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E-Newsletter

DCOIWA News

Drugs Control Officers (I) Welfare Association (Regd)

Email: dcoidcwa@gmail.com Website: www.dcoiwa.com

H.Q.: 15-21-150/6, New Balaji Nagar, Kukatpally, Hyderabad (T.S.) India 500072. Phone 8121296397, 8094357800, 9977187574

Monthly Newsletter

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Focus on R&D, secure Patents for New Drugs: PM

Patents

The appeal for all **scientists** and **entrepreneurs** to get down to **research and development** (**R&D**) and secure **patents** for new drugs has resonated from the Red Fort this 79th Independence Day by **Prime Minister Narendra Modi**. To make India truly **Atmanirbhar** in pharmaceuticals.

Why focus on R&D?

Because we are lagging behind in **R&D** since the **Department of Pharmaceuticals** (DoP) did a study about it, and the results are revealing.

While research-based efforts between **Industry** and **Academia** have yielded positive results in India, the efforts have been disjointed.

Thus, India boasts **2%** of researchers compared to the world's number, while the **US** and **China** hold **20%**.

OECD countries

Of the relevant **R&D** in the country, **75-80%** is government funded, while **20-25%** is privately funded.

For example, **3%** comes from universities, while, on the contrary, **69%** comes from the private sector in some **OECD countries**.

This means growth can happen in India as well, on a global scale.

Patent cliff: a generics prospect

India is known as the **pharmacy of the world**; with over **10,500 pharmaceutical manufacturing units** in India, there are **60,000 generic drugs** produced across **60 therapeutic areas**.

The tide is turning.

Several Indian pharma companies are now looking to develop not only in the generics arena post-COVID but also to create a pipeline for **biosimilars**.

Expiry of patents

The opportunity lies in the next decade, and

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Editorial Board

D C O I W A N E W S

Rakesh Dahiya

Editor-in-Chief
DCOIWA Newsletter

A Call to Action for a Healthier Tomorrow

Welcome, dear friends and fellow members of the Drugs Control Officer (I) Welfare Association (DCOIWA)! As we proudly present the 19th edition of our monthly newsletter, it feels like we're not just flipping a page on a calendar, but truly turning a new page in our shared mission. This publication is a testament to our collective dedication, a monthly snapshot of the tireless work and crucial developments that define our field.

Navigating a Changing Landscape

The world of drug control and pharmaceuticals is always in motion, and our work is never done. We're seeing big shifts, from the new online system for drug imports to the stricter rules on misleading pharma ads. These changes, like the recent UCPMP 2024 for ethical marketing and the move to launch "SHRESTH" to rank states for medicine safety, show that a stronger, more transparent system is on the horizon. Our work, often happening behind the scenes, is what makes these big pushes for safer medicines a reality. The recent news of the **CDSCO's new draft standards for IVD medical devices** and the quickened recall time for NSQ drugs in Karnataka prove that we're moving faster than ever to protect public health. This is a big deal, and it's our daily efforts that are making it all possible.

Honoring Our Heroes and Our Duty

This edition shines a light on some remarkable achievements. We celebrate the promotions and retirements of our colleagues, recognizing their long service and welcoming new blood into our ranks. We also take a moment to applaud those who stand firm in their principles, like the **Assistant Drug Commissioner who**

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bravely rejected a bribe. Stories like these remind us of the immense responsibility we carry and the integrity that must be our guiding star. They inspire us to be vigilant and to act with courage in the face of temptation. Our success isn't just measured in the number of raids conducted or licenses issued, but in the trust we build with the public.

A Shared Responsibility

As we look at everything covered in this issue—from the prime minister's call for more R&D to the bust of an illegal drug trade by DCA Telangana—it's clear that our work connects to a larger national narrative of health and progress. We are on the front lines, ensuring that every pill, every medicine, and every medical device meets the highest standards. The information on **FSSAI's food labeling guidelines**, the details on new recruits, and the latest on important events all serve to keep us informed and united. This newsletter is more than just a collection of articles; it's a tool for collaboration, a source of knowledge, and a reflection of our unwavering commitment to public well-being.

Let's continue to support each other, share our insights, and work together to build a healthier, safer India for everyone. Your dedication makes all the difference.

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President Note

DRUGS CONTROL OFFICERS (I) WELFARE ASSOCIATION

(Regd.No. 634 of 2022)
E-mail: dcoidcwa@gmail.com Website: www.dcoiwa.com

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Cell: 8121296397 - Telangana

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Mr. Tapan Ch
Cell: 9[illegible]

Date: 9th August 2025
Place: Philadelphia, USA

Note from the President –
Drugs Control Officers India Welfare Association

Dear Respected State Licensing Authorities,

This WhatsApp group has been created with the objective of sharing information, exchanging views, and strengthening our collective efforts as the safeguarders of drugs in India. Our prime motto remains steadfast — to ensure the right medicine reaches the right patient at the right time and at the right price.

The recent initiative proposed by Haryana Drugs Controller, Shri Lalit Goel, to form a committee of Northern States' Heads of Departments for inter-state information exchange is both timely and inevitable. Such a model, if extended to all States and Union Territories across India, will undoubtedly yield significant results.

I strongly recommend that we hold frequent meetings — either in person or through online platforms — to sustain this collaborative spirit and translate it into tangible outcomes.

Since the tenure of this group's members is limited, I urge each one of you to make meaningful contributions that will serve as a pathway for your successors. At present, we have all SLAs represented here except Kerala; I request that someone kindly take the initiative to include our colleague from Kerala as well.

I look forward to a positive and proactive response from all the leaders of this group.

With regards,

G. Koteshwar Rao
President
Drugs Control Officers India Welfare Association

H.Q. 15-21-150/6, New Balaji Nagar,
Kukatpally, Hyderabad (T.S), INDIA.
Phone : 8121296397, 8094357800,9977177574.

Focus on R&D, ……continue

(Continued from page 1)

it's known as the "**patent cliff**."

The patent cliff will see over **300 drug patents** expire per year between **2022** and **2032**.

For example, at present, blockbuster diabetic drugs are expiring, and the weight-loss equivalent to **semaglutide** is expected to go off **patent** about March 2026.

Indian companies can now enter the **U.S**. and regulated arenas with their versions and expound globally.

Source: [The Health Master]

Procedure to obtain license for Medical Store / Pharmacy

Rakesh Dahiya

Editor-in-Chief,
DCOIWA News
Organising Secretary, DCOIWA
SDCO cum Licensing Authority,
FDA Haryana

How to obtain license for Retail and/or Wholesale for Drugs and Homoeopathic medicines

For obtaining license for Retail and/or Wholesale for Drugs and Homoeopathic medicines, the list of documents required is provided below. Download the pdf file and prepare the documents accordingly.

Documents-required-for-obtaining-license-for-sale-of-drugs

List of Forms & Fee for obtaining the said licenses is provided below. Download the pdf file and prepare the Form accordingly and submit the required fee.

Form-and-Fee-for-obtaining-license-for-sale-of-drugs

Forms

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

Form 19

Form 19A

Form 19 AA

Form 19B

Form 19 C

Procedure for obtaining drug sale license

To download the procedure, how to obtain drug sale license, click below link

Procedure-for-obtaining-drug-sale-license

Submit your application (Online and / or hard copy) to Licensing Authority of your area after completing all the required documents. Procedure of submission of application may vary from State to State)

License conditions for allopathic drugs

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

License-conditions-for-Allopathic-Drugs

License conditions for Homeopathic medicines

Conditions of licenses is to be maintained after obtaining the required licenses for Homoeopathic medicines. Download the pdf file for ready reference.

(Continued on page 8)

Procedure to obtain license for Medical Store ….conitune

(Continued from page 7)

License-conditions-for-Homeopathic-Medicines

Note: Requirements of some of documents and procedure for submission of application may vary from State to State

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Schedule H, H1 & H2 drugs

Also read Schedule H, Schedule H1 & Schedule H2 drugs, click below links:

Schedule-H

Schedule-H1

Schedule-H2

Download fee structure

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

License fee structure for all licenses

Change of name of Medical Store / Pharmacy

If you want to change the name of a Medical Store / Pharmacy (Retail sale or wholesale), you have to apply to Licensing Authority of your area.

To download specimen performa for applying for change of name of Medical Store / Pharmacy, Click below link:

Specimen-performa-for-name-change-of-the-firm

License Retention Fee for Medical Store / Pharmacy

To download specimen performa for informing Licensing Authority regarding License Retention Fee for Medical Store/ Pharmacy, Click below link:

Specimen-perform-for-information-of-submitting-License-Retention-Fee

Compiled by:

Rakesh Dahiya

SDCO cum Licensing Authority

FDA Haryana

Click here for more articles of the Author

Drug Imports: New Online System for Dual Use NOC launched

Rakesh Dahiya

Editor-in-Chief, DCOIWA News
Organising Secretary, DCOIWA
SDCO cum Licensing Authority, FDA Haryana

Dual Use NOC

The **Central Drugs Standard Control Organization** (CDSCO) has launched a new online system for **Dual Use NOC** on its SUGAM Portal to enhance the "**ease of doing business**" (EoDB).

The **CDSCO** has issued an important circular on **01-08-2025**, having the details of the online process of obtaining a **No Objection Certificate** (NOC) for drugs imported in bulk for non-medicinal purposes.

The new online system, which becomes fully functional from **August 31, 2025**, is set to decrease the compliance burdens and enhance transparency in the regulatory process.

The Importance of Dual Use NOC

The regulation of "**Dual Use**" substances is critical for public health and safety.

These are drugs that, while having a mainly medicinal purpose, are also used in industries such as pharmaceuticals, food, and non-medicinal applications.

The new system provides clear guidance and a transparent process for importers, which ensures that all substances imported for non-medicinal use are fully in compliance with all regulatory requirements described under **Schedule D** of the **Drugs and Cosmetics Rules, 1945**.

The new system is having a **two-step procedure**, reducing the third-party interference and improving efficiency.

A Step-by-Step Guide

The new online system simplifies the NOC application, divided into two distinct phases, both managed through the SUGAM online portal.

Phase I:

Zonal/Sub-Zonal Office Application:

This initial phase I is used for the registration and obtaining a one-year **Dual Use NOC**.

Applicants must first register on the **SUGAM portal** and select the "**Dual Use NOC**" user role.

- The application, along with a set of mandatory documents, will be submitted.
- This application will be reviewed and verified by the officers of **CDSCO** Headquarters and the relevant zonal or sub-zonal office.

Mandatory Documents for Registration (Phase I):

- **Address Proof:** For address proof, a government-issued document is required, i.e., a Certificate of Incorporation, GST Certificate, or IEC Certificate. The details on this document must match exactly with the details

(Continued on page 10)

Drug Imports: New Online System …….continue

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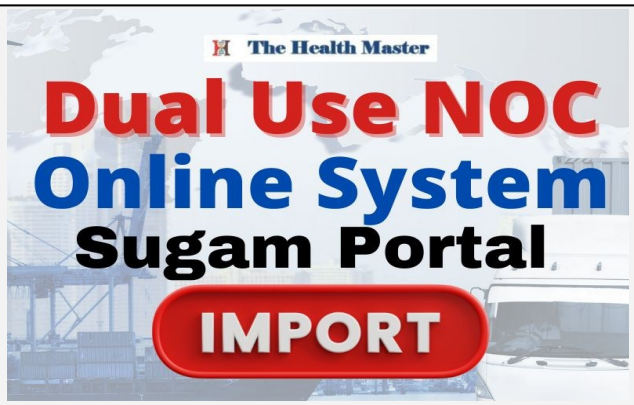
submitted on the portal.

- **Undertaking:** A duly filled, signed, and stamped undertaking form is required.
- **ID Proof of Authorized Person:** A valid ID proof for the authorized person is mandatory.



Phase II:

Port Office Consignment Release

- After approval of a one-year NOC in Phase I, the applicant can proceed to Phase II for the release of specific consignments at the port of entry.
- Some documents are required to be submitted on the online portal, which are to be verified by the officers of the concerned port office at the time of import of the substance.

Required Documents for Consignment Release (Phase II):

- **Covering Letter:** A letter outlining the purpose, drug name, quantity, and manufacturer's details.
- **Certificate of Analysis (CoA)**: The firm must upload the CoA document.
- **Bill of Entry Details:** The bill of entry number, date, customer name, country, and quantity must be filled out in the specified format.
- **Label and Invoice:** The original product label and purchase invoice are mandatory.

Key points for Importers

Applicants/importers must keep in mind the following several key points:

- **Timely Application:** It is advised that **Dual Use NOC** clearance be applied for at least two months before import to avoid any delays.
- **Clear Labeling:** Imported items and all accompanying documents, such as the Certificate of Analysis and Bill of Entry, must clearly state "**Not for Medicinal Use**" or "**for use as pharma aid**."
- **Ineligible Imports:** The new system is not applicable for imports intended for purification or sterilization.
- **Jurisdiction**: The application must be filed with respect to the actual importer's address and not that of the Custom House Agent (CHA).

Compiled by:

Rakesh Dahiya

SDCO cum Licensing Authority

FDA Haryana

Click here for more articles of the Author

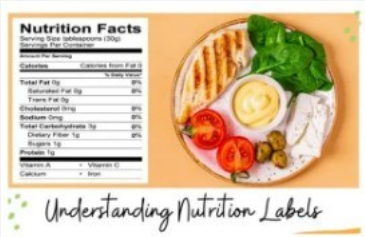
FSSAI: Food Labelling and Display – Chapter-20

Dipika Chauhan
Former, Deputy Commissioner
FDCA Gujarat

Food Labelling

Continued from…… FSSAI: Food Labelling and Display – Chapter-19

Guidance and instructions for Food Labelling



Display Clarity: Guidelines for Principal Display Panel

Enhancing Food Information: Schedule-I Labelling Requirements

Ensuring transparency in **food labelling**, Schedule-I outlines specific requirements for two distinct types of food products—fortified food and certified organic food.

1. Fortified Food Packaging

Mandatory Label Elements:

Every package of fortified food must prominently display the words "**fortified with ..... (name of the fortificant)**" on the label.

Inclusion of Logo:

Additionally, a specified logo, as outlined below, should be present on the label of fortified food packages.

Optional Tagline:

An optional tagline, "**Sampoorna Poshan Swasth Jeevan**," can also be included under the logo for further emphasis.

2. Certified Organic Food Packaging

Mandatory Logo:

Every package of certified organic food, in accordance with the Food Safety and Standards (Organic Foods) Regulations, 2017, must feature the logo specified below on the label.

Source: The Health Master

Lalit Kr Goel joins as State Drugs Controller Haryana

Lalit Kr Goel

Panchkula, Haryana — The pharmaceutical landscape in Haryana is buzzing with optimism following the promotion of **Lalit Kr Goel** to the esteemed position of State Drugs Controller-cum-Licensing Authority, **Food and Drugs (FDA) Haryana**.

The pharma industry, which is actively working to establish Haryana as a dominant manufacturing hub in North India, believes **Goel's** leadership will be a game-changer.

Lalit Kr Goel's Blueprint for a Better Future for the stakeholders

Lalit Kr Goel has outlined a series of key plans to create a healthier environment for pharmaceutical businesses.

These include:

- Streamlining the approvals and renewals with clear guidelines to significantly reduce processing delays for transparent and efficient licensing.
- Fair, uniform, and consistent enforcement of regulations to ensure the safe and effective delivery of drugs to the people of the region.
- In-time guidance and support with prompt responses to technical queries and clarifications on day-to-day operational issues.
- **Combating Counterfeit Drugs:** In an important move to safeguard public health, **Lalit Kr Goel** has announced a bold plan to form an interstate coordination committee to combat the threat of counterfeit, fake, and spurious drugs.

This initiative will bring together drug controllers from five northern states—Delhi, Haryana, Himachal Pradesh, Uttarakhand, and Punjab—to create a unified and robust strategy.

The committee's primary goal is to enable joint actions, share intelligence, and establish a seamless information-sharing network to dismantle drug rackets that operate across state borders.

(Continued on page 13)

Lalit Kr Goel ……..continue

(Continued from page 12)

This collaborative effort is seen as an important step towards creating a more robust enforcement mechanism and protecting the public from the dangers of substandard, fake, and spurious drugs.

Goel has indicated that the first meeting is planned for next month to formalize this collaboration, marking a CRUCIAL step forward in regional drug regulation.

A Leader with a Proven Track Record

Narender Ahooja, the former SDC of Haryana, also lauded **Goel**, calling him a highly knowledgeable expert on drug acts and rules.

Ahooja highlighted **Goel's** hands-on approach, where he provides helpful guidance to industries, especially MSMEs.

He expressed confidence that under **Goel's** leadership, the **FDA Haryana** will reach new heights, and the industry will thrive.

Vikas Pruthi, the general secretary of the Haryana Pharmaceutical Manufacturers Association (HPMA), expressed the industry's profound confidence in **Goel**.

He highlighted **Goel's** unwavering dedication, integrity, and deep understanding of regulatory affairs as qualities that have already inspired the sector.

This appointment comes at a time when the state's pharmaceutical industry is poised for substantial expansion.

The association strongly believes that **Goel's** tenure will usher in a transformative period marked by increased efficiency and unprecedented transparency.

Praise for **Lalit Kr Goel's** appointment is not limited to manufacturers.

Sharad Mehrotra, president of the Gurugram Chemists and Druggists Association (GCDA), described **Goel** as a disciplined, integrous, and humble individual who consistently seeks to learn.

Mehrotra praised his exceptional and straightforward approach, noting that he prefers to guide and educate rather than punish.

Satish Vij, president of the Haryana Drug Dealers Association (HDDA), added that **Goel's** vast experience and knowledge, particularly on topics like the NDPS Act and Schedule M, make him an ideal leader.

Vij is hopeful that **Goel's** work will significantly improve coordination between the trade and the department.

Source: The Health Master

15th August Award

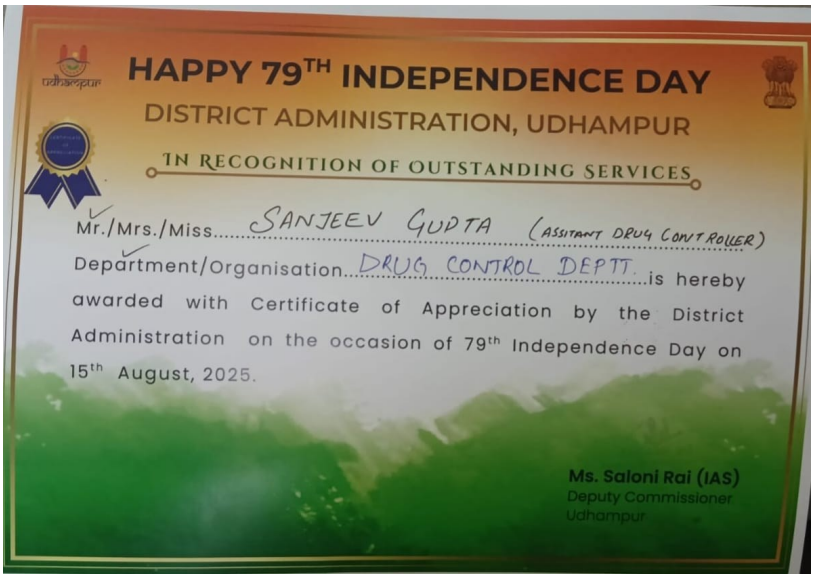
15th August Award Haryana

Sh. Mandeep Mann, Drugs Control Officer, FDA Haryana, receiving award from Hon'ble Chief Minister, Sh. Naib Singh Saini on 15th August 2025.

15th August Award

J&K

Sh. Sanjeev Gupta, Assistant State Drugs Controller, J&K receiving award on 15th August 2025



Celebration of National Independence Day 2025

Gujarat

Retired Deputy Commissioner of Gujarat F&DCA, Mr. Anil Kakkad has organized a Public ceremonial program to mark and celebrate our National Independence Day 2025 at public garden, Sector-22, Gandhinagar, Gujarat State. The event was attended with great enthusiasm by Society's Yoga Classes women, Social workers, senior citizens, children and other reputed residents. The National flag was hoisted by Shri Viththalbhai Patel, ex president of the society's and reputed builder (Shalin Group) on this historical event. Chanting of National anthem, Floral offering to National flag, Bhajans, Tributes to the sacrifice of freedom fighters, silent pray were also held.

Main organizer of the program Shri Kakkad in his keynote address emphasized on the dedication, devotion and sacrifice of our freedom fighters. He appealed all to preserve our invaluable freedom by all cost and maintain our rich heritage, culture and development for bright future of our great nation. Finally a rally marched with slogans of "Vande Mataram, Bharat Mata Ki Jai, Svatantra Bharat Amar Raho "carrying different banners and play cards of constitution of India.

New Draft Standards for TB IVD Medical Devices: CDSCO

The Drugs Controller General of India (**DCGI**) has determined new guidelines to align the approval process of Tuberculosis (TB) diagnostic medical devices with the newer things.

The Central Drugs Standard Control Organisation (**CDSCO**) has released a draft of guidelines that pertain to the standardization of the licensure of Tuberculous In **Vitro Diagnostics** (IVDs) focused on quality assessment and performance.

Such **TB IVD** medical devices will be more easily acquired and likely approved for efficacious testing across the country very soon.

What's Included?

This **54-page draft** comes from the Indian Council of Medical Research (ICMR) and **CDSCO** and contains proposed drafts to assess the various analytical and clinical performances relative to **IVDs**.

This impacts the most common forms of **IVD** medical devices, which reflect diagnoses for pulmonary **TB** but even more so for the more complicated and difficult-to-treat drug-resistant **TB (DR-TB)**, which influences entire communities at risk.

Therefore, any assessment includes an assessment of safety, sensitivity, and specificity, meaning that it must perform as intended and the intended conclusions must be validated before the comprehensive assessment for licensure in India is determined.

What are in vitro diagnostics?

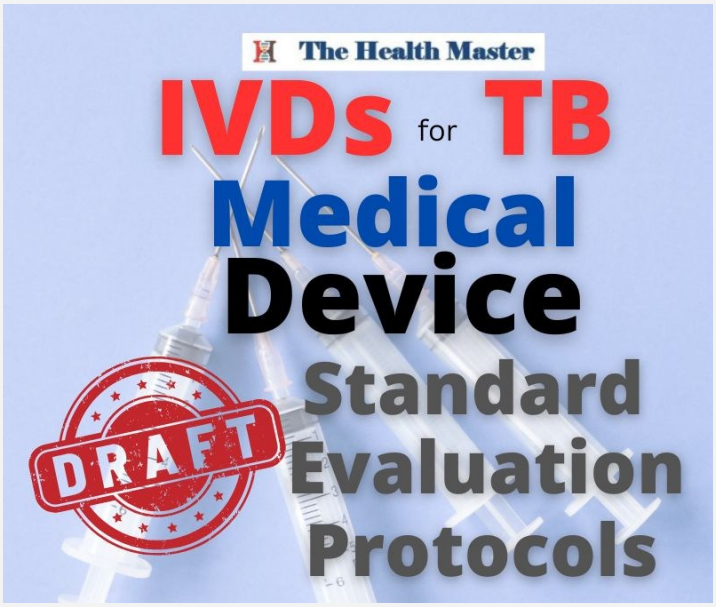
In vitro diagnostics are instruments that diagnose tests that are performed on samples taken from inside the body, such as blood, tissue, serum, urine, etc.

IVDs assess certain "**biomarkers**" within the sample taken to assess the individual's state of health or whether that person has been infected with some type of disease.

These new assessments are specifically applied to licensed **IVDs** used for stating a positive determination of **TB**.

What Happens Next?

The public comment window for this proposed draft decision is open until **September 7, 2025**, at which point **CDSCO** and **ICMR** will decide what to take from the commentary before completing the cycle.



This requires such testing based on the Medical Device Rules of 2017, which ensures that quality measures are maintained prior to licensure.

It's important that India recognize this process independent from comparative processes from the past, as only earlier this month drafts were created for licensing approval of **15** other kinds of **IVD** kits unassociated with **TB** but with **dengue**, **malaria**, **SARS-CoV-2**, etc.

Importance of These New Guidelines

For the public health panorama, this means a faster and more assured process for those seeking **TB** diagnostic medical devices.

This is pivotal for a medical landscape that must strive toward prevention and treatment of **TB** challenges that occur with frequency for millions of Indians annually.

The clearer the device acquisition process becomes, the better it will be for the laypersons and their disease treatment pathways.

Source: The Health Master

DCA Telangana busts illegal drug trade

DCA Telangana

DCA Telangana: Imagine this. A truck not transporting fruits and vegetables, but **hundreds of bottles of drugs,** across state lines without any form of registration. This was exactly what **drugs control administration Telangana** (DCA Telangana) busted in Telangana.

In a collaborative success between **DCA Telangana** and local police, a streamlined approach to a drug trafficking bust took place, letting all those participating in this illegal action know: they shouldn't play ball.

Major Drug Trafficking Busted

At Kotapally Check Post, officials were tipped off about a suspicious drug shipment destined for Maharashtra after it was halted in transit.

After inquiries, it was determined that a large volume of drugs was being transported without proper drug licensing, which turned out to be worth **Rs. 30,000.**

Ultimately, **two offenders were apprehended.**

One was found in possession of **26 types of drugs** and the other of **37.**

And these were not your ordinary over-the-counter pain relievers.

These included antibiotics, anti-ulcer medications, and cough syrups.

The Dangers of illegal Drugs

There are plenty of reasons why drugs are licensed from their inception to dispensing.

On a fundamental level, when people get medications, they want to believe they're safe and effective.

This is not the case for illegal drugs, however.

Drugs that are unregulated can never be certain if they are legitimate, safe, or even effective to begin with.

They can be forged or outdated; they can contain improperly measured ingredients or additional chemicals to muck up the works; they can be created in sweatshops or back alleys only to be stored in unregulated temperatures, killing people just the same.

Therefore, this shows that the illegal drug trade is a concern to all persons, primarily those who need these drugs.

A Strong Message

In a press release following the raid, the Director General of the **DCA Telangana** minces no words in detailing what wholesalers and distributors in Telangana should NOT be doing; **they should not be supplying drugs to unlicensed, nefarious individuals/shopkeepers.**

Furthermore, the advisement suggests that good practice is now compulsory so that anyone trading in any drug must first confirm a legal drug license and document such confirmation before any drug transaction occurs.

This is a move to ensure drugs do not fall into the wrong hands for public safety.

The **DCA Telangana** has mentioned that anyone who fails to comply will be on the lookout to receive penalties, including up to **five years** imprisonment, as this is not the first announcement of this kind since months ago regarding counterfeit drugs.

Source: The Health Master

Alert on theft: Multiple drugs of Novo Nordisk Stolen

Stolen

This is a public health alert about a recent theft that happened right in the middle of a drug transport, and the same has been **stolen**.

A bunch of injectable medications from the big pharmaceutical company, Novo Nordisk, were **stolen** while being moved from their Bhiwandi hub to several cities.

These cities include **Nagpur, Raipur, Cuttack,** and **Kolkata**.

The drugs in question are pretty special—they're made using **rDNA** origin technology and have to be kept super cold, specifically between **2 and 8 degrees Celsius.**

If they get too warm, their quality can go down the drain, which could be really dangerous for the people who need them.

What's Gone Missing?

The **stolen** stash includes several important medications, some of which are for managing diabetes and others for weight loss.

Details of the drugs with batch numbers:

- **Ryzodeg™ FlexTouch®:** This is an insulin solution for injection. The batch number is **RT6GY96**.
- **Fiasp® Penfill® and Fiasp® FlexTouch®:** Both are insulin solutions. Their batch numbers are **RR726A8** and **RP5P640**, respectively.
- **Wegovy® FlexTouch®:** This is a semaglutide injection for different dosages (0.5mg, 0.25mg, and 1mg). The batch numbers for these are **RP5S233, RP5S232,** and **RP5S210**.

Official Advice for Everyone

The government's Central Drugs Standard Control Organization (**CDSCO**) has issued an advisory to keep everyone safe.

They're urging everyone to be extra careful:

For Patients and Consumers:

Please, be very, very careful. Only buy these medications from sources you know and trust.

Always obtain a proper invoice of the drugs.

It is very important because without proper storage, the drug might not work, and it may be harmful for the health.

For Doctors and Health Professionals:

When you prescribe these drugs, please take a moment to educate your patients.

Tell them to report any unexpected side effects they might experience.

For Drug Regulators:

The CDSCO is asking all state and local drug controllers to keep their eyes peeled.

They need to watch out for these specific products in the market and take action if they spot them.

The **police** are currently investigating the matter to figure out what happened and where the **stolen** products ended up.

Source: The Health Master

Drugs Rules amended to include qualitative data of excipients

A Game Changer for Patient Safety: New Regulations for Drugs to Include Excipients by QR Code. The govt has issued a notification vide **GSR 554(E) dt 18-08-2025**.

The new regulation for drugs by the government is a monumental step for patient safety.

As of March 1, 2026, all drugs must have a **QR code** with additional information regarding the excipients of the drug.

This is a huge boon for those who need to be especially sensitive about what they're taking.

What Are Excipients and Why Are They Important?

Excipients are the cast members in a movie, as some would say.

They're not the stars (that's the active drugs); they're smaller supporting roles—but crucial nonfunctional.

Binders, fillers, preservatives, coloring agents—the things that comprise the composition of the drug to get it working properly.

They are important to know because while they are inactive, many people can have an allergic reaction to these components.

For example, parabens are one type of preservative; if someone is allergic to parabens, it could be difficult for him/her/them to find workable medicine.

But before now, finding this information on the medicine strip was nearly impossible and left patients and physicians alike guessing.

Where Did This Process Come From?

Thus, this was not a straight line to initiate this process.

This proliferation came from a complaint from a citizen who was inspired and directed to the Drugs Technical Advisory Board (DTAB) and other Drugs Consultative Committees (DCC).

There was much back and forth about whether or not this information could go on a medicine strip, which would be difficult given the size; whether it should go on a package insert, also difficult since many medicines don't come with an insert; or whether it should go on a separate piece of paper, yet again difficult since not all people would get it.

Finally, however, the committees concluded that a **QR code** would be best—simple enough and containing enough information without overloading—and voted for it.

The draft suggested information on excipients would be necessary, yet the voted decree submitted "qualitative details," signifying a more extensive list would be required.

What This QR Code Will Include

The new regulation adds qualitative details of excipients as the 9th piece of information stored in said **QR code**.

As of now, when residents scan certain drug label QR codes, they are privy to:

- Unique product identification code
- Proprietary name (brand name)
- Drug name (generic name)
- Manufacturer's name and address
- Batch number, manufacturing date and expiration date
- Manufacturing license number

Qualitative details of excipients (effective March 1, 2026)

How This Affects The Average Person

This isn't just an arbitrary piece of new legislation—it gives power back to the patient.

For those with allergies, they can rejoice knowing that before taking a drug they've been prescribed, all they need to do is scan the **QR code** before use to know if it's safe or not.

This will make educated decisions about health much easier for both doctors and patients alike.

Source: The Health Master

Action Against Misleading Pharma Ads, Sale Of NSQ Drugs

Misleading

Telangana's Health Minister Damodar Rajanarsimha instructs the **Drug Control Authority Telangana** (DCA Telangana) that misleading drug advertisements will not be tolerated and the selling of dangerous, **not-of-standard-quality** (**NSQ**) drugs is unacceptable.

The minister met with the **DCA Telangana** following a review of their recent operations.

Yet even though many were brought to action due to regulatory compliance from DCA Telangana inspections, more than 186 samples were declared as **NSQs** out of **7200 samples** secured.

Thus, the meeting was not one of rebuke, but rather one of stringent mandates to ensure the quality of medications utilized moving forward.

DCA Telangana efforts

During the meeting, the Health Minister praised the **DCA Telangana** for their inspections and rapid action taken against the defaulters but stated that drug control is a life-and-death matter and therefore, further efforts are necessary to ensure that the deeds have been done to clean out the marketplace of dangerous possibilities and that the worst offenders will not return to the marketplace ever again.

The key directives:

Punish All Involved: Everyone who had a hand in the selling of fake, **NSQ drugs** should be tried, convicted, and imprisoned.

- **Attack Misleading Advertising:** Anyone engaged in fake advertising to mislead customers into purchasing fake products should be found.
- **Close Repeat Offenders:** Any company that's engaged in poor quality control should be shut down for good.
- **Implement the PD Act:** The Preventive Detention (PD) Act should be applied for anyone manufacturing/selling drugs that are dangerous and already banned.
- **Penalize Prescription Liberation:** Measures should be taken to ensure antibiotics and narcotic-level drugs are NOT dispensed without prescription; this is critical for the **global antibiotic resistance** campaign.
- **Ensure DCA Telangana's Growth:** The drug testing lab upgrade should be expedited; hire more drug inspectors as necessary.

Source: The Health Master

New Advisory: Delhi Curbs Misuse of Pregabalin and Tapentadol

Pregabalin and Tapentadol

Delhi's **Government of NCT** has taken a proactive measure against a growing drug menace relative to addiction with respect to **Pregabalin and Tapentadol**.

The **Drug Control Department** (DCD) has issued a notice to all chemists in Delhi that they should not sell **Pregabalin** and **Tapentadol** without prescriptions.

This is an advisory to avoid addiction with a bunch of follow-up consequences.

What's different about this announcement from the others?

No More OTC Sales of Abused Combinations

Let us know that casual consumers will no longer be able to pick up powerful drugs for their medicine cabinet without any guidance.

On August 14, 2025, a letter signed by **Kamal Ranjan Chawla**, Head of Office and Controlling Authority of the **Drug Control Department**, was sent to all chemists' associations in Delhi; any Over-the-Counter (**OTC**) sale of the following formulations is thus advised:

- **Pregabalin**—often prescribed for neuropathic pain and seizures, but for many others, it's a potential high.
- **Tapentadol**—a potent opioid analgesic for pain relief, but for countless others, it's a way to get addicted.

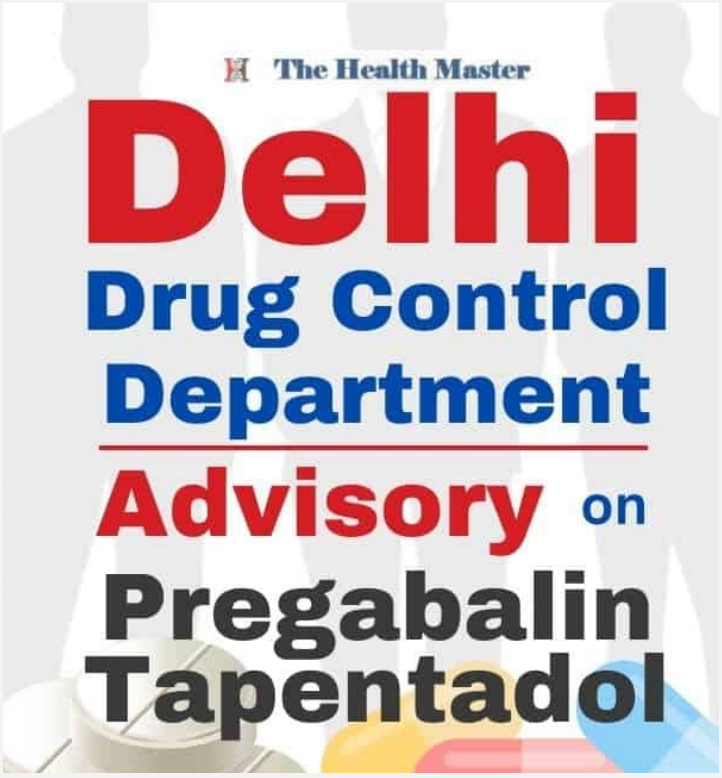
  These drugs should NEVER be dispensed without appropriate prescriptions because they are extremely addictive.

  These drugs are usually dispensed under a doctor's supervision, but in India, of late, they're out of control.

The Significance Behind the Release

This announcement is merely the latest step in a confrontation status that the National Capital is experiencing with substance abuse.

Such levels of abuse have been so high that the All India Organization of Chemists and Druggists (AIOCD) approached the union



home minister about both **pregabalin** and **tapentadol** abuse.

The latter can be found online anywhere and everywhere, making it an integral fight against both physical chemists and online organizations.

Moreover, this advisory serves as a reminder to chemists who may not be following existing drug laws relative to inventory as per the Drugs Rules, 1945, so this advisory informs that any firm or chemist found to be noncompliant will receive strict action.

This is not just a Delhi issue. This is everywhere else as well.

We've seen other states take measures against **pregabalin** and **tapentadol**. This is not an isolated, Delhi-only incident.

The misuse has become an all-India issue that deserves all-state action.

Therefore, the **Delhi Drug Control Department's** latest report is a step in the positive direction, where public health is concerned.

Source: The Health Master

Big Push for Safer Medicines: Launches "SHRESTH" to rank States

A landmark step has recently been initiated by the Union Health Ministry of India to ensure safe and effective **medicines**. The Union Health Ministry has launched a new ranking index called **SHRESTH** to standardize drug regulatory efforts among **all drug administrations** across India.

For the first time, a national ranking exercise has been crafted to gauge **drug regulatory agencies**. Therefore, this is a step in the right direction for the quality of every single **medicine** made in India.

SHRESTH: The New Frontier in medicine Assessment

But what is SHRESTH? It stands for **State Health Regulatory Excellence Index**.

In essence, it is an index that acts as a report card for **state drug regulators**.

The initiative stems from **India's drug regulatory body** known as the **Central Drugs Standard Control Organization (CDSCO)**.

The aim is to incite competition for better performance, which leads to better quality **medicines** for citizens.

According to Union Health Secretary Punya Salila Srivastava, such a cohesive structure is necessary for a diverse country like India to ensure that Indian-made **medicines** are accepted across the world.

Therefore, states need to know how they perform relative to their peers for growth opportunities, and this announcement provides just that.

How SHRESTH Will Be Assessed

For states that are substantial manufacturers of **medicines**, the criteria differ from those that just serve as distribution centers.

For Manufacturing States:

27 parameters will be assessed across 5 entities.

- **Human Resources**: Adequate people with training?
- **Infrastructure**: Enough labs/facilities?
- **Licensing Activities**: Quick licensing to manufacturers?
- **Surveillance Activities**: Fast market oversight for subpar drugs?

Responsiveness: Quick response to complaints?

For Primary Distribution States/UTs:

23 applicable parameters.

Eventually states will have to submit their data to the **CDSCO** in periodic increments, which will score and declare results.

Such benchmarking will bring transparency to what works and what needs improvement.

Setting a Standard for India

The need for an assessment across the nation did not arrive without international factors as well.

In addition, at the global level, the **World Health Organization (WHO)** has national **drug regulatory assessments**.

This is done through something known as the **Global Benchmarking Tool** (GBT) that pivots assessments on strengths and weaknesses with future actionable plans.

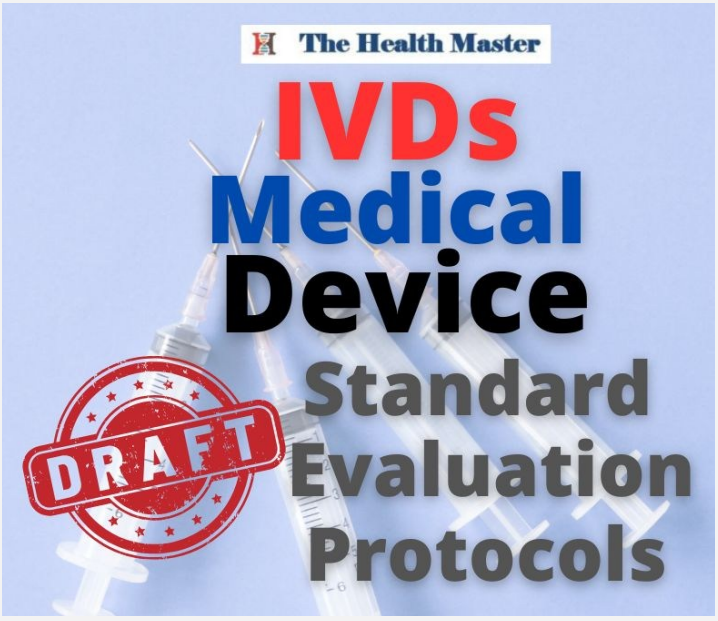
India's central **drug regulatory authority**, the **CDSCO**, has been doing well internationally.

For example, in the **year 2024**, they got maturity level 3 (out of 4) for vaccines, which shows competence and sustainability.

It's time to get the rest of the system in order to achieve that level.

Source: The Health Master

New Draft Standards for IVD Medical Devices: CDSCO



Medical Devices

The **Central Drugs Standard Control Organisation** (CDSCO) has teamed up with the **Indian Council of Medical Research** (ICMR) to create some super important new standards for **IVD medical devices**.

Think of it as a quality check handbook for all those **medical tests**.

They've just released a draft of these standards of protocol and are asking for feedback from stakeholders.

These new protocols are a game-changer for In-Vitro Diagnostics (IVDs)—that's the fancy name for all the **medical devices** that test things like your blood or urine outside the body.

These **medical devices** are crucial for everything from diagnosing diseases like dengue and malaria to checking on your general health.

The goal of the new standards is simple: make sure these diagnostic tools are top-quality, reliable, and safe for everyone to use.

Why These New Standards are important ?

The Indian government is tightening up the process for getting a license for these **medical devices**.

Before, the process could be a bit all over the place.

Now, with these new, clear protocols, manufacturers and labs will know exactly what they need to do to prove their products are high-quality.

This means that every time you get a blood test or a swab for a virus, you can have more confidence in the results.

The 180-page document is packed with detailed instructions for evaluating 15 different types of IVDs.

It covers everything from tests for common illnesses like dengue and malaria to more serious ones like the Nipah virus and SARS-CoV-2 (COVID-19).

These guidelines are all about making sure that a device's sensitivity, accuracy, and safety are properly checked before it gets the green light.

This collaboration between ICMR and **CDSCO** ensures that the **medical devices** you rely on are validated and trustworthy.

(Continued on page 26)

New Draft Standards for IVD ……continue

What are In-Vitro Diagnostics (IVDs)?

In-vitro diagnostics are **medical devices** that help doctors to know what's going on inside your body.

They simply take samples like blood, urine, or tissue to figure out the diseases, infections, or specific health issues.

These **medical devices** are the new inventions in modern medicine, from a simple blood sugar test to a complex genetic analysis.

Under the **Medical Device Rules, 2017**, a license is required for all IVDs.

These new standard protocols provide a standardized way to evaluate and grant those licenses.

This process ensures that only the best quality and most accurate **medical devices** make it to go into the market.

The New Protocols:

The new standards of protocol have a clear, step-by-step process for manufacturers and testing labs to follow.

This includes:

Performance Evaluation: A detailed evaluation of how well the **medical device** works in a controlled setting.

Field Evaluation: Testing the device in real-world conditions to make sure it's reliable.

These checks are crucial for confirming a device's clinical and analytical performance.

Think of it as a thorough background check and a job interview all rolled into one for a **medical device**.

The Call for Feedback

The **CDSCO** and **ICMR** have put these draft protocols out for public comment, giving everyone from scientists to manufacturers a chance to weigh in.

They've set a deadline of **August 25, 2025**, for all feedback by the stakeholders.

After finalization, these guidelines will become the new standards of protocols, ensuring a higher level of safety and quality for all diagnostic tests in India.

Read or Download CDSCO dt 11-08-2025 Draft standard IVD evaluation protocol drafted by ICMR and CDSCO

Source: The Health Master

UCPMP 2024: A New Era for Ethical Pharma Marketing

UCPMP 2024

The government is taking some serious steps to ensure that the healthcare system remains fair and focused on patient well-being and strictly implements the **Uniform Code of Pharmaceutical Marketing Practices 2024** (UCPMP 2024).

A Look at the New Rules

Recently, the Indian government shed some light on the actions it's taking.

According to a statement in the **Lok Sabha**, there have been several complaints filed under the **UCPMP 2024**.

While the number of complaints might seem small, the government's response shows a clear commitment to tackling the issue.

In one instance, a company was even reprimanded for offering doctors things like travel and fancy hospitality—a clear no-no.

The details were made public, which sends a strong message to others in the industry.

The **UCPMP 2024** isn't just a suggestion anymore.

The latest version, **UCPMP, 2024**, is much clearer and more direct.

It specifically bans companies from giving gifts, money, travel, or hospitality to doctors and their families.

This isn't just a slap on the wrist; the penalties can be quite significant.

Companies might have to pay back the money or items, and they can be publicly reprimanded.

This kind of transparency is a powerful tool.

Doctor-Pharma interaction

It's a comprehensive, multi-layered approach involving several different laws and regulations.

The Indian Medical Council Regulations, 2002:

These are the ground rules for doctors themselves.

They explicitly forbid doctors from accepting any kind of gifts, cash, or perks from pharmaceutical companies.

(Continued on page 28)

UCPMP 2024: A New Era ……. continue

(Continued from page 27)

The punishments for breaking these rules can be severe, ranging from a simple warning to being removed from the medical register for a long time.

The Income-tax Act, 1961:

This one hits the companies where it hurts—their wallets.

Under this act, any money a pharma company spends on these "unethical" benefits given to doctors can't be considered as a tax deduction.

It makes it financially unattractive for pharma companies to be involved in such practices.

The Drugs and Magic Remedies Act, 1954:

This older law focuses on advertising of drugs.

It stops companies from making wild or false claims about their drugs, especially for critical diseases.

Due to this law, pharma companies have to depend on doctors to promote their drugs properly, which is why the doctor-pharma relationship is so important to regulate.

Why This Matters for Patients

Ultimately, all these rules are in place for one reason: to protect the health of the people.

When a doctor prescribes a drug, the patient wants to be sure that the prescribed drug is the best option for them, not because the doctor has been influenced by a pharma company.

These new measures aim to:

Promote the right prescription: Ensuring doctors choose the right medicine for the right reasons.

Prevent unethical influence: Cut off the links through which pharma companies might try to influence doctors' decisions.

Increase transparency: The new **UCPMP 2024** requires pharma companies to disclose how much they spend on things like professional development events for doctors and the value of free samples they distribute.

The government is also making sure that what the doctor writes on your prescription pad is exactly what you get.

A rule under the **Drugs Rules, 1945**, ensures that a pharmacist can't substitute a prescribed drug with a different one, especially for important medications.

This small but crucial detail is another layer of protection for patients.

Source: The Health Master

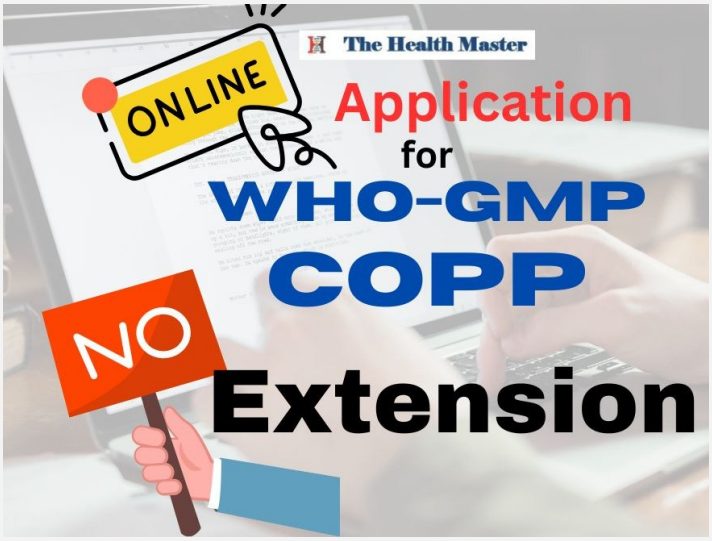
Final Call: No more extensions for WHO-GMP certification

WHO-GMP

The era of shuffling paper applications for **WHO-GMP** certification is officially over.

In a move that's been in the works for a while, the **Drugs Controller General of India** (DCGI) has announced a firm, **final deadline: August 15, 2025**.

From this date forward, all applications for the **World Health Organization** (WHO) **Good Manufacturing Practices** (GMP) (**WHO-GMP**) **Certificate of Pharmaceutical Product** (COPP) must be submitted exclusively through the Online National Drugs Licensing System (**ONDLS**) portal.



No extension

There will be no more extensions, no more physical files, and no more exceptions for **WHO-GMP** certification.

The **DCGI** initially set a **July 15 deadline** for this transition as per the circular dated **June 25**.

However, some industry associations raised their concerns, emphasizing the need for more time for properly adopting the new online process.

Keeping in view the said concerns, the **DCGI** provided a one-month extension, extending the final date to **August 15, 2025**.

What's Next for the Pharma Industry?

With this final deadline, the **DCGI** has sent a letter to all the **State Licensing Authorities** (SLAs) asking them to instruct all manufacturing units in their jurisdictions to adopt the **ONDLS** portal immediately.

Source: The Health Master

Click here WHO-GMP & CoPPs online: Step by step procedure

New Recruitment Rules for Deputy Drugs Controller, CDSCO

The Central Drugs Standard Control Organisation (CDSCO) is the regulatory body for pharmaceuticals, cosmetics, and medical devices in India.

The Union Ministry of Health and Family Welfare has recently published new recruitment rules for the post of **Deputy Drugs Controller (India) (DDCI)** and other key positions.

New Recruitment Rules: Deputy Drugs Controller (DDCI)

The new rules establish a detailed framework for filling **39 posts** for the position of **Deputy Drugs Controller (India) (DDCI)** at **CDSCO**.

This is a **Group A** position with a pay scale at Level **12** in the pay matrix, ranging from **₹78,800 to ₹2,09,200**.

The number of posts is subject to change based on the workload of the department.

Process of Recruitment

The recruitment for **DDCI** will be through promotion.

Here's a breakdown of the eligibility criteria for potential candidates:

Internal Promotion: Assistant Drugs Controllers (India) at **Level 11** with five years of regular service and successful completion of a two-week training program are eligible.

Deputation: This includes a short-term contract. The maximum age for candidates applying through deputation is **56 years**. The term for deputation is typically no more than four years.

This deputation process is open to officers from:

- Central or State Governments
- Union Territory Administrations
- Recognized Universities and Research Institutions
- Public Sector Undertakings
- Statutory or Autonomous Organizations

It's worthwhile to mention here that departmental officers who are already on the stage of the promotion line are not eligible for appointment via deputation.

Similarly, those on deputation cannot be considered for promotion to the post.

Recruitment Rules for Other Key Positions

The new rules also address recruitment for other important roles within the **CDSCO**.

Senior Assistant (Administration) (SAA)

There are **14** new posts for **Senior Assistant (Administration)** (SAA). The recruitment methods are as follows:

Direct Recruitment: The age limit for direct recruits is between **18 and 27 years**.

Promotion: **Junior Assistant (Administration)** staff at **Level 3** with **eight years** of regular service and relevant training can be promoted.

Multi-Tasking Staff (MTS)

A total of **12** posts for Multi-Tasking Staff (MTS), a **Group C** position, have been created. This is a crucial support role within the organization.

Direct Recruitment: The age limit is between **18 and 27 years**.

The pay scale is at **Level 1**, ranging from **₹18,000 to ₹56,900**.

Source: The Health Master

NSQ drug recall time reduced – 30 days to 3 days: Karnataka

In an important decision to enhance patient safety and drug quality, the **Food and Drugs Administration Karnataka** (FDA Karnataka) has drastically reduced the time of "**Not-of-Standard Quality" (NSQ) drug** recall from the market.

This deceptive action by **FDA Karnataka**, reducing the **NSQ drug** recall time from **30 days** to just **3 days**, is a direct response to eliminate the **NSQ drugs** from the state.

The decision leads to a zero-tolerance approach to unsafe drugs and holds manufacturers and distributors accountable for their **NSQ drugs**.

The **FDA Karnataka** has been on high alert, with its enforcement wing conducting surprise inspections and collecting random drug samples in the state.

These continuous checks recently led to the discovery of **59 samples** that failed to meet mandatory standards, giving the urgent need for a faster drug recall process.

A Wave of Enforcement Actions and Public Warnings

This heightened scrutiny is not just about identifying faulty drugs; it's about swift and decisive action.

In the recent past month, the **FDA Karnataka** has taken important steps, filing **29 court cases** against pharmaceutical companies for serious violations of the **Drugs and Cosmetics Act 1940 & Rules framed thereunder**.

These enforcement actions target a wide range of products, from common over-the-counter medications to critical drugs for chronic conditions.

The Karnataka government is also actively alerting the public and healthcare professionals.

Various warnings have been issued to retail medical stores, wholesalers, and hospitals, urging them to immediately send back these **NSQ drugs** to the dealers from whom they have acquired these **NSQ drugs**.

Patients are also continuously advised to be vigilant and not purchase these drugs.

Medical practitioners are also being urged to ensure they do not prescribe these **NSQ drugs**.

Understanding the risk due to NSQ Drugs

Not-of-Standard Quality drug (**NSQ drug**) is a serious concern with public health.

These are the drugs that do not meet the mandatory quality standards set by regulatory authorities.

(Continued on page 32)

NSQ drug recall time reduced …..continue

(Continued from page 31)

This includes:

Purity issue: The drug contains various contaminants or impurities.

Strength issue: The active ingredient in the drug is either too high or too low, affecting the therapeutic effect of the drug.

Dissolution issue: The tablet or capsule doesn't dissolve in the body within the prescribed time, preventing the drug from being absorbed effectively in the body.

Labeling issue: The labeling of the drug or information is not correct or misleading.

The above-said issues can directly impact the safety and efficacy of the drug, leading to adverse effects on the health of the people.

This is why organizations like the **Central Drugs Standard Control Organization** (CDSCO) regularly publish lists of **NSQ drugs**, to keep healthcare providers and consumers informed.

High-Profile NSQ Drugs Recalled

The drugs identified as **NSQ** are not limited to one specific category but span a broad spectrum of therapeutic areas.

Companies from across the country, not just Karnataka, are facing action.

The recalled drugs include popular formulations used for:

Pain and Fever: Panoxen (diclofenac sodium and paracetamol)

Diabetes and Hypertension: Glimepiride & Metformin, Telmisartan

NSQ Drugs Recall

Infections: Cefixime, Ofloxacin, and Ornidazole

Gastric Issues: Pantoprazole, Esomeprazole

Chronic Conditions: Rosuvastatin (for cholesterol), Sodium Valproate

Other Critical Formulations: Povidone iodine solution, Methylcobalamin, Vitamin B complex, and various injections like sodium chloride and adrenaline bitartrate.

Health and Family Welfare Minister **Gundu Rao** confirmed that during a recent crackdown, his department recalled substandard drugs worth **Rs. 40 lakh** in **July 2025** alone.

Beyond NSQ:

The **FDA Karnataka** is continuing surveillance efforts to target illegal activities within the pharmaceutical industry.

This includes issuing show-cause notices to **231 medical stores** for selling drugs, such as sleeping pills and antibiotics, without obtaining a valid prescription.

This proactive and quick response from the **FDA Karnataka** sets a new benchmark for the safety and efficacy of the drug safety, protecting people of the region.

Source: The Health Master

FDA Haryana secures Convictions in Landmark Drug Cases

The Food and Drugs Administration Haryana (FDA Haryana) has successfully prosecuted two separate drug-related offenses, leading to convictions and substantial penalties.

These rulings, by the Hon'ble Court of Additional District & Sessions Judge, **Tarun Singhal**, in District Fatehabad on **August 2, 2025**, show the **FDA Haryana's** strict enforcement of the **Drugs and Cosmetics Act, 1940**.

Each conviction resulted in a **three-year prison** sentence and a hefty fine of **Rs. 1 lakh**.

The Cases: A Detailed Look at Illicit Drug Trade

The two cases brought to light critical issues concerning the illegal sale and misuse of pharmaceutical drugs.

Sincere efforts by **FDA Haryana** Officers in both cases were key to securing justice.

Case 1: Unlicensed Kariyana Store

The first case involved a raid on a local kirana store in the village of Kukdawali.

FDA Haryana's the then Drugs Control Officer, **Suresh Chaudhary**, discovered a shocking cache of regulated pharmaceuticals.

The store's owner, Naresh s/o Sh. Madan Lal, was found to be stocking two types of allopathic drugs without obtaining a drug license.

The drugs are:

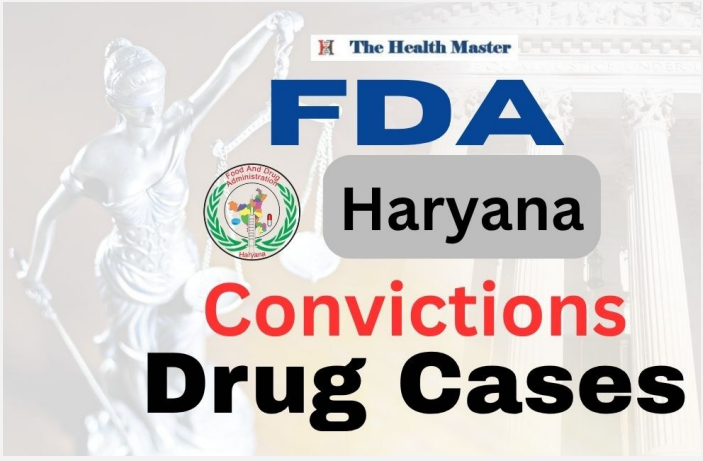
Alto 0.5 Tablets (Alprazolam tablets): 370 tablets of this potent sedative were seized by the FDA Haryana officer.

Alprazolam is a widely prescribed drug for anxiety and panic disorders, but its illegal sale contributes to a growing problem of substance abuse.

Oxytocin Injections: 50 injections of Oxytocin were seized. This injection is primarily used to induce labor, this hormone is also misused in agriculture to accelerate the growth of vegetables, posing a high risk to consumers.

The conviction of the store owner sends a clear message that all establishments, regardless of their primary business, are subject to the same strict drug regulations.

Case 2: Unlicensed Pharmacies



The second case again focused on an unlicensed premises, i.e., Minda Medi Pharma Private Limited, owned by Sunil Kumar son of Sh. Krishna Kumar in Model Town, Fatehabad.

The then Drugs Control Officer **Rajneesh Kumar Dhaniwal** of **FDA Haryana** had seized the stock of Mecotus Plus Syrup found stocked without having a valid drug license.

Mecotus Plus Syrup: This cough syrup contains Codeine. The unregulated sale of codeine-based syrups is a major concern, as they are frequently abused for their euphoric and intoxicating effects.

This conviction underscores the importance of purchasing drugs only from licensed pharmacies to ensure the safety of the consumer and prevent the growing issue of drug abuse.

Legal Battles

Throughout both court proceedings, **Dinesh Rana**, Drug Control Officer for **FDA Haryana**, Fatehabad, played a key role.

His strong presentation of the evidence and expert testimony was instrumental in persuading the court and securing the convictions.

These cases clearly show the commitment of **FDA Haryana** to combat the illicit drug trade, safety and security of public health, and strictly enforcing the regulatory compliance across the state.

These cases serve as a powerful deterrent and reinforce the importance of a robust regulatory framework to safeguard the health of the people of the region.

Source: The Health Master

Govt. appoints Adnl. DGHS as the Compounding Authority

Compounding Authority

The Ministry of Health and Family Welfare has announced the appointment of the **Additional Director General of Health Services**, who oversees the **Central Drugs Standard Control Organization** (CDSCO), as the new **compounding authority**.

This appointment is made in accordance with **sub-rule (1) of rule 3** of the **Drugs and Cosmetics (Compounding of Offences) Rules, 2025**.

This **compounding authority** will be responsible for exercising the powers and functions of the Central Government concerning the compounding of offenses and addressing matters that arise from these rules.

The appointment of the **compounding authority** has been issued by the notification, vide **No. S.O. 3551(E), dated 01-08-2025**, and was published in The Gazette of India and came into effect on the same day.

Importance of the compounding authority:

The appointment of the Additional Director General of Health Services as the **compounding authority** is an important development in the regulatory compliances for drugs and cosmetics in India.

This appointment is aiming for the smooth process of handling offenses under the new **Drugs and Cosmetics (Compounding of Offences) Rules, 2025.**

By the appointment of this central authority within the **CDSCO**, the government aims to increase the efficiency, transparency, and consistent approach in the regulatory compliance

with respect to the compounding of offenses.

The official will now have the specific powers and functions to address and compound offenses, which is crucial for maintaining the integrity of the pharmaceutical and cosmetic industries.

What is the compounding of offenses?

Compounding of offenses is a legal process in which someone accused of a minor, non-serious, or less severe offense can avoid prosecution by paying a penalty in accordance with the law.

The compounding of offense is typically applied to less critical violations and helps to reduce the burden on the judicial system and to spare the accused the lengthy process of prosecution.

With this new appointment, the **Additional Director General of Health Services** is now empowered to facilitate this process for offenses related to drugs and cosmetics.

Source: The Health Master

FDA Haryana

Ambala, 23-08-2025

in late evening a decoy operation was done by joint team of Hemant Grover, DCO Ambala-II along with Dr. Mukesh Kumar Dy. Civil Surgeon Ambala Health Deptt.

Prop. of firm M/s Sharma Medical Hall, situated at: Shop No. 02, Opp Civil Hospital, Ambala City, Distt. Ambala, had sold the MTP Kit tablets to decoy patient in lieu of Rs. 1000/- by loosing tablets and dispensed in a envelop with telling decoy patient how to take the tablets in absence of Reg. Pharmacist.

The empty strip was recovered form the drainage and an FIR was registered against the accused under MTP Act.

Hence in view of above and to "STOP" the furtherance the offence this shop is hereby sealed u/s 22(1)(d) of the Drugs & Cosmetic Act 1940 & Rules 1945 in public interest at large.

Source: Hemant Grover DCO, FDA Haryana

Karnal: 11-08-2025

A team comprised of Dr. Vikas MO CHC Nissing Karnal, Dr. Govind MO CHC Sambhli Karnal and Vikas Rathi Drugs Control Officer Karnal-II reached at the un-registered clinic with titled as Maharishi Ved Vyas Clinic Care situated at Near Maharishi Ved Vyas Mandir VPO Bastali, Tehsil Nissing,

Karnal in order to investigate a complaint of illegal medical practitioner.

Vineet Kumar S/O Sh. Raj Kumar was found present on the spot. He introduced himself as owner of said clinic.

Team disclosed the identity and purpose of visit to him.

The said clinic was searched in his presence. On search of said clinic, it was found stocked with medical instruments which were being used in illegal medical practice and a huge quantity of allopathic drugs along with used vials.

On asking the accused to produce any valid degree or any other documents regarding practicing as registered medical practitioner, he produced documents or degree from Indira Gandhi University which is not valid to do medical practices in Indian System of Medicines i.e in allopathic and is not registered in state of Haryana for practice.

On further asking regarding any drugs licenses issued on that premise under Drugs and Cosmetic Act 1940 and Rules 1945 framed there under for stocking of the drugs, he did not produce any document.

He further could not produce sale and purchase record of these allopathic drugs and also could not disclose that from whom he had acquired the drugs in context.

Many people were gathered on the spot to whom team requested to become the independent witness but one person joined the team as witness.

Thereafter team seized seventy nine different types of allopathic drugs used / unused inventory along with medical instruments.

A list was thereof prepared at spot.

These medical instruments and drugs were packed in two cardboard boxes and sealed. Team members and accused signed all the documents prepared on spot and sealed cardboard boxes. Accused, all prepared documents and sealed cardboard boxes were handover to police officials for further necessary action.

Source: Vikas Rathee, DCO, FDA Haryana

FDA Haryana

Sirsa: 09-08-2025

Keshav Vashisth Drugs Control Officer, Sirsa-III on the bssis of secret information with SHO Kalanwali, sampled & seized four types of bellow mentioned drugs from unlicensed residential premises:

- Tapentadol Hydrochloride Tablets (13450)
- Pregabalin Capsules(35490)
- Altoprax-Z(zopiclone) Tablets(3900)
- Nefopam Hydrochloride Tablets(280)

All above drugs containing as active constituents misused as intoxicants, were found stocked for sale & distribution in unlicenced residential premises of Sandeep kumar were seized & sampled vide Form 16& 17.

On enquiry it came to the notice of team that mr. Sandeep Kumar is also proprietor of firm M/s Sandeep Medical Hall, Kalanwali, R/o Kalanwali, Distt. Sirsa.

The shop of Sandeep kumar namely M/s Sandeep medical Hall kalanwali was also througly inspected & was sealed by Keshav Vashisth DCO Sirsa-III.

The raid continued over night from 6pm 09.8.25 p.m to 10.8.25 (6am) ie today morning 10.8.25 .

Action will be taken under provisions of D&C Act & law.

Source: Keshav, DCO, FDA Haryana

Sirsa: 07-08-2025

Suneel Kumar, Drugs Control Officer, Sirsa-II alongwith police official of ANC Staff Sirsa raid on M/s Manu Medical Agency,5778,First Floor Gali No.1,Kirti Nagar,Sirsa.

A secret complaint of above said firm regarding illegal stocking & selling of medical intoxicated drug's.During throughly Checking,45700 Tablets of Tapentadol Tablets & 6450 Capsules of Pregabalin Capsules IP 300 mg recovered from the premises and the Mr.Rahul (Prop.) of the firm Could not produce any sale/purchase records of these medical intoxicated drugs.

These drugs seized vide on Form-16.Inspection report Filled & shop sealed .Further action will be taken as per D&C Act.

Source: Suneel Kumar, DCO, FDA Haryana

Send your news and articles to:
dcoiwanewsletter@gmail.com

FDA Haryana

Jhajjar: 06-08-2025

Raids on Medical Stores in Bahadurgarh

Following a confidential complaint regarding the illegal sale of Medical Termination of Pregnancy (**MTP**) kits, a team of health officials conducted raids on two medical stores in Bahadurgarh: R.K. Medical Store and Komal Medical Store (Komal Clinic).

The team included Dr. Upender, Deputy Civil Surgeon and MTP Nodal Officer for Jhajjar, Dr. Deepak Sharma, Sh. Vinod Kumar, a Senior Assistant from the Civil Surgeon's office in Jhajjar, and a Drug Control Officer from Gurugram Suresh Kumar who was temporarily stationed in Jhajjar.

During the raids, officials used a **decoy customer** to confirm the complaint. Both stores were found to be illegally selling MTP kits. The MTP Nodal Officer has since submitted an official complaint, along with spot and seizure memos, to the police to file a First Information Report (**FIR**).

An inspection report was completed and sealed at the scene. Further action will be taken in accordance with the Drugs and Cosmetics (**D&C**) Act. The raids concluded at 6 a.m. on August 7, 2025.

Source: Suresh Kumar, DCO, FDA Haryana

Kaithal: 07-08-2025

A team from Kaithal, including the Chetan Verma, DCO Kaithal and Dr. Sachin along with Dr. Pearl, the LMO of CHC Guhla, inspected the Rohtak Nursing Home in Cheeka. The inspection was initiated to investigate the illegal sale of medicine and MTP kits by Dr. Aman Singla.

During the search, a large quantity of narcotic drugs was found concealed in a bed box and a store room at Dr. Singla's residence. Police were called to the scene and an FIR was registered against Dr. Aman Singla under the NDPS Act.

Source: Chetan Verma, DCO, FDA Haryana

FDA Haryana

Karnal: 04-08-2025

A raid was conducted at M/s Krishna Pharmacy, located at Pingli Chowk, Kaithal Road, Karnal. The raid was led by Vikas Rathee, DCO, Karnal, along with Dr. Shinu Choudhary, NO PC & PNDT CH Karnal, and Dr. Rahul, MO UPHC Shiv Colony Karnal.

The investigation was initiated based on information from Rajender, a resident of Shiv Colony, Karnal. Rajender reported that on June 27, 2025.

He had purchased an MTP (Medical Termination of Pregnancy) kit from the pharmacy for his pregnant wife.

An ultrasound at the Civil Hospital Karnal confirmed that his wife had undergone an abortion. Statements from both Rajender and his wife were recorded by the team.

Upon arrival at the pharmacy, Vijay Kumar, who identified himself as the proprietor, was present.

After the team explained the purpose of their visit, Kumar denied selling any MTP kits to Rajender.

A thorough search of the premises was conducted, but no MTP kits were found in stock.

During the inspection, several other violations were discovered, which were documented in an inspection report.

A spot memo was also prepared and signed by all team members.

To prevent further offenses, the pharmacy was sealed under Section 22(1(d) of the Drugs and Cosmetic Act of 1940 and its associated rules.

Additionally, an FIR (First Information Report) No. 0237 was filed against the proprietor under the MTP Act on August 5, 2025.

Source: Vikas Rathee, DCO, FDA Haryana

Gurugram: 04-08-2025

A joint team, including members from the CM Flying Squad and health officials from Nuh and Gurugram, raided the **Care Well Clinic** in Tauru, Nuh. The raid was conducted to dismantle a network involved in illegal abortions using **MTP (Medical Termination of Pregnancy) kits**.

During the search, the team found and seized two MTP kits, surgical instruments, and 36 types of other medicines related to abortion procedures. The clinic was operating without the necessary MTP registration. The lone staff member present could not produce any documents or medical degrees authorizing her to perform these procedures.

The clinic was sealed on the spot, and an FIR was filed against the staff member. She faces charges under various sections, including the MTP Act, the Drugs and Cosmetic Act, the BNS Act, and the NMC Act.

Source: Suresh Kumar, DCO, FDA Haryana

FDA Haryana

Sirsa: 02-08-2025

A Major Crackdown on Illegal Drug Trafficking: Sirsa Authorities Seize 48,395 Pregabalin Capsules

In a significant operation targeting the illegal drug trade, law enforcement and drug control authorities in Sirsa have seized a massive cache of Pregabalin capsules. The seizure, which took place on August 2, 2025, highlights the ongoing efforts to combat the misuse and illicit distribution of controlled substances within the region. This detailed report sheds light on the events of the day, the individuals involved, and the broader implications of this crackdown.

The Operation: A Tip-Off Leads to a Major Haul

The operation began with a crucial tip-off received by the Sirsa Police. Based on this secret information, a coordinated team was formed, including Sh. Suneel Kumar, the Drugs Control Officer (DCO) for Sirsa-II, and officials from the Odhan Police Station, led by the SHO. Acting swiftly on the intelligence, the team successfully intercepted two individuals, Mandeep Singh and Jaswinder Singh, and recovered a staggering 48,395 capsules containing Pregabalin. The seizure was formally documented through the issuance of Form 16 and Form 17, which are standard procedures for such actions.

Unraveling the Network: Suspects and Their Connections

During the initial interrogation, a clear link was established between the two suspects and the pharmaceutical trade. Jaswinder Singh was identified as a partner in a firm named M/s Jass Medical, located in Odhan. Similarly, Mandeep Singh was found to be the proprietor of M/s Sidhu Medicose, situated in the village of Jalalana, in the Sirsa district. These connections suggest that the illegal drug trafficking operation was being facilitated through licensed pharmaceutical channels, a common modus operandi for such crimes. The use of legitimate businesses as a front for illicit activities poses a significant challenge to law enforcement agencies and underscores the need for stringent oversight of the pharmaceutical supply chain.

The Aftermath: Sealing of Premises and Further Actions

Following the seizure and the identification of the individuals' business affiliations, a thorough inspection of both M/s Jass Medical and M/s Sidhu Medicose was conducted under the direct supervision of Sh. Raman Sheoran, the Senior Drugs Control Officer (SDCO), Sirsa. The inspection revealed irregularities, leading to the immediate sealing of both premises. This action was taken to prevent any further illegal activities and to secure evidence for the ongoing investigation.

Simultaneously, a show-cause notice was served to the proprietors of both firms under Rule 66(1) of the relevant act. This legal step was executed by the Licensing Authority (LA)/SDCO, Sirsa, directly at the scene. The show-cause notice requires the individuals to explain why their drug licenses should not be suspended or canceled, a crucial step in the legal process that could lead to severe penalties.

The Dangers of Pregabalin Abuse: A Growing Concern

Pregabalin, a drug primarily used to treat neuropathic pain, epilepsy, and generalized anxiety disorder, has become a substance of abuse. Its misuse can lead to severe side effects, including dizziness, drowsiness, blurred vision, and a high potential for addiction. The illegal trade of such medicines bypasses critical medical oversight, putting public health at grave risk.

Source: Suneel Kumar, DCO, FDA Haryana

FDA Haryana in News

स्वास्थ्य विभाग की टीम ने झोलाछाप डॉक्टर के क्लीनिक पर की छापामार कार्रवाई

निसिंग, (जगमार्ग न्यूज)। गांव बस्तली में सोमवार को झोलाछाप डॉक्टर के क्लीनिक पर स्वास्थ्य विभाग की टीम ने छापामार कार्रवाई की। जिसमें औषधी नियंत्रण अधिकारी विकास राठी, चिकित्सा अधिकारी विकास अत्री, डॉ. गोविंद स्वास्थ्य विभाग की टीम ने निसिंग थाना से एसआई रमेश राणा, कमर्मवीर मोगा ने टीम सहित क्लिनिक पर पहुंच झोलाछाप डॉक्टर विनीत कुमार को दरदबोचा। औषधी नियंत्रण अधिकारी विकास राठी ने बताया कि झोलाछाप डॉक्टर विनीत कुमार क्लीनिक की तलाशी लेने पर, वहां अवैध चिकित्सा पद्धति में इस्तेमाल किए जा रहे चिकित्सा उपकरणों व भारी मात्रा में दवाईयां मिली। आरोपी विनीत कुमार से पंजीकृत चिकित्सक के रूप में प्रैक्टिस करने से संबंधित किसी वैध डिग्री या किसी अन्य दस्तावेज के बारे में पूछने पर, उसने इंद्रा गांधी विश्वविद्यालय से प्राप्त दस्तावेज प्रस्तुत किए,जो कि भारतीय चिकित्सा पद्धति करने के लिए अधिकृत नहीं है। दवाओं के भंडारण के लिए ड्रग्स एंड कॉस्मेटिक एक्ट 1940 और उसके अंतर्गत बनाए गए नियम 1945 के तहत उस परिसर में जारी किए गए किसी भी ड्रग लाइसेंस के बारे में आगे पूछने पर, उसने कोई दस्तावेज प्रस्तुत नहीं किया। वह इन दवाओं की बिक्री व खरीद का रिकॉर्ड भी नहीं दिखा सका। आरोपी झोलाछाप के पास से टीम ने 69 चिकित्सा उपकरण व विभिन्न प्रकार की दवायां भी जब्त की हैं। आरोपी विनीत कुमार सीलबंद कार्डबोर्ड बॉक्स व तैयार दस्तावेजों को आगे की आवश्यक कार्रवाई के लिए थाना पुलिस को सौंप दिया गया। पुलिस ने आरोपी छोलाछाप विनीत के खिलाफ मामला दर्ज कर गिरफ्तार कर लिया है।

स्वास्थ्य विभाग की टीम ने बस्तली गांव में झोलाछाप डॉक्टर की क्लीनिक पर की छापामार कार्रवाई

69 चिकित्सा दवाइयां सहित उपकरण टीम ने किए जब्त, आरोपी को किया पुलिस के हवाले

सवेरा न्यूज/रिंकु गोंदर

निसिंग, 11 अगस्त : गांव बस्तली में सोमवार को झोलाछाप डॉक्टर के क्लिनिक पर स्वास्थ्य विभाग की टीम ने छापामार कार्रवाई की, जिसमें औषधी नियंत्रण अधिकारी विकास राठी ,चिकित्सा अधिकारी विकास अत्री,डा. गोविंद स्वास्थ्य विभाग की टीम ने निसिंग थाना से एसआई रमेश राणा ,कमर्मवीर मोगा ने टीम सहित क्लिनिक पर पहुंच झोलाछाप डॉक्टर विनीत कुमार को दरदबोचा। औषधी नियंत्रण अधिकारी विकास राठी ने बताया कि झोलाछाप डॉक्टर विनीत कुमार क्लिनिक की तलाशी लेने पर, वहां अवैध चिकित्सा पद्धति में इस्तेमाल किए जा रहे चिकित्सा उपकरणों व भारी मात्रा में दवाईयां मिली। आरोपी विनीत कुमार से पंजीकृत चिकित्सक के रूप में प्रैक्टिस करने से संबंधित किसी वैध डिग्री या किसी अन्य दस्तावेज के बारे में पूछने पर, उसने इंद्रा गांधी विश्वविद्यालय से प्राप्त दस्तावेज प्रस्तुत किए, जोकि भारतीय चिकित्सा पद्धति करने के लिए अधिकृत नहीं है।

गांव बस्तली में स्वास्थ्य विभाग की टीम आरोपी झोलाझाप डॉक्टर के साथ।

दवाओं के भंडारण के लिए ड्रग्स एंड कॉस्मेटिक एक्ट 1940 और उसके अंतर्गत बनाए गए नियम 1945 के तहत उस परिसर में जारी किए गए किसी भी ड्रग लाइसेंस के बारे में आगे पूछने पर, उसने कोई दस्तावेज प्रस्तुत नहीं किया। वह इन दवाओं की बिक्री व खरीद का रिकॉर्ड भी नहीं दिखा सका। आरोपी झोलाछाप के पास से टीम ने 69 चिकित्सा उपकरण व विभिन्न प्रकार की दवायां भी जब्त की हैं। आरोपी विनीत कुमार सीलबंद कार्डबोर्ड बॉक्स व तैयार दस्तावेजों को आगे की आवश्यक कार्रवाई के लिए थाना पुलिस को सौंप दिया गया। पुलिस ने आरोपी छोलाछाप विनीत के खिलाफ मामला दर्ज कर गिरफ्तार कर लिया है।

Karnataka

Measures taken by the Drug Administration wing of FDA Karnataka for Public Health protection.

Source: Dr. Bharatesh R Jagashetty, FDA Karnataka

Uttar Pradesh

Demand to honor the Assistant Drug Commissioner who rejected a bribe.

An honest officer's actions against fake medicines, Pharmacist organization asks the Chief Minister.

BILASPUR: Assistant Drug Commissioner Naresh Mohan Deepak recently seized fake medicines worth over two crore rupees in a raid. During the raid, businessmen tried to bribe him with one crore rupees in cash and said the amount would be doubled.

However, Deepak showed his integrity and dedication to duty by rejecting the bribe and with the help of the STF, seized the cash along with the fake medicines. This action is seen as a strong step to strengthen the food and drug administration department in the state.

While reacting to this, O.S.D. and State Vice President of Uttar Pradesh, Jaideep Kumar Gupta, praised Naresh Mohan Deepak's honesty and courage, saying it is an inspiration for the entire department.

In anger, Chief Minister Yogi Adityanath and State Minister Dayalu Shankar Mishra have written a letter asking for a special honor for Deepak from one hundred thousand five hundred registered pharmacists and one lakh thirty-five thousand drug sellers in the state.

They have requested that Naresh Mohan Deepak be personally honored so that his courage and honesty can be praised on a public platform and serve as an inspiration for other officers. The pharmacist organization says that this honor will not only send a strong message against corruption in society but also become a medium to encourage honest officers.

Source: Pooran Chand, FDA UP

Uttar Pradesh

अभियान चलाकर मेडिकल स्टोर्स से लिये दवा के नमूने

- मण्डलायुक्त के निर्देश पर सहायक आयुक्त ने गठित की टीम
- दवाओं के नमूनों को जाँच के लिये भेजा जा रहा लैब

झाँसी : मेडिकल स्टोर्स पर निरीक्षण करती औषधि प्रशासन विभाग की टीम।

झाँसी : शनिवार को औषधि प्रशासन विभाग की टीम ने नकली व अधोमानक दवा के खिलाफ महानगर में अभियान चलाया। विभिन्न नर्सिंग होम्स में स्थापित व अन्य स्थानों पर स्थित मेडिकल स्टोर्स का निरीक्षण करने के बाद टीम ने निरीक्षण किया और वहाँ से विभिन्न कम्पनि की दवा के 10 नमूने एकत्र किये। इन नमूनों को जाँच के लिये लैब भेजा जा रहा है।

मण्डलायुक्त विमल कुमार दुबे ने नकली व अधोमानक दवा की बिक्री पर पूरी तरह से प्रतिबन्ध लगाए जाने के आदेश जारी किये हैं। आयुक्त के निर्देश के बाद सहायक आयुक्त औषधि दीपक शर्मा बाजार में बेची जाने वाली दवाओं की निगरानी के लिये टीम का गठन किया। टीम में औषधि निरीक्षक डॉ. देवयानी दुबे व ललितपुर के औषधि निरीक्षक विनय मिश्रा को शामिल किया गया। टीम द्वारा अस्पतालों एवं नर्सिंग होम्स में संचालित मेडिकल स्टोर्स का संयुक्त निरीक्षण किया। इस दौरान मैक्स केयर स्पर्श हॉस्पिटल में सरोज फार्मेसी, संजीवनी हॉस्पिटल में संजीवनी मेडिकल, नारायण फिवर क्लीनिक में मुकुट मेडिकोज, सुशीला हॉस्पिटल कोछाभाँवर में सुशीला मेडिकल व जैन क्लीनिक आदि मेडिकल स्टोर का निरीक्षण किया। विभिन्न बिन्दुओं पर जाँच करने के बाद निरीक्षण के दौरान औषधि निरीक्षकों की टीम ने दवाओं के 10 नमूने संग्रहित किये। सहायक आयुक्त अनुसार लैब से रिपोर्ट मिलने के बाद अग्रिम कार्यवाही की जाएगी। उन्होंने कहा कि बाजार में बिकने वाली दवाओं की निगरानी के लिये निरन्तर अभियान जारी रहेगा।

नामचीन कंपनियों की फैक्ट्री में तैयार हो रहीं हूबहू नकली दवा, क्यूआर स्कैन भी फेल

उत्तराखंड, हिमाचल से एक वाक्स मंगाकर उसी बैच नंबर के 10 बाक्स करते तैयार, नेपाल, बांग्लादेश तक नकली दवाओं की सप्लाई, हवाला से दवाओं का भुगतान

पहले कभी नहीं पकड़ी गई एक करोड़ की रिश्वत

लेदर के बीच छिपाकर लाते थे नकली दवाएं

मरीजों ने खा लीं करोड़ों की नकली दवा, 10 रुपये की दवा बनाकर 100 रुपये में बिक्री

नशे के लिए कफ सिरप के अवैध कारोबार से करोड़ों की कमाई

नकली दवा सिंडिकेट का पर्दाफाश, एक करोड़ की रिश्वत लाया कारोबारी गिरफ्तार

संचालक ने एसटीएफ से की **रिश्वत की पेशकश**, भारी मात्रा में दवाइयां बरामद

36 घंटे बाद भी एसटीएफ और औषधि विभाग की कार्रवाई जारी

2.50 करोड़ की दवाइयां जब्त, 14 दवाओं के नमूने लिए

- आधा दर्जन नामचीन दवा कंपनियों की 216 कार्टन दवाएं जब्त
- रिश्वत देने, नकली दवा सहित चार मुकदमे किए जाएंगे दर्ज

जागरण संवाददाता, आगरा: स्पेशल टास्क फोर्स (एसटीएफ) ने नामी-गिरामी कंपनियों की नकली दवाइयों की बिक्री के बड़े सिंडिकेट का पर्दाफाश किया है। यह जायडस और सनफार्मा जैसी नामी कंपनियों के रैपर में नकली दवाएं पैक कर बेचता था। जांच को रुकवाने के लिए नकली दवा कारोबारी हिमांशु अग्रवाल एक करोड़ रुपये लेकर रिश्वत देने आया लेकिन इंस्पेक्टर ने उसे गिरफ्तार कर लिया। हिमांशु की निशानदेही पर बड़ी मात्रा में नकली दवाइयां मिली हैं। अब तक एसटीएफ की ओर से ढाई करोड़ से ज्यादा की दवाइयां सीज की जा चुकी हैं। शनिवार रात दो बजे तक कार्रवाई जारी थी। आगरा को नकली दवा कारोबार में देश की सबसे बड़ी मंडियों में माना जाता है। यह अब तक की सबसे बड़ी रिश्वत के साथ गिरफ्तारी मानी जा रही है।

लखनऊ स्थित एसटीएफ मुख्यालय को आगरा थोक दवा बाजार में मल्टीनेशनल कंपनी जायडस, ग्लेनमार्क, सनफार्मा, सनोफी सहित आधा दर्जन कंपनियों के नाम से नकली दवाइयों के बेचे जाने की शिकायत मिली थी। दो महीने से एसटीएफ और औषधि विभाग की टीम पूरे कारोबारी नेटवर्क का सुराग लगाने में जुटी थी। शनिवार सुबह 10 बजे टीम सैयद गली मोती कटरा स्थित हेमा मेडिको फर्म पर पहुंची। संचालक हिमांशु अग्रवाल निवासी कर्मयोगी कमलानगर ने कार्रवाई रोकने के लिए एक करोड़ रुपये की रिश्वत देने की पेशकश की। एसटीएफ के इंस्पेक्टर यतींद्र शर्मा ने मुख्यालय को पूरी जानकारी दी। इसके बाद कारोबारी को रंगे हाथ पकड़ने के लिए जाल बिछाया। दोपहर को हिमांशु अग्रवाल बैग में 500-500 रुपये की नोट की गड्डियों से भरे तीन बैग लेकर बाइक से फव्वारा मार्केट पहुंचा। टीम ने तभी उसे कैश के साथ गिरफ्तार कर लिया, वहां से कोतवाली थाने ले गई। वहां नोटों मंगाई गई, जो 200 गड्डियों में थे। पूछताछ के बाद हिमांशु अग्रवाल को लेकर एसटीएफ फिर उसकी फर्म पर लेकर पहुंची। दवा कंपनियों के प्रतिनिधि भी बुला लिए। दवाओं के क्यूआर कोड स्कैन करने के साथ रैपर के प्रिंट की जांच कराई। टीम ने रात एक बजे तक सर्दी जुकाम, दर्द सहित ढाई करोड़ की कीमत की 214 कार्टन दवाइयां जब्त कर ली थीं। सहायक औषधि आयुक्त अतुल उपाध्याय ने बताया कि मुबारक महल स्थित हे मां मेडिको एजेंसी और गोगिया मार्केट स्थित बंसल मेडिकल एजेंसी की होलसेल की दुकानें और गोदाम सील कर दी थीं,

हे मां मेडिको से दवाएं जब्त करती औषधि विभाग की टीम • सौजन्य: औषधि विभाग

गिरफ्तार दवा कारोबारी हिमांशु अग्रवाल • सौ. एसटीएफ

चाचा संग शुरू किया था काम

एसटीएफ अधिकारियों के अनुसार हिमांशु अग्रवाल ने अपने चाचा बबलू के साथ दवाइयों का काम शुरू किया था। नेटवर्क हिमांशु खुद संभालता था। एसटीएफ को देने के लिए कुछ ही घंटों में उसने एक करोड़ कैश का इंतजाम किया था। पूछताछ में कई राज खुलने की उम्मीद है। संबंधित सामग्री » 4

चेन्नई से आई एक करोड़ की नकली एंटी एलर्जिक टैबलेट जब्त

दवा माफिया ने सर्दी जुकाम और एलर्जी में इस्तेमाल होने वाली सनोफी कंपनी की ऐलेग्रा-120 टैबलेट की खेप चेन्नई से मंगाई थी। शुक्रवार रात को दवाइयों की खेप आगरा कैंट रेलवे स्टेशन पर उतारने के बाद आटो से इन्हें फव्वारा बाजार स्थित बंसल मेडिकल गोगिया मार्केट ले जाया जा रहा था। पहले से नजर रख रही एसटीएफ और औषधि विभाग की टीम ने आटो को पकड़ लिया। आटो से ऐलेग्रा-120 की 2.97 लाख टैबलेट जब्त की हैं। सनोफी कंपनी के प्रतिनिधि ने प्रारंभिक जांच के बाद नकली बताई है। आटो चालक ने बताया कि आगरा कैंट पर रहने वाले एजेंट फरहान ने दवाएं बाजार भेजने को कहा था। टीम ने फरहान के घर पर छापा मारा। गिरोह से जुड़े कई कारोबारियों, हाकर और ट्रांसपोर्ट कंपनी पर भी छापेमारी की जा रही है। रविवार को बंसल मेडिकल स्टोर और गोदाम की जांच होगी।

Best Wishes On Promotion

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

Sh. Lalit Kumar Goel as State Drugs Controller, FDA Haryana

Sh. Ripan Mehta as Dy. State Drugs Controller, FDA Haryana

Sh. Karan Singh Godara as Asstt. State Drugs Controller, FDA Haryana

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.

Sh. Naripen Kumar Goel, Asstt. State Drugs Controller, FDA Haryana

Sh. Manmohan Molasariya State Licensing Authority Madhya

Congratulations

Laughter dose

Source: PK Jaggi, Co-Editor

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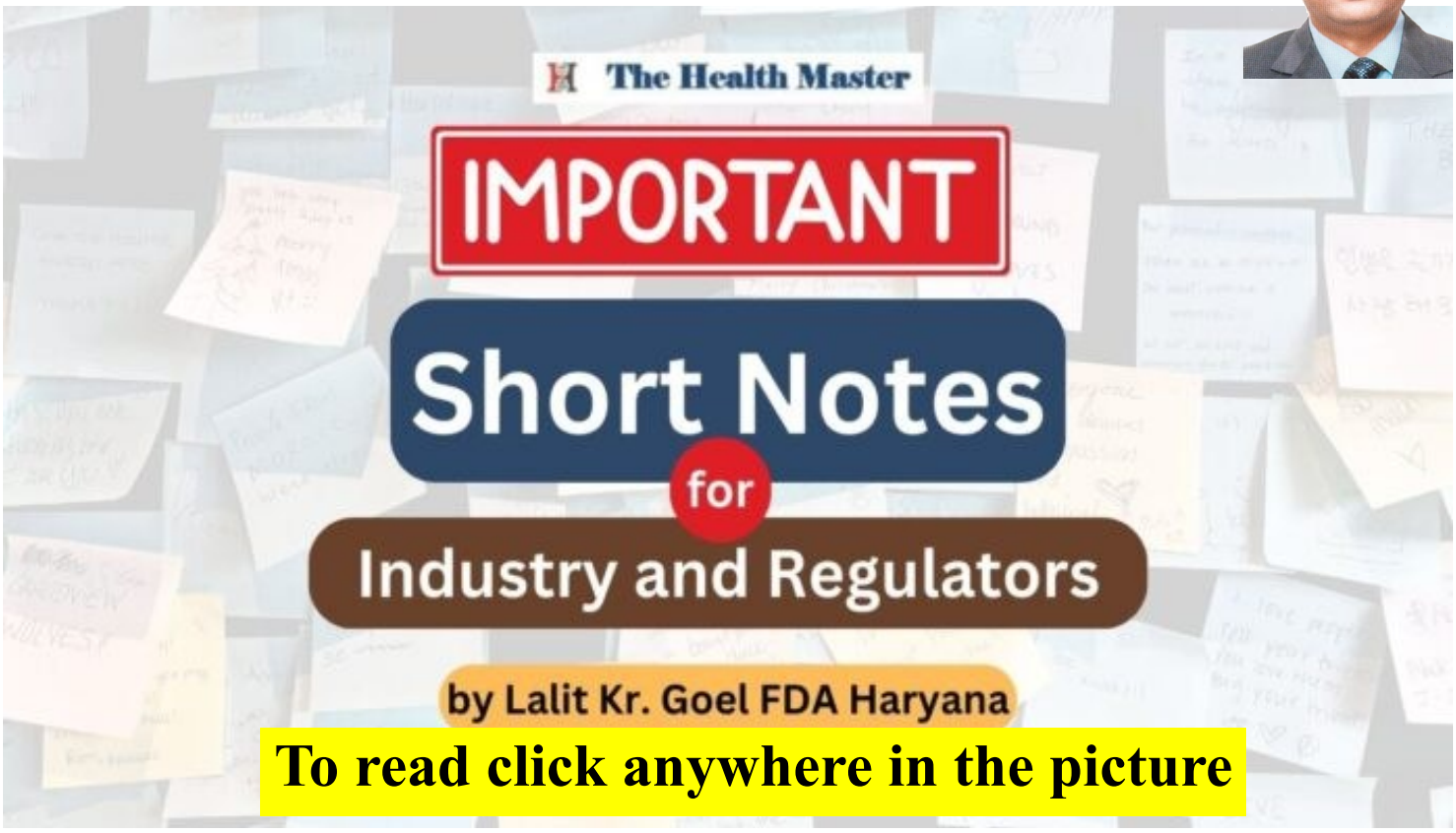
Important short notes for Industry and Regulators
By Lalit Kr. Goel, FDA Haryana



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

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FAQs on Glycerin (Pharma Industry)

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

FAQs – on Glycerin (Pharma Industry)

Q1. Whether Glycerin is a drug or cosmetic?

Ans: Glycerin has dual use. It can be used as drug, cosmetic and food.

Q2: Whether Glycerin is officially in any pharmacopoeia?

Ans: Yes, it is official in IP and USP.

Q3: Whether Glycerin IP can be used in food and cosmetics?

Ans: Yes, as IP book is a standard of products for specifications and testing.

Q4: Is any reference / document / data of dual use of API of Glycerin as the drug, food, and cosmetic?

Ans: Yes, as per DCG(I) letter dated 05.07.2019 regarding the dual use of APIs.

Q5: Whether oral Glycerin can be manufactured under form 25?

Ans: Yes, Oral Glycerin is official in IP and can be manufactured in Oral Liquid Section only.

Q6: Can Glycerin be manufactured in external section or for repack?

Ans: Glycerin can be manufactured in external section if for external use only and can be repacked the same under repacking license.

Q7: Can Glycerin product manufactured as drug claim as beauty product?

Ans: No, it comes under the definition of cosmetics.

Q8: What are the contaminations detected in Glycerin?

Ans: Di-ethylene Glycol (DEG)

Q9: What are the main instruments required for testing DEG in Glycerin?

Ans: Gas Chromatograph is required to detect presence of DEG in Glycerin.

Q10: When this test of DEG was introduced in IP?

Ans: This test was introduced after JJ Hospital, Bombay tragedy in early 1980 wherein many died due to containing DEG as contamination in Glycerin.

Q11: Name the Commission which conducted enquiry of JJ Hospital, Bombay tragedy?

Ans: Lante Commission.

Q12: What are the precautions for the person dealing in manufacturing of Glycerin?

Ans: They should get Glycerin tested for contamination like DEG in their product.

Click for more article of the Author

FAQs

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

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Notifications: EC Act (Essential Commodities Act)

Important Notifications

Compiled by
Rakesh Dahiya
FDA Haryana

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2022

S.O. 5249(E) dt 11-11-2022 – National List of Essential Medicines 2022 – EC Act 1955

S.O.-5249E-dt-11-11-2022-National-List-of-Essential-Medicines-2022-EC-Act-1955

2021

S.O. 3249(E) dt 12-08-2021 – **Amendment in paragraph 18 of DPCO, 2013**

S.O.-3249E-dt-12-08-2021-Amendment-in-paragraph-18-of-DPCO-2013

S.O. 2899(E) dt 20-07-2021 Order on **Amendment in the Drugs (Prices Control) Order, 2013** for inclusion on Form VI

S.O.-2899E-dt-20-07-2021-Order-on-Amendment-in-the-Drugs-Prices-Control-Order-2013-for-inclusion-on-Form-VI

2020

S.O.-1207 (E) dt 24-03-2020 – regarding **retail price of 3ply mask Melt Blown non-woven fabric**

S.O.-1207-E-dt-24-03-2020-regarding-retail-price-of-3ply-mask-Melt-Blown-non-woven-fabric

S.O.-1197 (E) dt 21-03-2020 – regarding **retail price of 2ply, 3ply mask and sanitizer**

S.O.-1197-E-dt-21-03-2020-regarding-retail-price-of-2ply-3ply-mask-and-

(Continued on page 56)

Notifications: EC Act (Essential Commodities Act)

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(Continued from page 55)

sanitizer

S.O. 1087 (E) dt-13-03-2020 Essential Commodities Act (EC Act) Notification regarding **Mask and Hand Sanitizer**

S.O.-1087-E-dt-13-03-2020-EC-Act-Notification-regarding-Mask-and-Hand-sanitizer

2019

S.O. 39(E) dt 03-01-2019 **Amendment of Paragraph 9 and 32 of DPCO 2013**

S.O.-39E-dt-03-01-2019-Amendment-of-Paragraph-9-and-32-of-DPCO-2013

2016

S.O.1192(E) dt 22-03-2016 **Amendment of Paragraph 11 of DPCO 2013**

S.O.1192E-dt-22-03-2016-Amendment-of-Paragraph-11-of-DPCO-2013

2015

S.O. 686(E) dt 09-03-2015 **Amendments in Dr**ugs (Prices Control) Order, 2013

S.O.-686E-dt-09-03-2015-Amendments-in-Drugs-Prices-Control-Order-2013

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Pharmaceuticals

Important Notifications

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Latest Notification

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The Gazette of India

Compounding Authority

Notification S.O. 3551(E) dt 01-08-2025

S.O. 3551(E) dt 01-08-2025 Appointment of Compounding Authority under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025

S.O. 3551(E) dt. 01-08-2025 Appointment of Additional Director General Health Services as Compounding Authority

CDSCO Circular

CDSCO

CDSCO Circular dt 01-08-2025 New online Dual Use System on SUGAM Portal

CDSCO Circular dt 01-08-2025 New online Dual Use System on SUGAM Portal

Latest Notification

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The Gazette of India

New Drugs and Clinical Trial

Notification GSR 587(E) dt 27-08-2025

GSR 587 (E) dt 27-08-2025 Draft notification of New Drugs and Clinical Trials (.... Amendment) Rules, 2025 regarding Application, Sample Size, BABE Studies, Fee etc.

GSR 587 (E) dt 27-08-2025 Draft notification of New Drugs and Clinical Trials (.... Amendment) Rules, 2025 regarding Application, Sample Size, BABE Studies, Fee etc.

Notification GSR 588(E) dt 27-08-2025

GSR 588 (E) dt 27-08-2025 Draft notification of New Drugs and Clinical Trials (.... Amendment) Rules, 2025 regarding permission of new drug, Working days etc.

GSR 588 (E) dt 27-08-2025 Draft notification of New Drugs and Clinical Trials (.... Amendment) Rules, 2025 regarding permission of new drug, Working days etc.

GSR 554(E) dt 18-08-2025 Qualitative details of all excipients to be mentioned on label

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th August, 2025

G.S.R. 554(E).——Whereas a draft of certain rules further to amend the Drugs Rules, 1945 was published, as required under sub-section (1) of sections 12 and sub-section (1) of 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 391 (E), dated the 12th July, 2024, in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on the 12thJuly, 2024;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (2nd Amendment) Rules, 2025.

(2) They shall come into force from 1st March, 2026.

2. In the Drugs Rules, 1945, in rule 96, in sub-rule (7), —

(a) In clause (vii), for the words "date of expiry; and", the word "date of expiry" shall be substituted;

(b) After clause (viii), the following clause shall be inserted, namely:-

"(ix) qualitative details of excipients."

[F. No. X.11035/44/2024-DRS]

NIKHIL GAJRAJ, Jt. Secy.

Note: The principal rules were published in the Official Gazette *vide* notification No. F. 28-10/45-H(1) dated the 21st December, 1945 and last amended *vide* notification number G.S.R. 127(E), dated 11th February, 2025.

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.

Click for more details

December-2025

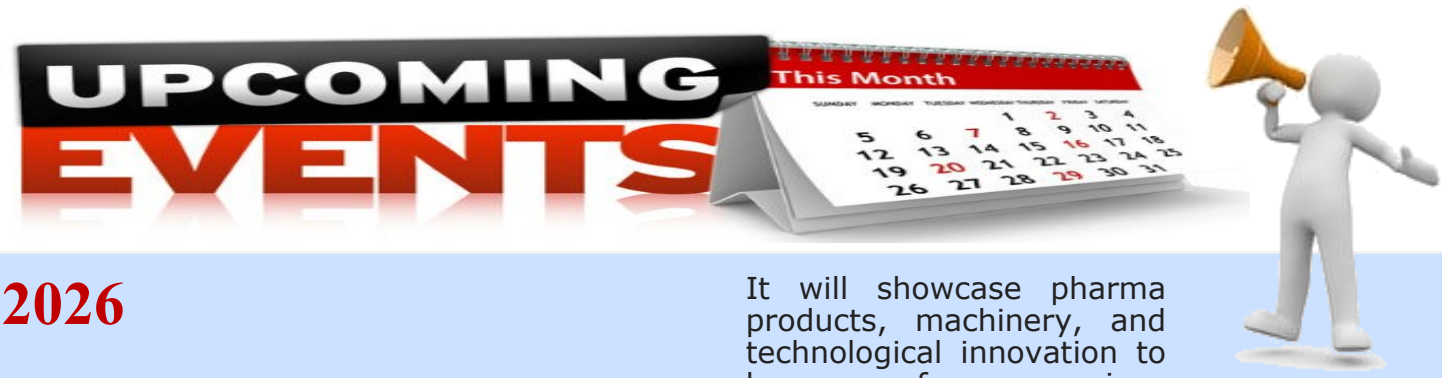
PharmaTech Expo Bengaluru

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.

Click for more details

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.

Click for more details

Obituary

In the loving memory of

Late Shri Alkesh Yadav

Drugs Inspector
Madhya Pradesh

Condolence message

DRUGS CONTROL OFFICERS (I) WELFARE ASSOCIATION

(Regd.No. 634 of 2022)
E-mail: dcoidcwa@gmail.com Website: www.dcoiwa.com

Honorary President
Dr. HEMANT G. KOSHIA
Cell: 99784 05054 - Gujarat

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G. KOTESHWAR RAO
Cell: 8121296397 - Telangana

General Secretary
BALDEV CHOUDHARY
Cell: 8094357800 - Rajasthan

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Mr. Rakesh Dahiya
Cell: 99116 00019, Haryana

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Cell: 98790 60666, Gujarat
Dr. A. Ramkishan
Cell: 63057 50926, CDSCO
Dr. Manish Kapoor
Cell: -9418081270 - Himachal Pradesh
Mrs. Kanchan Sinha
Cell: 9774548986 - Tripura

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Cell: 8974822360 - Tripura
Mr. Tapan Ch...
Cell: 9...

Date: 10th August 2025
Place: Hyderabad

Condolence Message

It is with deep sorrow that we inform the untimely demise of Shri Alkesh Yadav, Drugs Inspector, Indore, Madhya Pradesh, who passed away due to a cardiac arrest.
On behalf of the Drugs Control Officers India Welfare Association, I, G. Koteshwar Rao, National President, express my heartfelt condolences to the bereaved family and pray for his soul to rest in eternal peace.

As a mark of respect to our departed colleague, I request all Drugs Control Officers across India to observe two minutes of silence today at 11:00 AM.

May the Almighty give strength to his family to bear this irreparable loss.

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

H.Q. 15-21-150/6, New Balaji Nagar,
Kukatpally, Hyderabad (T.S), INDIA.
Phone : 8121296397, 8094357800,9977177574.

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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.

How to become a member

Register Online

Download Form

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