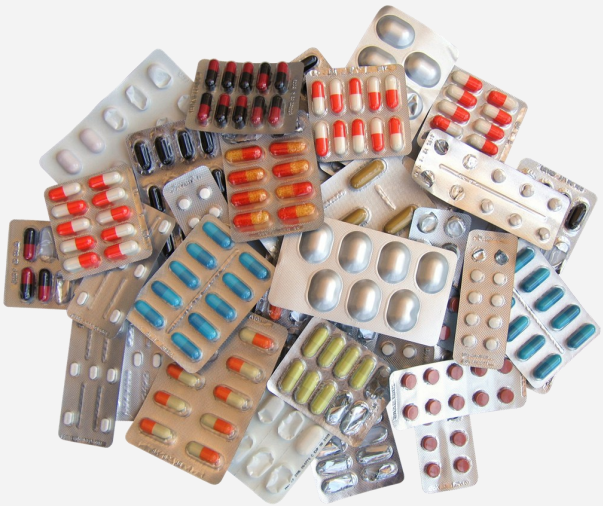
A raid was conducted by Mukesh Kumar, DCO Gurugram III (camp at Punhana) along with the teams of the CMFS and Health department at Hazi H Hospital in Punhana Distt. Mewat.

Complaint for FIR has been submitted by the Dr. Manpreet to concerned PS.

Additionally, 22 types of the allopathic medicines were seized by DCO Gurugram vide form 16 from the residential premises of the Waseem Akram situated in front of his said hospital.

Custody order taken from the court. Further action will be taken as per Drugs and Cosmetics Act..

Source: Mukesh Kumar, DCO, FDA Haryana



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Madhya Pradesh

Three years' imprisonment and a fine of ₹1 lakh for possessing and selling medicines without a license

Katni: The Sessions Judge, District Katni, sentenced Atmaram Vidhwani, owner of M/s Shiva Trading Company in Shalimar Market, to three years' rigorous imprisonment and a fine of ₹1 lakh under the Drugs and Cosmetics Act, 1940, for possessing and selling medicines without a license and bill. In 2020,

The then Drug Inspector, Swapnil Singh, inspected the company's warehouse and found some medicines.

The dealer had not presented any necessary documents, such as purchase bills or a valid drug license, for storing or selling these medicines. Due to the lack of documents and the unlicensed possession of the medicines, all the allopathic medicines were seized on the spot.

Later, Drug Inspector Manisha Dhurve thoroughly investigated the case in February 2024 and presented it before the Chief Judicial Magistrate.

The case was heard in court from 2024 to 2025, during which time the accused, Atmaram Vidhwani, failed to submit the required documents.

The court sentenced him to 3 years rigorous imprisonment, a fine of Rs 1 lakh, 1 month additional imprisonment in default of fine and 1 year rigorous imprisonment, a fine of Rs 25 thousand and 15 days additional imprisonment in default of fine under Section 28 of the Drugs and Cosmetics Act, 1940.

Source: DI, FDA Madhya Pradesh

Puducherry

Joint Investigation on Fake Medicines in UT Puducherry

As per the direction of Dr. E. Anandakrishnan, Drugs Controller, UT Puducherry, a joint investigation was carried out in response to complaints regarding the manufacturing of fake medicines in the Union Territory.

The investigation was conducted by Drugs Inspectors Tmt. Indhumathi and Jenifer Anbarasi V from the Puducherry Department of Drugs Control, along with officials Sakthivel, Pushapraj, and Devagiri from the Central Drugs Standard Control Organization.

On the first day of the drive, Monday, 01/09/2025, the team conducted a raid at Mettupalayam Industrial Estate, Puducherry, which continued until 12:00 AM. During the raid, officials discovered:

Empty hard gelatin capsules worth ₹99.47 lakh stored in a godown without a valid license, along with some manufacturing equipment.

Evidence showed that the capsules were supplied by Natural Capsule Pvt. Ltd., Pichai Veeranpettai, Puducherry.

Additionally, tablets, primary and secondary packing materials manufactured by Fabulous Life Sciences,

Vilupuram, and marketed by Nebulae Pharmaceuticals, Chennai, Tamil Nadu, were found on the premises.

All seized items will be handed over to the Puducherry Court, and the team received orders to seal the premises. On 02/09/2025, the premises were officially sealed in the presence of officials from the Revenue Department and Police.

This operation demonstrates a coordinated effort between state and central authorities to curb the manufacture and distribution of unlicensed and counterfeit medicines in the region.

Source: Dr. E. Anandakrishnan, Drugs Controller, UT Puducherry

Best Wishes On Promotion

Kerala Promotions

The DCOIWA family extends its best wishes for the future endeavours of the officers who have recently assumed his position following his well -deserved promotion.

1. Dr. Nishith MC, Senior Drugs Inspector, Throssur.
2. Dr. Mahalakshmy R, Senior Drugs Inspector, Trivandrum.
3. Mr. Aji S, Regional Drugs Inspector, Kollam
4. Mr. Noufal CV, Regional Drugs Inspector, Kozhikkode.
5. Mr. Mahesh CD, Assistant Drugs Controller, Trivandrum.
6. Mr. Vinod V, Assistant Drugs Controller, Trivandrum.
7. Mr. Sasi PK, Deputy Drugs Controller, Thiruvananthapuram

Best Wishes On Promotion

Haryana Promotion

The DCOIWA family extends its best wishes for the future endeavours of the officer who have recently assumed his position following his well -deserved promotion.

Sh. Rakesh Dahiya promoted as Asstt. State Drugs Controller, FDA Haryana

CDSCO Promotions

The DCOIWA family extends its best wishes for the future endeavours of the officers who have recently promoted to the post of Drugs Inspector.

S. No.	Name of officer
1	Sh. J. Ravi Kumar
2	Smt. Haritha Sameeraja Nagampalli
3	Smt. Ranjita Nayak
4	Smt. Sonali Suman
5	Smt. Bindu Kumari
6	Sh. Mangal Jyoti Das
7	Smt. Vandana Malviya
8	Smt. Monika Patanwar
9	Smt. Saranya Bhogadhi
10	Smt. Rajeswari Koruprolu
11	Smt. Lipika Roy
12	Smt. Kavita
13	Dr. Kotharapu Rama Koteswara Rao
14	Smt. Jyotsna Mala Das
15	Sh. Abhishek Kumar
16	Dr. Rajiv Kumar
17	Sh. Sravan Kumar Muppu
18	Smt. Renuka Pothu
19	Smt. Kamatam Thulasi Lakshmi
20	Smt. Koppula Tejaswini
21	Sh. Nitish Kumar
22	Dr. Sumanta Kumar Ghosh
23	Sh. Prashanth Kumar Killi
24	Smt. Bulusu Sai Gayatri
25	Smt. Aswini M.
26	Smt. Maradani Meena Devi

CDSCO Promotions

The DCOIWA family extends its best wishes for the future endeavors of the officers who have recently promoted to the post of Drugs Inspector.

27	Sh. R. Venkateshwarlu
28	Sh. M. Sundara Karthikeyan
29	Smt. Swapna Gandham
30	Smt. Sowmya Katreddy
31	Smt. Gannamani Swathi
32	Sh. Saurabh Sahu
33	Smt. Pavani Killamsetty
34	Smt. Sana
35	Sh. Vanga Harish
36	Smt. Kelothu Danthi Bai
37	Sh. Andhavarapu Santosh Kumar
38	Smt. Teku Rajya Lakshmi
39	Smt. Ippili Rekha
40	Smt. Gunja Chaturvedi
41	Sh. Budhabhaskar Gotru
42	Smt. Boyina Anusha
43	Dr. Lohithasu Duppala
44	Sh. Velisetti Vijaya Kumar
45	Smt. Gajji Manasa
46	Sh. Santha Vardhan Malapolu
47	Smt. Maloth Padma Kumari
48	Ms. Vejendla Manasa Rojamble
49	Smt. Thottempuri Priyanka

CDSCO Transfers Best Wishes

The DCOIWA family extends its best wishes for the future endeavors of the officers who have recently transferred and assumed his position .

Sh. Sushant Sharma, DDC(I) has been transferred from Baddi Zone to CDSCO (HQ)

Sh. Ajay Sachan, DDC(I) North Zone has been assigned additional charge of Baddi Zone.

Best Wishes on retirement

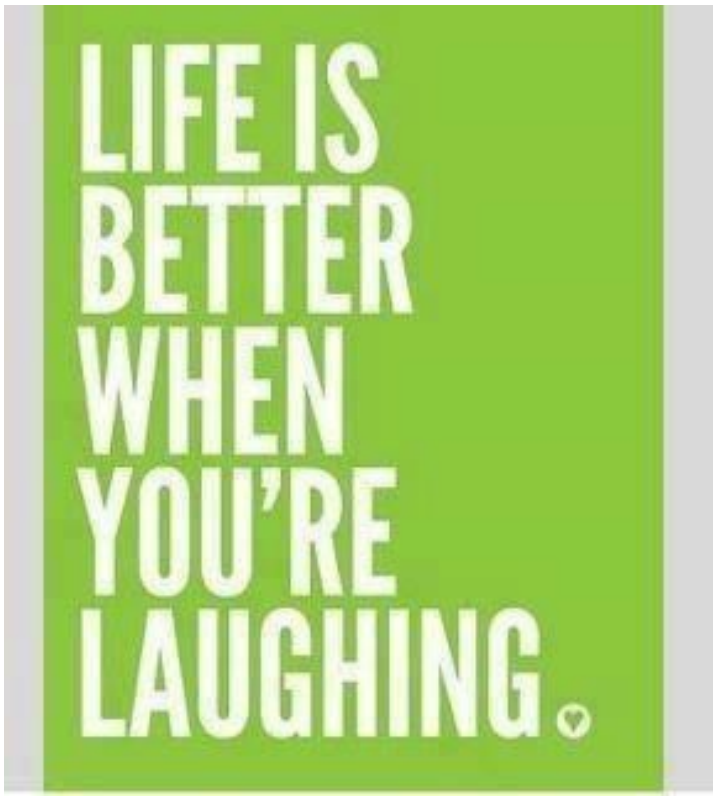
The DCOIWA family extends its best wishes for the future endeavours of the following officer who have recently retired. May God bless them with all happiness and healthy life.

**K G. Gadewar.
Assistant commissioners
FDA Pune**

**Mrs. Lotika Khajuria,
State Drugs Controller,
FCO J&K**

Congratulations

Laughter dose



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Sub-Standard Drugs

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Important links

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USFDA Inspection

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- USFDA puts import Alert on Sun Pharma: Halol
- USFDA issued Form 483 to Biocon with 5 observations
- USFDA issued Form 483 to Aurobindo with 8 observations

USFDA Approval

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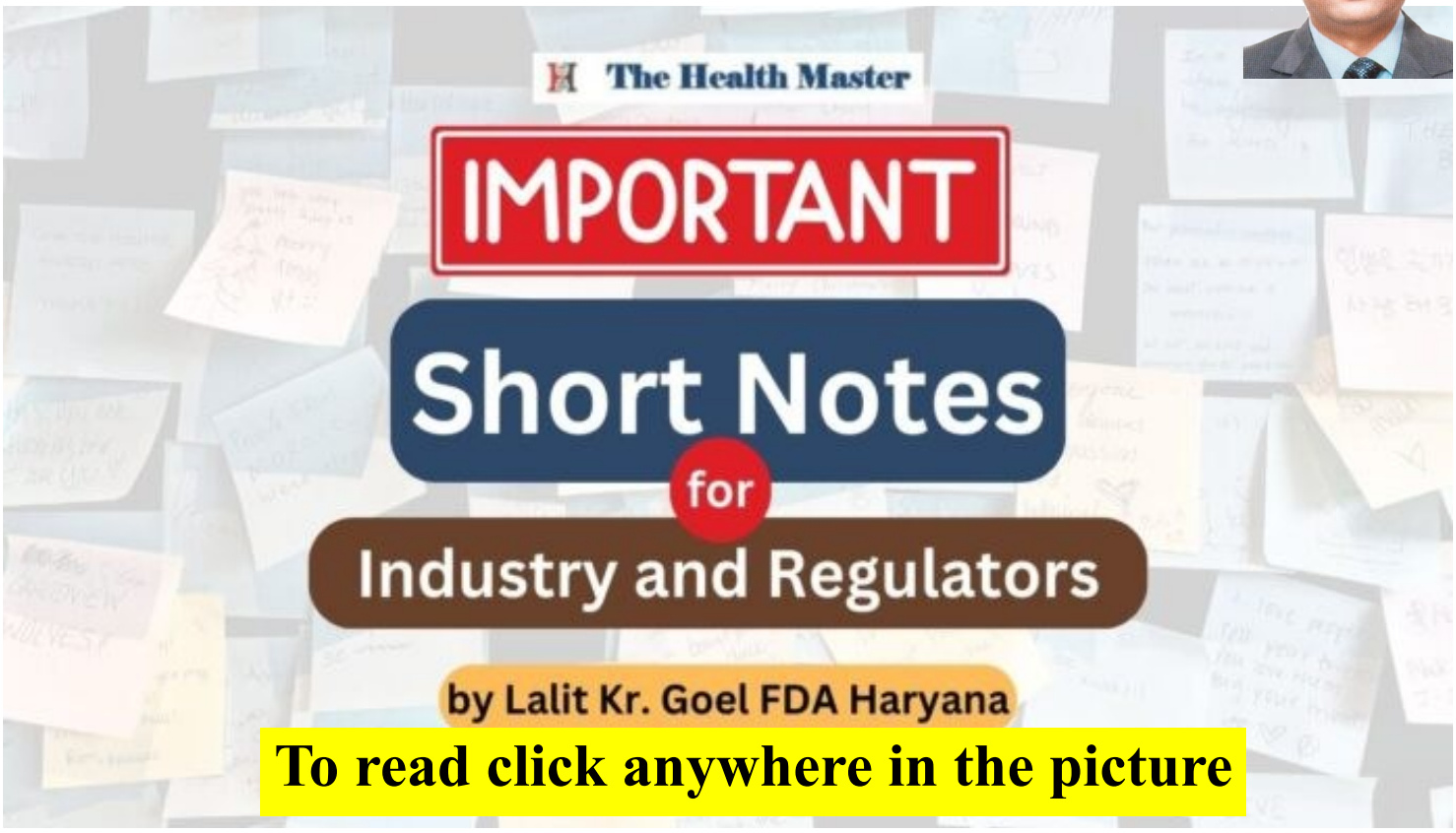
Important short notes for Industry and Regulators
By Lalit Kr. Goel, FDA Haryana



To read click anywhere in the picture

Key Notes on Revised Schedule M: Compilation
By Rakesh Dahiya, FDA Haryana

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FAQs on Ear Drops

by
Lalit Kr. Goel
Deputy State Drugs Controller,
FDA Haryana

Q1. Under which category of Schedule-M Ear Drops or preparation are covered ?

Ans: Ear Drops or preparation are covered under **Schedule-M**. Part-I-D if non-sterile and Part-1-I if sterile.

Q2: Whether Ear Drops are Sterile or Non-Sterile preparations ?

Ans: Ear drops are of both types – Sterile and Non-Sterile preparations. The ear drops intended for use in surgical operation / injured ear are sterile preparations.

Q3: Where is the general Monograph of Ear Drops is given?

Ans: It is given on page 1088 of the **Indian Pharmacopoeia** 2018.

Q4: In which section Non-Sterile Ear Drop preparation can be manufactured?

Ans: Non-sterile Ear Drops can be manufactured in external section as given in Part-I-D of Schedule M.

Q5: In which section Sterile Ear Drop preparation can be manufactured?

Ans: Sterile Ear Drops can be manufactured in sterile area and sterile dedicated area to avoid mixing of external preparation in other sterile preparation.

Q6: What are the special labelling requirements for the Ear Drops?

Ans: In addition to the requirements under Rule 96, 97 and general requirements under IP-2018 all the ear drops should be labelled with "**For external use only and not for injection**"

Q7: Whether sterile Ear Drops should meet the sterility test?

Ans: Yes and their dropper should also compliant with sterility test.

Q8: Whether sterile Ear Drops contain any anti-microbial preservatives?

Ans: No, multi dose preparations may contain anti-microbial however standard dose shall not contain anti-microbial preservatives.

Q9: Whether Ear Drops are Schedule-H drugs?

Ans: All the Ear Drop preparations containing antibiotics or steroids are covered under Schedule-H drugs.

Q10: What are the pack-sizes of ear drops allowed under Drugs Act?

Ans: 3 ml, 5 ml and 10 ml pack sizes are allowed under Drugs Act.

Q11: Is there any exemption in pack sizes of ear drops under Drugs Act?

Ans: No such exemption is given under Schedule P-I of Drugs Act.

Click for more article of the Author

FAQs

by
Lalit Kr. Goel
Deputy State Drugs Controller,
FDA Haryana

To read all FAQs on various topics, Click the below links

Notifications: Homoeopathy

Important Notifications

Compiled by
Rakesh Dahiya
FDA Haryana

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2024

GSR No. 669(E) dt 28-10-2024 **Drugs (Fifth Amendment) Rules, 2024** regarding **Homoeopathy**, Ayurvedic, Siddha and Unani Drugs

GSR No. 669(E) dt 28-10-2024 Drugs (Fifth Amendment) Rules, 2024 regarding Homoeopathy, Ayurvedic, Siddha and Unani Drugs

GSR No. 98(E) dt 02-02-2024 Draft notification for **Homoeopathy sale and manufacturing** – Drugs (Amendment) Rules, 2024

GSR No. 98(E) dt 02-02-2024 Draft notification for Homoeopathy sale and manufacturing – Drugs (Amendment) Rules, 2024

2022

Bachelor of Homoeopathic Medicine and Surgery (B.H.M.S) Regulations-2022

Bachelor-of-Homoeopathic-Medicine-and-Surgery-B.H.M.S-Regulations-2022

2021

GSR 473(E) dt 02-07-2021- Draft Drugs and Cosmetics (Amendment) Rules, 2021 – **Homoeopathy**

GSR-473E-dt-02-07-2021-Draft-Drugs-and-Cosmetics-Amendment-Rules-2021-Homoeopathy

2020

The National Commission for Homoeopathy Act 2020

The-National-Commission-for-Homoeopathy-Act-2020

(Continued on page 59)

Notifications: Homoeopathy

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2017

G.S.R-1380E-10-11-17-Homeopathy-for Mfg., Sales and Experience-person

G.S.R-1380E-10-11-17-Homeopathy-for Mfg., Sales and Experience-person

2009

GSR 917(E) dt 22-12-2009 – Schedule K – Homoeopathic Hair Oil – Drugs and Cosmetics (7th Amendment) Rules 2009

GSR-917E-dt-22-12-2009-Schedule-K-Homoeopathic-Hair-Oil-Drugs-and-Cosmetics-7th-Amendment-Rules-2009

***Compiled by*:**
Rakesh Dahiya, ***SDCO cum Licensing Authority, FDA Haryana***

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Pharmaceuticals

Important Notifications

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CDSCO Circular

CDSCO

CDSCO dt 15-09-2025 Clarification for regulatory pathway for approvals of Cocrystals

CDSCO dt 15-09-2025 Clarification for regulatory pathway for approvals of Cocrystals

CDSCO dt 11-09-2025 Stickering on Medical Products due to reduction in Goods Service Tax (GST) rate

CDSCO dt 11-09-2025 Stickering on Medical Products due to reduction in Goods Service Tax (GST) rate

CDSCO Notice dt 09-09-2025 Inviting comments on consideration of the proposal regarding problem faced by the blind or visually impaired people to read medicines tablets and capsules strips

CDSCO Notice dt 09-09-2025 Inviting comments on consideration of the proposal regarding problem faced by the blind or visually impaired people to read medicines tablets and capsules strips

Latest Notification

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S.O. 4171(E) dt 15-09-2025 Ceiling Prices of Orthopaedic Knee Implants for Knee Replacement System based on the decision of 137th Authority meeting dated 15.9.2025

S.O. 4171(E) dt 15-09-2025 Ceiling Prices of Orthopaedic Knee Implants for Knee Replacement System based on the decision of 137th Authority meeting dated 15.9.2025

S.O. 4170(E) dt 15-09-2025 NPPA has fixed retail prices of 9 formulations under Drugs (Prices Control) Order, 2013 based on the decision of 137th Authority meeting dated 15.9.2025.

S.O. 4170(E) dt 15-09-2025 NPPA has fixed retail prices of 9 formulations under Drugs (Prices Control) Order, 2013 based on the decision of 137th Authority meeting dated 15.9.2025

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For Animal use

Download S.O. 4338(E) Dt. 23-09-2025 Section 10A, 26A Prohibition of import manufacture sale and distribution of 34 antimicrobials and group of antimicrobials and their formulations for Animal use.

Download S.O. 4338(E) Dt. 23-09-2025 Section 10A, 26A Prohibition of import manufacture sale and distribution of 34 antimicrobials and group of antimicrobials and their formulations for Animal use

Upcoming Events

2025

CPHI & PMEC India 2025

November-2025

Date: November 25-27, 2025
Location: India Expo Centre in Greater Noida, India
Description: the highly anticipated CPHI & PMEC India 2025, taking place from November 25-27 at the India Expo Centre in Greater Noida, Delhi NCR, Informa Markets India is thrilled to kick off a series of dynamic events across three key pharmaceutical hubs: Ahmedabad, Bengaluru, and Chandigarh.

This Industry Connect Program facilitates engaging discussions on the current landscape of the pharmaceutical industry, highlighting the needs and challenges that will shape the conversations at CPHI & PMEC India 2025, while providing exhibitors an excellent opportunity to present innovative solutions to a targeted audience of pharmaceutical professionals.

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December-2025

PharmaTech Expo Bengaluru

Date: December 19-21, 2025
Location: Bengaluru, India
Description: PharmaTech Expo is one of the largest pharma exhibitions in India and is a place for thousands of people from the business to share their experiences related to products, customers, business, and sales. This pharmaceutical and lab expo brings together people from across the globe to one destination. It is one of the biggest B2B trade shows of the sector that involves people from the healthcare and pharma machinery industries to participate and share innovation related to advanced technologies in the pertinent sector.

It will showcase pharma products, machinery, and technological innovation to buyers from various countries, including India, China, the USA, & Germany, which are major markets for this sector. This event will surely give you a huge platform to establish and enhance your business by meeting active suppliers looking for collaboration with the Indian pharma and healthcare market. Meeting new investors and fellow businessmen from the same fraternity would definitely be a win-win situation for both parties. If you are from the pharmaceuticals and healthcare industry and want to explore the involution of business, come and be a part of this mega pharma trade fair.

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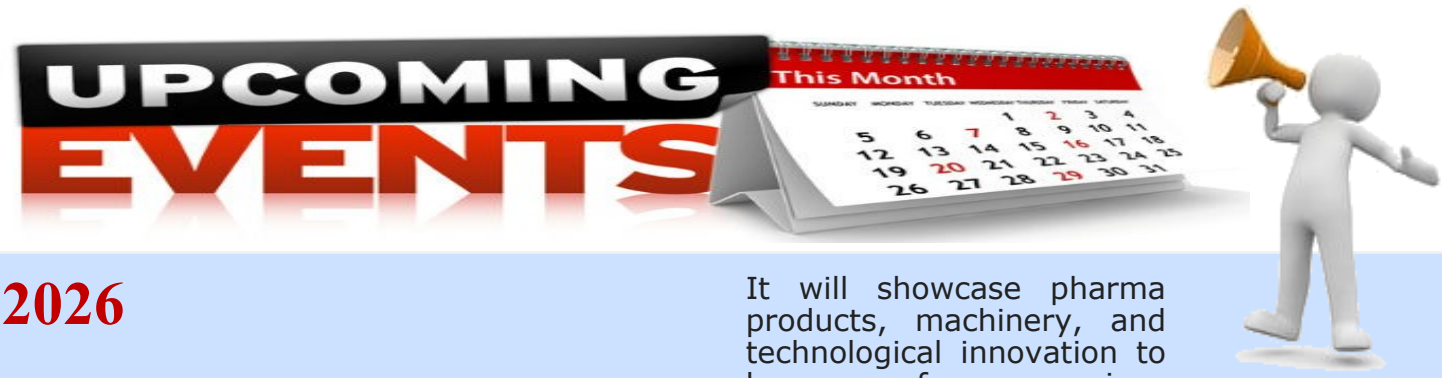
Upcoming Events



2026

April-2026

PharmaTech Expo Chandigarh

Date: April 09-11, 2026
Location: Chandigarh, India
Description: PharmaTech Expo is one of the largest pharma exhibitions in India and is a place for thousands of people from the business to share their experiences related to products, customers, business, and sales. This pharmaceutical and lab expo brings together people from across the globe to one destination. It is one of the biggest B2B trade shows of the sector that involves people from the healthcare and pharma machinery industries to participate and share innovation related to advanced technologies in the pertinent sector. It will showcase pharma products, machinery, and technological innovation to buyers from various countries, including India, China, the USA, & Germany, which are major markets for this sector. This event will surely give you a huge platform to establish and enhance your business by meeting active suppliers looking for collaboration with the Indian pharma and healthcare market. Meeting new investors and fellow businessmen from the same fraternity would definitely be a win-win situation for both parties. If you are from the pharmaceuticals and healthcare industry and want to explore the involution of business, come and be a part of this mega pharma trade fair.

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20 DCOIWA News October 2025

DCOIWA Mission

To unite and organize the working and retired Drugs Control Officers from Indian States, Union Territories and CDSCO, with an object of coordinating their activities for establishment of social justice and regulating the relations of the officers with government agencies. Call : 8121296397, 8094357800,9977177574

a) To unite and organize the working and retired Drugs Control Officers from Indian States, Union Territories and CDSCO, with an object of coordinating their activities for establishment of social justice and regulating the relations of the officers with government agencies.
b) To safeguard and promote interest of its members all over the country
c) To redress the grievances of the members.
d) To promote a sense of fraternity, feeling of belonging and brotherhood amongst its members.
e) To cooperate, accept affiliations and federate with the officers associations, federations, and confederations in the country where similar objectives are seen with international bodies.
f) To achieve professional excellence through better coordination amongst its members.
g) To offer better services to the public.
h) To make dedicated efforts for welfare of its members.
i) To conduct seminars, webinars, social activities, competitions, quiz programs etc. time to time.
j) To take up any other activity conducive to the betterment in the discharge of their functions effectively and efficiently.

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Dear Members,

As we conclude this edition of our e-newsletter, I would like to express my gratitude to our contributors and readers for their continued support. Your engagement is invaluable, and we appreciate the diverse perspectives that make our community thrive.

We strive to bring you relevant and insightful content, and we welcome any feedback or suggestions you may have for future editions. Our goal is to foster a collaborative space for knowledge-sharing among DCOIWA members, regulators, and pharmacy professionals.

Thank you for being a part of our community. We look forward to bringing you more enriching content in the upcoming editions.

Best regards,

Rakesh Dahiya
Editor-in-Chief
DCOIWA News