Issue 2 April 2024

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, 9977177574

Monthly Newsletter

For circulation among DCOIWA members only

In collaboration with The Health Master

# Understanding the Deliberations on 16 FDCs by the DTAB Subcommittee

DTAB
Drugs Technical Advisory Board

## FDCs

In the realm of pharmaceuticals, the evaluation and regulation of Fixed Dose Combinations (FDCs) play a critical role in ensuring public health and safety.

The sub-committee constituted by the Drugs Technical Advisory Board (DTAB) has recently garnered attention for its forthcoming meeting scheduled on April 5, 2024.

This meeting aims to delve into the assessment of **16 FDCs** previously flagged as irrational by the esteemed Prof. Kokate Committee. Let's delve deeper into the significance of this meeting and its implications.

**1. Background of the Issue**

***1.1 Prof. Kokate Committee Report***

The genesis of the current deliberations can be traced back to the recommendations put forth by the **Prof. Kokate Committee**. This committee identified **16** FDCs among the **294** under scrutiny, deeming them irrational.

***1.2 Regulatory Response***

In response to the findings of the Prof. Kokate Committee, the DTAB convened to examine the report and endorsed the need for further evaluation, particularly focusing on the flagged FDCs.

**2. The Role of DTAB Subcommittee**

***2.1 Composition***

The DTAB **sub-committee**, led by **Dr. Nilima Kshirsagar**, comprises experts in clinical pharmacology and regulatory affairs.

Their expertise is instrumental in evaluating the safety, efficacy, and rationality of pharmaceutical combinations.

***2.2 Objectives of the Meeting***

The upcoming meeting on **April 5, 2024**, serves as a platform for stakeholders to present their perspectives on the identified FDCs.

It provides an opportunity for comprehensive deliberation before the sub-committee makes further recommendations.

**3. Stakeholder Engagement**

***3.1 Importance of Stakeholder Participation***

Stakeholders, including manufacturers and regulatory bodies, hold valuable insights into the development and usage of

*(Continued on page 2)*

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

# Editorial Board

## Editor-in-Chief:

**Rakesh Dahiya**

## Co-Editor:

**P. K. Jaggi**

## Editorial Board:

**A. Manikandan IAS**

**Dr. A. Ram Kishan** (CDSCO)

**N.V. Raghu Ram** (Karnataka)

**Dr. Amal Kumar** (Bihar)

**Naripen Kumar Goyal** (Haryana)

**Dr. Arvind. H. Zala** (Gujarat)

**Dr. Ram Chandra Besra** (Jharkhand)

**Dr. Kiran Kumar Jannu** (Telangana)

**Mrs. K Limasenla Longchar** (Nagaland)

**Mijom Lollen** (Arunachal Pradesh)

**Piyush Jiaswal** (Chhatisgarh)

**Shabir Ahmad Pandit** (J&K)

**Dr. BR Jagashetty** (Karnataka)

**Dr. Swapnil Patil** (Delhi)

## Advisory Board:

**G. Koteshwar Rao** (National President)

**Baldev Choudhry** (Hon. Gen Secretary)

**Lalit Kr. Goel** (Founder member)

# 16 FDCs ...continue

*(Continued from page 1)*

FDCs.

Their active involvement enriches the deliberative process and ensures a holistic assessment.

***3.2 Call for Participation***

The FDC division of the Central Drugs Standard Control Organisation (CDSCO) has issued a call for stakeholders to attend the online meeting and present their viewpoints.

The absence of stakeholders may influence the committee's decision-making process.

**4. Evolution of Regulatory Oversight**

***4.1 Historical Context***

The scrutiny of FDCs dates back to **2007** when concerns were raised regarding unapproved combinations in the market.

Subsequent regulatory actions, including directives for withdrawal and committee formations, underscore the evolving regulatory landscape.

***4.2 Recommendations and Categorization***

The categorization of **FDCs** into rational, requiring further data, and irrational reflects a nuanced approach to regulatory decision-making.

It emphasizes the importance of evidence-based assessments in determining the fate of pharmaceutical combinations.

**5. Future Implications**

***5.1 Impact on Pharmaceutical Industry***

The outcome of the deliberations holds significant implications for manufacturers and marketers of the identified FDCs.

Compliance with regulatory directives and alignment with rationality criteria are imperative for sustained market presence.

***5.2 Public Health Considerations***

The ultimate objective of regulatory oversight is to safeguard public health interests.

Rationalization of FDCs ensures that medications adhere to safety and efficacy standards, enhancing patient outcomes and confidence in healthcare interventions.

**Source:** The Health Master

# DCOIWA writes letter to Chief Secretary, Manipur regarding certain objections on qualification for Analyst Post

DRUGS CONTROL OFFICERS (I) WELFARE ASSOCIATION
(Regd.No. 634 of 2022)
E-mail: dcoidcwa@gmail.com Website: www.dcoiwa.com

President
G. KOTESHWAR RAO
Cell: 8121296397 - Telangana

General Secretary
BALDEV CHOUDHARY
Cell: 8094357800 - Rajasthan

Treasurer
Dr. PARMANAND VERMA
Cell: 9977177574 - Chhattisgarh

Vice-Presidents:
Mr. Lalit Kumar Goel
Cell: 70567 02999, Haryana
Dr. M. Dhilip Kumar
Cell: 9840071715, Tamilnadu
Mr. Larap T.D. Toi
Cell: 8794150350 - Meghalaya
Mr. Venkatesh Sinari
Cell: 9850608501 - Goa
Mr. Tapan Choudhry
Cell: 9230610226 - West Bangal
Mrs. Garima Sharma
Cell: 9418086497 - Himachal Pradesh
Joint Secretaries:
Mr. Rakesh Dahiya
Cell: 99116 00019, Haryana
Mr. Chandan Kumar Giri
Cell: 8895478543 - Odisha
Mr. Pooran Chand
Cell: 9760366100 - Uttar Pradesh
Dr. Mrinal Kanti Sarkar
Cell: 8974822360 - Tripura
Mrs. Dipika Chauhan
Cell: 7990351251 - Gujarat
Mr. Biswajit Talukdar
Cell: 7086084833 - Assam
Organizing Secretary:
Mr. Amit Kumar Bansal
Cell: 9198463261 - Uttar Pradesh
EC Members:
Dr. E. Ananda Kirouchenane
Cell: 9443959680 - Puducherry
Dr. Manish Kapoor
Cell: -9418081270 - Himachal Pradesh
Mr. Rajkumar V. Zadbuke
Cell: 9892827738 - Maharashtra
Mr. Ashutosh Kumar Chaube
Cell: 9415632071 - Uttar Pradesh
Dr. Mahalakshmy .R
Cell: 9497004156 - Kerala
Dr. Zaffer Ahmad
Cell: 6006520235 - Jammu & Kashmir
Mr. Neeraj Kumar
Cell: 9458900286 - Uttarakhand
Mrs. Kanchan Sinha
Cell: 9774548986 - Tripura
Mr. Ibom Ete
Cell: 8257045591 - Arunachal Pradesh

Date: 28th March, 2024
Place: Hyderabad.

Lr.Rc.No. DCOIWA/Pres/002/2024 Dt. 28-03-2024

To,
Shri Dr. Vineet Joshi IAS
Chief Secretary, South Block, Old Secretariat,
Government of Manipur, Imphal - 795001
Email: cs-manipur@nic.in

Respected sir,

Sub: Govt. of Manipur, GO No. G (MSDTL) / 1/2021-DHS-Govt. Analysts Posts - Certain objections on qualification-Request for Rectification-Reg.

Iam writing to address the advertisement released by Directorate of Health Services, Manipur on Feb. 27, 2024, regarding the recruitment of Government Analyst with Ref. No. G(MSDTL)/1/2021/DHS.

As a National President of DCOIWA, I must highlight that the specified qualification in this advertisement conflict with Rule 44 of Drugs & Cosmetics Rules 1945.( copy enclosed).

This discrepancy suggests a lack of understanding with in the manpower section regarding drug laws and regulations.

Therefore, I urge for an investigation in to the draffting authority responsible for this advertisement.

Iam writing this appeal letter on request of our association members from Manipur State Chapter.

Thankyou sir for your attention to this matter.

Sincerely Yours,

G. Koteshwar Rao
National President ( 8121296397)

Copy to Mr. Brajkishore Singh (President ) and Mr.Yanglem Ronen Singh Secretary of DCOIWA, Manipur Chapter for necessary follow-up.

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

# Ketamine: Understanding its Classification and Regulations in India

Lalit Kr. Goel

**Deputy Drugs Controller,**
**FDA Haryana**

## Ketamine

Ketamine, a well-known anaesthetic and analgesic drug, has garnered attention not only for its medical applications but also for its classification under regulatory frameworks.

## Understanding Ketamine's Classification

### The Categorization Process

- Ketamine's classification as a psychotropic substance was formalized through notification no. **S.O. 311(E) dated 10.02.2011**, issued by the Department of Revenue, Ministry of Finance, Government of India.

**Ketamine also classifies as small quantity (10gm)** and **commercial quantity (500gm) under NDPS Act 1985 vide notification No. S.O. 1430(E) dated 21.06.2011** issued by the Department of Revenue, Ministry of Finance, Government of India.

### Scheduled X Drug Declaration:

**Further, it was declared as a Scheduled X drug under notification no. GSR 724(E) dated 07.11.2013**, issued by the Department of Health, Ministry of Health and Family Welfare, Government of India.


## Regulatory Requirements for Ketamine

### Mandatory Label Warnings

### Labelling Mandates

Both warnings for psychotropic substances and **Scheduled X** drugs are obligatory to be printed on the label of **ketamine**.

**NRx should be printed in red colour on the top left corner on the label.**

## Licensing Regulations

### Necessity of Separate License

Manufacturing and sale of ketamine drug require a separate license under **Schedule X**, as mandated by regulatory authorities.
**Ketamine is not Essential Narcotics Drugs (END) for the purpose of Recognized Medical Institute (RMI).**

## Compliance and Enforcement

### Ensuring Adherence to Regulations

### Regulatory Oversight

**Regulatory bodies enforce stringent measures to ensure compliance with labelling requirements and licensing regulations for ketamine**

### Monitoring Supply Chains

Inspection and monitoring of supply chains are conducted to verify adherence to regulatory mandates concerning ketamine

——

# Regulatory Control to Combat the Menace of Spurious / Counterfeit Drugs

**K.C. Aggarwal**

**Former Deputy Drugs Controller, Delhi**
**Registered Advocate - Delhi**

Spurious drugs pose a significant threat to patients' lives, genuine drug manufacturers, and the overall image of our country. Counterfeit drugs have a deceptive capacity, often resembling the original product from legitimate sources, making purchasers unsuspecting. The proliferation of low-quality medicines jeopardizes public health at all levels. Modern therapeutics have dramatically improved human life expectancy, but the rising prevalence of counterfeit drugs undermines their efficacy. This trend damages the credibility of healthcare systems and leads to illness, disability, and death among consumers.

Efforts to eradicate spurious and counterfeit drugs intensify, but with limited success. According to Section 17(B), a drug is considered spurious if it::

- Is manufactured under another drug's name.
- Imitates or substitutes another drug in a manner likely to deceive.
- Bears a fictitious manufacturer's name.
- Is wholly or partially substituted by another substance.
- Falsely claims to be a product of a specific manufacturer.

Counterfeit drugs often target antibiotics, hormones, steroids, anti-hypertensive drugs, and even anti-cancer medications. Varieties of counterfeits include products without active ingredients, with incorrect ingredients, with correct ingredients but fake packaging, and exact copies of genuine products.

**Factors Leading to Counterfeiting of Drugs:**

1. Lower cost compared to genuine drugs.
2. Inadequate drug legislation and regulation, lacking deterrence.
3. Minimal infrastructure and overhead expenses.
4. Lack of regulatory control.
5. Advanced printing technology mimics genuine packaging.
6. Involvement of organized criminal networks.
7. Lucrative profits.
8. Corruption and conflicts of interest.

**Adverse Effects of Counterfeiting:**

1. Patients receive ineffective treatment, undermining confidence in healthcare systems.
2. Industries suffer reputation and financial losses.
3. Countries face tarnished global reputations.

**Combatting Counterfeit Medicines:**

1. Strengthen regulatory control and awareness campaigns.
2. Efficient training of regulators to investigate and monitor drug movements.
3. Training drug inspectors to enhance performance and expedite legal proceedings.
4. Equip drug testing labs with international standard instruments.
5. Conduct thorough surveys to track counterfeit drug movements.
6. Train pharmacists to procure medicines from genuine sources and report suspicions.
7. Establish dedicated task forces to assist drug administrations.
8. Maintain whistleblower policies for public engagement.
9. Impose strict liability on counterfeit drug manufacturers.
10. Release press information to raise awareness.

**Recent Instances of Spurious Drugs:**

- Suspicious stocks of Telma 40 and Telma H tablets found at a retail counter.
- Suspected counterfeit Rosvas 10 tablets at the stockist level.
- Recent arrest of an individual manufacturing counterfeit anti-cancer drugs.

**Conclusion:**

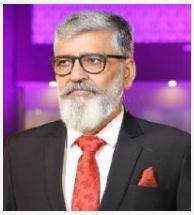
Spurious drugs endanger lives and thrive on consumer ignorance and ineffective regulations. Continuous surveillance, regulatory cooperation, and public awareness are crucial to safeguarding patient health and maintaining medication quality.

—

# How to stop Fake Medicine Business

**NK Ahooja**

Professor, MVN University Palwal, Haryana
Former State Drugs Controller
Food and Drugs Administration, (FDA)
Haryana, India |



## Fake Medicine

The contemporary challenge confronting society is the proliferation of **fake medicine**.

To address this issue effectively, it is imperative to grasp the definition of fake medicine as outlined in the **Drugs and Cosmetics Act**.

Section 17-B of the Act delineates fake medicine, which must be comprehended by all stakeholders.

## What is fake Medicine:

1. Manufactured under another company's name.
2. Contains substances other than the prescribed medicine.
3. Bears the name of a different company at the manufacturing level.
4. Lacks the specified medicine or contains it in insufficient quantities.
5. Produced under a company's name that does not correspond with the actual manufacturer.

## Preventive Measures:

### *Measures for Consumers:*

1. Verify the chemist's license before purchasing medicine.
2. Avoid unlicensed medicine vendors and report them to the Food and Drug Administration.
3. Ensure the seller is a licensed pharmacist.
4. Obtain a valid bill for purchased medicine.
5. Verify the medicine's details on the bill against its packaging.
6. Seek medical advice post-purchase.
7. Report any suspicions regarding medicine quality.


### *Measures for Medicine Sellers:*

1. Source medicine only from licensed manufacturers or wholesalers.
2. Refrain from purchasing cheap medicines without a bill.
3. Cross-check details of purchased medicine.
4. Store medicines appropriately.
5. Familiarize with security features of medicines.
6. Conduct all transactions with bills.
7. Display the license conspicuously.
8. Sell medicines under pharmacist supervision.

### *Measures for Drug Administration:*

1. Increase the number of drug inspectors.
2. Enhance training for drug inspectors.
3. Exercise caution during sample collection.
4. Acknowledge inspectors seizing fake medicine.
5. Upgrade drug testing laboratories.
6. Foster advanced lab capabilities for fake detection.

### *Measures for Manufacturers:*

1. Incorporate security features like QR codes in packaging.
2. Verify medicine sales through representatives.
3. Establish a brand protection team.
4. Promptly address complaints about fake medicines.
5. Safeguard printing materials.
6. Communicate changes in packaging.
7. Ensure products meet personal standards.
8. Regulate machinery sales to licensed manufacturers.
9. Mandate printer registration.

Implementation of these measures will aid in combating the **fake medicine** trade, ensuring consumer safety, and preserving public health.

Additionally, incentivizing individuals who report fake medicines while maintaining their anonymity is essential.

**Source: NK Ahooja**

# FSSAI: Food Labelling and Display – Chapter-3

Dipika Chauhan

Former, Deputy Commissioner
FDCA Gujarat

## Food Labelling

**To be continued…… FSSAI: Food Labelling and Display – Chapter-2**

## Decoding Labels: Unveiling the Ingredients List on Food Packaging

In the intricate dance of Flavors and compositions within packaged foods, the ingredients list takes centre stage, revealing the secrets of a product's formulation.

The regulations governing the disclosure of these ingredients, outlined under the **Food Safety and Standards Act,** are meticulous and pivotal for consumer awareness with respect to food labelling.

Let's delve into the intricacies of presenting the list of ingredients on **food labels**.

## 1. The Ingredients Odyssey: A Clear Declaration

### *Appropriate Title: Ingredients/List of Ingredients*

The ingredients list embarks with a clear title, such as "**Ingredients/List of Ingredients**."

This establishes a standardized beginning, ensuring consumers can easily identify where to find crucial information about the composition of the product.

### *(b) Descending Order of Composition*

The arrangement of ingredients is not arbitrary; it follows a logical sequence.

Ingredients are listed in descending order of their composition by weight or volume during the product's manufacture.

This provides consumers with insights into the relative proportions of each component.

### *(c) Food Additives and Technological Functions*

Ingredients, including food additives, play specific roles in the technological function of the product.

If a food additive carries over into the final product, it must be included in the list of ingredients, emphasizing transparency in formulation.

*(Continued on page 8)*

# FSSAI: Food Labelling …… continue

*(Continued from page 7)*

## *(d) Specific Names for Ingredients*

Generic terms are left at the doorstep; each ingredient must be identified by its specific name.

This specificity avoids ambiguity and ensures that consumers understand precisely what goes into their chosen product.


## *(e) Compound Ingredients Revelation*

For compound ingredients — those resulting from the fusion of two or more ingredients — transparency is paramount.

They are declared either as a compound with an accompanying list of components in brackets or by individually declaring all the ingredients as if they were standalone components.

Exceptions exist for compound ingredients constituting less than 5% of the food.

## *(f) Declaration of Added Water*

Water's role in a product, whether added separately or inherent in other ingredients like brine or syrup, is clearly outlined.

However, in certain instances where water or volatile ingredients evaporate during manufacturing, no declaration is required.

## *(f) Reconstituted Foods and Ingredient Disclosure*

In the realm of dehydrated or condensed foods designed for reconstitution, the label must not only reveal the ingredients in their dehydrated or condensed state but also provide instructions for preparation, ensuring accurate information for consumers.

## *(g) Quantitative Ingredient Disclosure*

When certain ingredients hold significance, either highlighted on the label or essential for characterizing the food, their ingoing percentage at the time of manufacture must be disclosed.

This prevents potential consumer deception and ensures that vital components are transparently represented.

## 2. Compliance as a Cornerstone

Adherence to these regulations is not merely a legal obligation but a commitment to consumer trust.

Manufacturers play a vital role in ensuring that the ingredients list is not just a collection of words but a transparent window into the essence of their products.

**To be continued……. FSSAI: Food Labelling and Display – Chapter-4**

**Source: Dipika Chauhan**

# The proposal for a Unified Drug Regulatory Authority in India

Dr. Bharatesh R Jagashetty

Former National Adviser (Drugs Control) to MoHFW, GOI & CDSCO | Former State Drugs Controller, FDA Karnataka |
Presently working as Legal Consultant for Pharma field |

## Drug Regulatory Authority

In the landscape of pharmaceutical regulation, India stands at a pivotal moment. The formation of the **Indian Drug Regulatory Authority** (IDRA) by renaming the **Central Drugs Standard Control Organization** (CDSCO) and establishing the **Indian Drug Regulatory Services** (IDRS) cadre could revolutionize the sector.
This article delves into the imperative of this transformation and its potential ramifications.

## Need for Reform

The existing regulatory frameworks, though robust, lack uniform interpretation and implementation.
Harmonizing these laws is essential to foster industry growth and ensure public health.
Additionally, there's a pressing need to address challenges such as counterfeit drugs, regulatory red tape, and fragmented enforcement across states.

## Current Scenario: CDSCO

The **CDSCO** serves as the primary regulatory body, but its structure requires modernization.
The creation of the **IDRS** cadre can enhance expertise and efficiency within regulatory functions.
Moreover, there's a need for continuous training and capacity building to keep pace with evolving pharmaceutical technologies and global regulatory standards.

## One Nation, One Regulatory Authority

Harmonizing state and central regulations under a unified licensing authority streamlines processes, mitigating bureaucratic hurdles and promoting industry expansion.
This move aligns with the government's vision of "**One Nation, One Market**," facilitating seamless operations for pharmaceutical companies across India.

## Unified Licensing Authority

The establishment of **IDRA** with branches across states mirrors central excise department practices, promoting compliance and resource efficiency.
However, it's crucial to ensure that decentralization doesn't compromise regulatory oversight, and adequate checks and balances are in place to maintain quality standards.

## Administrative Reform: Merger of State Enforcement Wings

A significant administrative shift involves merging state enforcement wings with the central authority, enhancing regulatory coherence.
This transition demands careful planning, stakeholder consultation, and allocation of resources to address potential resistance and operational challenges.

## Proposed Indian Drug Regulatory Authority (IDRA)

**IDRA**, akin to global counterparts like **USFDA** or EMA, promises global recognition and operational efficacy.
To achieve this, **IDRA** should adopt best practices in regulatory science, pharmacovigilance, and risk management while fostering collaboration with international regulatory agencies.

## Indian Drug Regulatory Services (IDRS)

Creating a dedicated cadre akin to **IAS/IPS/IFS** ensures specialized personnel for effective regulation and oversight.
However, recruitment criteria, career progression, and performance evaluation mechanisms need refinement to attract and retain top talent in regulatory roles.

**Similar to the IAS/IFS model, IDRS officers could contribute to diverse sectors such as:**

*(Continued on page 10)*

# The proposal .....continue

*(Continued from page 9)*

- Health & Family Welfare,
- Medical Education,
- Agriculture,
- Horticulture & Sericulture,
- Animal Husbandry & Fisheries,
- Forest,
- Ecology & Environment,
- Ayush,
- Finance,
- e-Governance,
- Education,
- Food & Civil Supplies,
- BT & IT,
- Women & Child Welfare,
- Import/Export,
- Ports,
- Labour, Law, and
- Home Affairs.

This multi-departmental engagement would leverage their expertise and contribute to comprehensive regulatory oversight across various domains.

## Streamlining Licensing Processes

Simplified licensing processes align with government initiatives to improve ease of doing business and attract investment.
This entails leveraging technology for online application, review, and approval of licenses while ensuring transparency, accountability, and data security.

## Central Intelligence Wing

Establishing a centralized intelligence wing aids in curbing counterfeit and substandard products, bolstering consumer safety.
This requires robust surveillance mechanisms, collaboration with law enforcement agencies, and stringent penalties for offenders to deter illicit activities.

## Drug Control Repository

A centralized repository facilitates information dissemination, crucial for combating issues like look-alike and sound-alike drugs.
Additionally, it serves as a knowledge hub for stakeholders, providing insights into regulatory requirements, product safety profiles, and market trends.

## Regulation of E-Pharmacies

Effective regulation of e-pharmacies is imperative for consumer safety, demanding timely formulation and enforcement of rules.
This involves addressing concerns related to prescription verification, product authenticity, data privacy, and responsible medication dispensing practices.

## Leap Towards Digital Technology

Adopting digital solutions enhances efficiency and transparency, advancing regulatory capabilities.
Key initiatives include the development of a unified regulatory portal for license management, online training modules for regulatory personnel, and real-time monitoring systems for adverse drug reactions.

## Conclusion

The formation of **IDRA** and **IDRS** alongside digital regulatory systems marks a transformative stride in pharmaceutical regulation.
It not only ensures industry growth but also underscores the government's commitment to public health and safety.
However, successful implementation requires concerted efforts from policymakers, regulators, industry stakeholders, and the public to overcome challenges and realize the full potential of these reforms.

——

# Pharma Printers must come under the ambit of Drugs Act

NK Ahooja

Professor, MVN University Palwal, Haryana
Former State Drugs Controller
Food and Drugs Administration, (FDA)
Haryana, India

## Counterfeit drugs

Counterfeit drugs are posing a threat to the Indian pharmaceutical industry. Counterfeiters are manufacturing drugs which belongs to other company in their name and style.

Most of the time counterfeiters are not even adding any active pharmaceutical ingredients (API) in these products.

The counterfeit drugs which are even not having the APIs are causing the health hazard.

As the patients are consuming these drugs but actually these drugs are not having the active ingredients and have no pharmacological action.

## The Menace of Counterfeiting

These counterfeiters are supplying the drugs without any invoices without issuing any bills therefore even when the counterfeit drugs seized in the market by the drug inspectors, it becomes very tough for the investigating officer to reach actually who has manufactured these counterfeit drugs.

Without establishing the supply chain of these drugs investigations could not reach up to the counterfeiters.

In these cases, the inspectors are issuing notices to the manufacturer whose name is disclosed on the label but who is not the actually manufacturer of this product.

Rather the name of manufacturing unit on the label is a victim of the fraud of the counterfeiters.

When these genuine manufacturers tried to protect their brand becomes whistle blowers but sometimes feels harassed and frustrated due to certain lacunae in law and casual approach of investigation.

## Recent Cases highlights the severity

in a very recent case FDA officers of Chhattisgarh raided and took hold of Distributor swapping labels and secondary packing of Eye Drops removing the labels and box of one company and pasting the label and secondary box of other company due to price difference.

**In another case DCA Telangana conducted raids on the places of counterfeiter and recovered many counterfeit drugs.**

## Legal Regulatory Solution

### Packing Material:

The word manufacturer is defined in the Drugs and Cosmetics act 1940 in Section 3(f) which includes '**packing**'.

Packing of any drug is not possible without '**printed packing material'** and '**printed secondary boxes**.

Then why these printers who are supplying the printed primary and secondary packing materials to is counterfeiters should not be held responsible as they are printing and supplying this printed packing material without ascertaining if it actually belongs to the counterfeiters.

Therefore, these printers printing packing materials for counterfeiters are actually culprit and main accused with counterfeiters. Section 120 B can be invoked against these printers.

### Excipients:

**Section 3(b) (iii)** part of definition of Drug prescribed "**all substances intended for use as components of a drug**" are also drug.

All the excipients and additives including empty gelatin capsule are included as drug by virtue of this definition. However, this does not include the printed packing materials.

*(Continued on page 12)*

# Pharma Printers .....continue

*(Continued from page 11)*

But taking a clue from this definition the printed packing materials which are integral part of the drug may be regulated which is need of the hour.

## Rule 104:

A prohibition against altering inscriptions on containers labels or wrappers of drug in which a permission or registration is required from the competent licensing authority even for stickering.

Even when the rates are reduced by issuing gay notification of ceiling price by **National Pharmaceuticals Pricing Authority** (NPPA). This proves beyond doubt that packing is regulated.

## Schedule M:

That the **Schedule M** read with Rule 71, 74,76 and 78 which prescribe **Good Manufacturing Practices** (GMP) for Pharmaceutical Products at Sr. no. 17 under heading Specifications provides common specifications at point 17.1 '**For Raw Materials and Packaging Materials**' which proves and equates the importance of Packing Materials with Raw Materials.

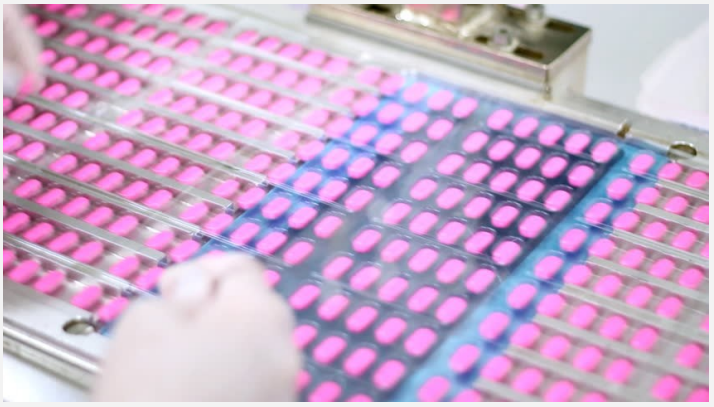
In case of Raw Materials even for Additives Excipients etc. having No Pharmacological Action there is a requirement of Drug Manufacturing License under Drugs Act 1940 but for printed packing material there is no such regulatory pathway.

## Proposed Solutions

**Regulators**: Regulators must prescribe a method of Licensing / Registration for printers of packaging materials, ensuring accountability and traceability.

**Pharma Printers:** All pharma printers must verify the following:

1. Copy of License and its validity at the time of taking order from its actual manufacturing unit.
2. Printer should check the product approval issued by competent authority in favour of manufacturer.
3. Printer must get a final signed approval on specimen of printed packing material before commencing the printing on commercial scale.



4. Printer should keep the records of actual printing rolls, quantity printed, copy of Drug manufacturing License (DML) of manufacturer, order of manufacturers with date and quantity, Final supply with receipt by authorised person only.
5. Printer must keep a record of Security Features included in printed packing materials which can be used during Investigations by Drugs Inspectors.
6. Rolls used for printing should be either in exclusive possession of Brand owner or a double lock system may be used.
7. For Contract manufacturer or marketing firms the printed packing material should be a joint responsibility of manufacturer marketer and printer. All these should be held responsible.
8. Printer premises printing Packing Materials for Drugs should remain open for Inspection at least once in a year as prescribed under Rule 52 which are duties of Inspectors for manufacturing units and are subject to instructions of Controlling Authority.
9. Printing of Printed Packing Materials for Counterfeiters should be made punishable under Drugs Act also and same penalties may be prescribed which are for Spurious or Unlicensed Manufacturers.

**Source: NK Ahooja**

# Compounding of Offences under Drugs & Cosmetics Act 19400

## COMPOUNDING OF OFFENCES UNDER DRUGS & COSMETICS ACT 1940 & THE JAN VISHWAS (AMENDMENT OF PROVISIONS) ACT, 2023 NO. 18 OF 2023

**R K Singla**

**Former State Drugs Controller,**
**FDA Haryana**

**COMPOUNDING OF OFFENCES UNDER DRUGS & COSMETICS ACT 1940**

**&**

**THE JAN VISHWAS (AMENDMENT OF PROVISIONS) ACT, 2023 NO. 18 OF 2023**

### Salient features of the Jan Vishwas (Amendment of provisions) Act 2023:

1. In the Jan Vishwas (Amendment of provisions) Act 2023, the Government has made some amended in various existing laws, & many offences with punishable up to 2 years have been decriminalised & only fine has been prescribed for such offences.

2. At Sr. No. 6 of the Jan Vishwas (Amendment of provisions) Act 2023, provision for amendment of some offences punishable under Drugs & Cosmetics Act 1940 has also been made.

3. The provision for Compounding of offence under clause (b) of sub-section (1) of Section 13, Section 28 & Section 28A of the D&C Act was already there which was inserted w.e.f. 2009.

4. The Government has also made the offences punishable under clause (d) of section 27 and clause (ii) of section 27A, of the Drugs Act as compoundable through THE JAN VISHWAS (AMENDMENT OF PROVISIONS) ACT, 2023 NO. 18 OF 2023.

5. The provisions of compounding in cases of offences under clause (d) of section 27 and clause (ii) of section 27A, of the Drugs Act, will be in force only from 31st December 2024 as per Notification no. S.O. 1577 (E) dated 28th March 2024, thereby meaning that, the offences committed prior to 31st December 2024 are not compoundable.

6. The amendment or repeal by this Act of any enactment shall not affect any other enactment

in which the amended or repealed enactment has been applied, incorporated or referred to;

and this Act shall not affect the validity, invalidity, effect or consequences of anything

already done or suffered, or any right, title, obligation or liability already acquired, accrued or incurred or any remedy or proceeding in respect thereof, or any release or discharge of, or

from any debt, penalty, obligation, liability, claim or demand, or any indemnity already granted, or the proof of any past act or thing;

7. Apart from Drugs, the provisions of compounding of offences will also be applicable in the cases of medical devices, cosmetics, homeopathic medicines, disinfectants etc.

8. The fines and penalties provided under various provisions in the enactments mentioned in the Schedule shall be increased by ten per cent. of the minimum amount of fine or penalty, as the case may be, prescribed therefor, after the expiry of every three years from the date of commencement of this Act.

9. The amendments in Section 29 & 30 of the Drugs Act have also been made, which are related to publication of the test report of Government Analyst, wherein the offences under these sections will be punishable only with fine. The fine has been increased under these sections & the imprisonment for the subsequent offence has also been abolished.

The Ministry of Health & Family Welfare, Government of India has fixed the date 31st December 2024 (vide Notification No. S.O. 1577 (E) dated 28th March 2024), when these amendments made with regard to the Drugs & Cosmetics Act 1940, under Jan Vishwas Bill 2023, will be in force.

## Compounding of Offences ...continue

**A comparison of the Sections in Sections 29, 30 & 32-B prior to amendments & after the amendment has been compiled in the following table:**

| S.No. | Section of D & C Act | Heading of the Section | Old provisions (Prior to amendment under Jan Vishwas Act 2023) | New amended provision (After amendment under Jan Vishwas Act 2023) |
|---|---|---|---|---|
| 1. | Section 29 | Penalty for use of Government Analyst's report for advertising. | -Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine which may extend to five thousand rupees. | -Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be "liable to penalty which may extend to one lakh rupees". |
| 2. | Section 30 | Penalty for subsequent offences. — | (1) Whoever having been convicted of an offence, —<br><br>(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees:<br>Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees; | (1) Whoever having been convicted of **an** offence, —<br><br>(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees:<br><br>Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees; |

## Compounding of Offences ...continue

| | | | | |
|---|---|---|---|---|
| | | | (b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees]; | (b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees]; |
| | | | (c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than fifty thousand rupees, or with both. | (c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than fifty thousand rupees, or with both. |
| | | | (1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both. | (1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees], or with both. |
| | | | (2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to two years, or with fine which shall not be less than ten thousand rupees or with both. | (2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with the words fine which shall not be less than five lakh rupees. |

## Compounding of Offences ...continue

| | | | | |
|---|---|---|---|---|
| 3. | Section 32 B | Compounding of offences | — (1) Notwithstanding anything contained in the Code of of Criminal Procedure, 1973, (2 of 1974) any offence punishable under clause (b) of sub-section (1) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify:<br><br>Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:<br><br>Provided further that in cases of subsequent offences, the same shall not be compoundable.<br><br>(2) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition | (1) Notwithstanding anything contained in the Code of of Criminal Procedure, 1973, (2 of 1974) any offence punishable under clause (b) of sub-section (1) of section 13, clause (d) of section 27 and clause (ii) of section 27A, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that to that Government of such sum as that Government may, by rules made in this behalf, specify:<br><br>Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:<br><br>Provided further that in cases of subsequent offences, the same shall not be compoundable.<br><br>(2) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence |

# Compounding of Offences ...continue

| | | | | |
|---|---|---|---|---|
| | | | for the offence shall be allowed without, the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.<br><br>(3) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.] | shall be allowed without, the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.<br><br>(3) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.] |

**Cases where Compounding is not allowed :-**

(a) In the subsequent offences,

(b) When the accused has been committed for trial; or

(c) The accused has been convicted and an appeal is pending & Such a case can be compounded only with the leave of the Court.

**Procedure for Compounding the offence:**

The cases can either be compounded by the Central Government i.e the Secretary of Ministry of the Ministry of Family Welfare or the Additional Chief Secretary or the Principle Secretary of the State Governments or Lieutenant Governor of the Union Territories of any other officers of the Central or State Government has to be authorised .

**Authorization of officers by Central & State Governments & Union Territories:**

The officers have to be notified/appointed/authorised by the Central, State Governments & Union Territories for compounding of the offences.

Date of implementation of compounding of offence including through JAS VISHWAS AMENDMENT OF PROVISIONS) ACT, 2023 has been fixed for 31st December 2024.

**Conclusion:**

The Offences under the following sections can be compounded;

(i)under clause (b) of sub-section (1) of section 13; and

(ii) clause (d) of section 27; and

(iii) clause (ii) of section 27A; and

(iv) section 28; and

(v) Section 28A.

**Caution for the stake holders:**

As per sub-para (1) of Section 32 of Drugs Act , the provisions of compounding won't be available for the second & subsequent offences of under clause (b) of sub-section (1) of section 13, clause (d) of section 27 and clause (ii) of section 27A, section 28 and section 28A of this Act. Therefore, these provisions are only for the 1st offence under the relevant provisions of the Drugs Act. Hence, the manufacturer/dealers/retailers /wholesalers shouldn't become complacent towards quality of drugs.

—-

# LEGAL WRITING

**Rajinder Kumar Harna**

**Former, Assistant Drugs Controller, FDA Haryana**

**LEGAL WRITING**

**Introduction to the Article:**

Three 'R's are well recognized which must be possessed by any literate person to have a meaningful happy life in the society. Effectiveness with which the person is bestowed with brings &determines the results out of it.

Persons like Regulatory officers placed at various echelon in the Government Entrustment enforce law over a very sensitive and important subject of health, disease and disorders and deal with drug laws.

The law makers have shown their great wisdom in enacting the Drugs and Cosmetics Act 1940 and Rules thereunder. They have framed law on a very wide subject which is riddled with technicalities , involved in, Import, Manufacture for sale or distribution and Sale or distribution of drugs. Each term, sentence of the statute has expression and purpose for legal effect. Law governs the conduct of human beings towards everything surrounding him. Reading this law is great knowledge. Understanding this law gives wisdom. Correspondence and dispatches under the Act express the understanding of the written law in the statute and its proximity to the intent of the law maker. In this article "Legal Writing " various aspects will be discussed objectively. Care will be taken to confine it with the intent of the Statute, fidelity of implementation and proximity achieved to the intent of the legislation.

Legal means connected to law . Section 43 of IPC defines term "illegal": Applicable to every thing which is an offence or which is prohibited by law legally . Drafting herein means writing or making of document which may be used for legal purposes.

LEGAL writing salient features: It carries Purpose to be achieved Audience to be reached

Pack of facts in chronological order

Justification of purpose

Conclusion on purpose

AWE OF THE LAW :
The legal writing must deliver

FEELING OF RESPECT FOR LAW AND EITHER DETERRENCE
OR
ACCEPTACE , IMPLEMENTATION, APPRECIATION
AND
ADMIRATION
AND SENSE OF COSEQUENCES IF LAW IS IGNORED


Without curtailing or diminishing the rights of the adversely
affected person. By writing we make a document.

**Document :** CrPC Section 29: The word "document" donates any matter expressed or described upon any substance by means of letters, figures, or marks , or by more than one of those means, intended to be used, or by which may be used, as evidence of that matter
Electronic record in any form is a document under section 65-B (1) of the Indian Evidence Act. 1872 . Such record during evidence must be accompanied with a certificate issued by the person who prepared the electronic record as provided under section 65-B(2) of the Evidence Act.

**DOCUMENTS MEANT TO BE SUBMISSIONS BEFORE A JUDICIAL COURT:-**

**Paper and sizes :**

WHITE LEGAL PAPER of dimension 356mm x 216mm (14"x 8.5") is prescribed in supreme court for any petition, however from April 2020, white paper size A4 (210mmx297mm (8.3"x11.7")) has been permitted. No dictate for lower courts. But High Courts also prescribe the same for courts subordinate to it. There in no mention against or for light green colour of the paper legal size, which is commonly seen

**GSM OF PAPER: 70 TO 80**

PRINT in double space with margins 1.25" on top, 0.75" on bottom,
1.75" on left side and 0.75" on the right side.
FONT 14, double line space, font type times new roman
DISTRICT COURTS: both legal or A4 size font 14, double line space: gsm, margins, are same as above
LANGUAGE : Language of the court: Two languages, out of which one is English and second as per Rule of the High Court of the State
PAGE NUMBER: In the middle of top of page in Arabic numerals .

**LAWS OF CONCERN TO DRUGS REGULATORS IN INDIA**

**Following are Special Law**

- Drugs and Cosmetics Act 1940 and Rules Thereunder, (the Drugs Act)
- DPCO 2013 under Essential Commodity Act 1955
- Narcotic Drugs and Psychotropic Substances 1985
- Drugs and Magic Remedies (Objectionable Advertisements) Act 1954

*(Continued on page 19)*

# LEGAL WRITING ….continue

*(Continued from page 18)*

- The Information Technology Act 2000

**Applicable GENERAL LAWS:**

Code of Criminal Procedure, 1973, The Indian Evidence Act 1872, The General Clauses Act 1897, IPC...forthe purpose of 32 (3) of the Drugs and Cosmetics Act 1940, Factory Act 1948.... for the purpose Schedule M Part I and Bio-medical waste (management and handling) rules 1996

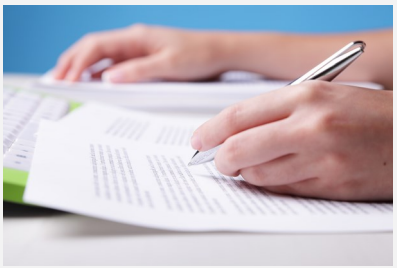
**PURPOSE OF LEGAL WRITING** is to Bring Harmonization In Understanding Among The Opposing Parties And The Adjudicator During Procedings , Facts And Law Based, To Avoid Complexities And Confusions. Law Is Not By Choice Of Individuals. Law Emerges From Understanding Of Human Conduct With Any Or Every Thing Arround. In Legal Writing Meaning, Definitions Interpretations Given Under Law Must Be Followed Scrupulously.

**PRIOR TO LEGAL WRITING:**

KNOW WELL THE STATUTE UNDER WHICH THE PURPOSE OF WRITING IS HELD, e.g Drugs and Cosmetics Act 1940 and Rules there under. NOTATION OF THE STATUTE IN DOCUMENT; instead of writing full name of the statute notations can also be used. EXAMPLE : 27-23-1940 MEANS OFFENCE UNDER SECTION 27 OF THE ACT 23 OF 1940: it means the punishment u/s27 OF The Drugs And Cosmetics Act 1940 And Rules Thereunder. But it is not used in correspondence with general public. EXAMPLE: 21-61-1985 MEANS punishment u/s 21 of the NDPS Act

**BASIC STRUCTURE OF A DOCUMENT:**

Every document written must have title or subject showing date time and place details of participant persons. Body expresses the purpose, activity, materials involved, documents received, against whom the document has been prepared. The document must distinctly show the signature of the author with particulars and date, similarly that of addressee and witnesses.
Below the text or overleaf, acknowledgement of receipt of any material document or notice be made, signed with particulars and dated. Statements if any made by the accused etc or witnesses should be in their hand writing. If for any reason the person required to tender written statement is unable to write then a writer among the witnesses can be nominated , reasoned for such a necessity. If the person required to sign refuses to sign on any document or his oral statement reduced to writing, then this fact should be mentioned and attested by witnesses again separately in addition to their usual signatures. Expression be made in writing on the documents prepared that the contents of the documents have been read over to the person concerned and he confirms to have understood it. In matter where the suspect flees the site during the documentation, this fact be mentioned and attested by all. One copy of the document be pasted on the prominent part of the site. Later on, copy of the same can be sent by Post to the address of the site, residential or any other address obtained from any documents. Register Cover postal receipt is enough to prove compliance by regulatory officer. Last known address is enough for regulatory compliance if despite of an effort in due course of search does not reveal credible new address. Sending messenger with local witness is very credible.



THE REGULATORS normally make legal writings in the matters of (a) the ones prescribed under schedule a under drugs rule, under the Act in the form of Formats, and correspondence with the Manufacturers, dealers ,institutes, superiors, Government authorities or officers, and submissions before various courts.

**WHICH DOCUMENTS SHOULD BE TREATED TO BE LEGAL DOCUMENT :**

When an officer under the Drugs and Cosmetics Act or any other Statute while discharging his duty is writing /drafting any document it must be presumed that it has or can assume legal character, since any document which is prepared by him may be summoned by any court of law which otherwise not appearing to be a legally written document

**LEGAL WRITING/DRAFTING:**

Under Criminal Proceeding Three Things Must Be Included In A Document
1. TIME.....24 hour clock or 12 hour clock
2. PLACE ..... the site of event
3. PERSON.....names address and other particulars of person regarding whom the writing is being done

These elements create credibility and help recreate the picture of event during examination of author-witness in the court of law.

**FORMATTED DOCUMENT:** e.g. From 16 or Form 17, Form 18 etc. The purpose is printed on it mDOCUMENT REQUIRED but not Formatted. e.g. u/s 23(5)(b) application before a Magistrate to obtain custody of drugs seized. This formal request spells, details of time place and person
INFORMATION: supply of copy of Form 13 of Standard quality drug when no offence in the matter is made out
NOTICE: it is an alert to the affected person informing him regarding detection of offence committed by him on a particular time and place. It also spells adverse impending consequences .
Connect present activity or observation with the past in the documents in multiple events or correspondence. Every document prepared and event which took place on different dates or at different places or with different persons. Such document must be connected with its preceding documents in chronological order and be connected to succeeding documents / events. Every document becomes a link from point to point to the conclusion of evidence connecting the offence detected with persons revealing time and place and manner with reference to specific provisions involved or violated. No link should be missing.

**NOTICES WHILE EXERCISING U/S 22 OF THE ACT:**
**There should always be cause of action against the addressee**

*(Continued on page 20)*

# LEGAL WRITING ….continue

*(Continued from page 19)*

On left upper corner mention the designation and address of sender ( The Regulator Officer), followed by
name and status of the person in the firm complete address with pin code
Subject: include (i) any reference of previous correspondence in the matter (ii) matter for which the notice is being sent. mention provisions making the cause of action
No need of salutation when writing to accused or suspect person
Start in imperative formation. Example: Be it known ... or it is brought to your notice that.....
Use active voice only. Specifically the subject if several persons are involved in a sentence or paragraph. Stress the act or omitted which constitutes an offence and in what manner. First write reference to any previous letter or visit or action made related to the matter. Then state facts starting from the first date of matter which will form contents of legal matters before a judicial court. Facts related to other persons need not be in details. All facts which are intimate to the addressee be given in detail , in chronological order. In the penultimate paragraph make mention of any information or documents which the addressee is required to send with its reply. Mention time limit for reply. Reasonable time is 4 weeks but urgency of matter may justify lesser time.
In the last paragraph mention the legal responsibilities or liabilities accruing against the Addressee. DO NOT USE WORDS CONVEYING THREATS, CASTING APPREHENSIONS REGARDING LIFE LIBERTY OR PROPERTY .
Do not mention " Yours Sincerely "or "Yours Faithfully "etc Sender should sign the authored document on lower right side of document with his name, designation and date. If it is to be sent by post then SEND BY REGISTERED POST ONLY: Section 27 Meaning of service by Post. The General Clauses Act 1897 . It may be noticed that there is no registration of any letter by Post Office. I accepts only Register Cover. Legally it is expressed as letter sent under Registered Cover. Similar is the case with Registered Parcel.

**DOCUMENTS PREPARED AT SPOT :**

MENTION NAME AND OTHER PARTICULARS WITNESSES AND GET THEIR SIGNATUREs. Where the officer is writing a document in his authorized office, *no witness is required.*

It is always preferred to include witness if the officer is preparing a document in public place or at spot of occurrence of offence or conduction of investigation and /or exercising his powers under S22 of the Drugs Act. Mention the name of witnesses and their status in the document. Also put title under the name with words "WITNESS". Include public witnesses preferably two in number , of the area INCLUDE public witness during sudden inspection (raids) and during normal inspections where prosecutable offences have been detected and also during seizure on Form 16 . Always include public witness where offender flees away or in case where there is obstruction in discharge of duty.

Signature of the authoring Officer should be in lower right side of the document with name , designation and date mentioned . Get signature of accused person, or offender, or suspect or would be accused person on the lower left of each page of the document. His Name, parentage, and date should also be got scribed. Status of person as owner of the
premises or medicines or article found in his possession be mentioned below his signature. Witnesses should sign in lower part of each page of the document with name date and status " WITNESS", address, occupation etc. Witness must be major.

ATTITUDE OF THE WRITER: Keep positive attitude towards the objective of writing based on facts only without any cryptic or coloring meaning. Believe that the document may be scrutinized by court of higher authority, at any time in future, even when the officer has retired. The solution is to cultivate habit of legal drafting . No document is trivial. It must be drafted meticulousl. **The key to being a good writer is to be a good reader** Understand the statute and law with cool and impartial mind. Do not step into the shoes of court or Judicial Officer. While quoting chapters, sections and rules, believe in keeping the book open before your eyes**.** Reaffirm your memory by referring to the book times and again,.
**DOCUMENTS SHOULD BE NUMBERED :** In a bunch of documents all documents must be serially numbered and kept together in a file bearing a title.

**DISPATCHES:** All documents should be treated without any undue delay. Each dispatch should bear dispatch no. and date for further reference.
SUMMARY:

- A GOOD WRITER IS A GOOD READER FIRST.
- READ SUPREME COURT JUDGEMENTS.
- IMPROVE VOCABULARY
- IMPROVE GRAMMER, PUNCTUATIONS.
- USE SHORT SENTENCES
- DONOT USE ADJECTIVES OR EMOTIONAL WORDS

**SALUTATION:**

- WRITING APPLICATIONS,COMPLAINTS, REVISION OR APPEAL ETC., OR REPLY TO COURTS ADRESS AS HONOURABLE , WHILE COURT BELOW AS THE LEARNED COURT. ALL SUPERIOR COURTS ARE ADRESSED AS HONOURABLE.
- TO SUPERIORS OFFICERS: RESPECTED SIR, INCLUDES MADAM
- TO CONTEMPORARY: SIR. DEAR SIR WHILE WRITING DEMI OFFICIAL (DO)

**LETTER**

- DONOT PUT WORD SHRI OR SHRIMATI BEFORE THE NAME OF ACCUSED

**About Author:**
Rajinder Kumar Harna, M.Pharm. and LLB
Retired Assistant State Drugs Controller FDA Haryan

Author dedicates this article to Late Sh. KR Jain who retired as State Drugs Controller Haryana. Author expresses gratitude to DCOIWA for this opportunity.

**Source: Rajinder Kumar Haryana, Haryana**

# MAN, MIND AND MEDICINE

**Dr. Ram Chandra Besra**

**Drugs Inspector (HQ) Jhajkhand**

**President, DCOIWA Jharkhand Chapter**

**MAN, MIND AND MEDICINE**

Along with understanding human brain and their behavior, it would be more logical to understand about humans also.
After all, why are humans the best in the living world?
What are the qualities in humans that make them different from other living beings?
To get answers to these questions, we have to know the evolution of humans in brief.

Human being along with their anatomical, physiological and morphological changes occurs in the span of time, the brain also developed. Humans have developed their mind along with the physical development. The result of this mental development is that they have discovered many great and important things from ancient times to modern times. The development of human's mind responsible factor and makes them able so created society, developed script, civilizations, language and literatures.
Do humans have senses, humors and behaviors?

Human brain is what enabled humans to develop in arts and crafts, science and technology, games and sports, cultures and traditions and many other areas. There is also mention of human creations in history and religious scriptures. Human brain helps humans to differentiate between happiness and sadness, love and disgust, good and bad, hot and cold etc. The consequences of good and evil behavior of human beings are reflected on oneself, in the family and also on the society.

These days we keep getting information about the behavior and actions of humans through TV, social media and print media. The results of man's good and bad actions are clearly visible in the mind.
What is the relation between humans and their brain?
We will try to understand the thinking of humans and their behavior to judge their actions. Mention of humans, human brain and their behavior seems appropriate.
Humans (*Homo sapiens*) or modern humans are the most common primates and last surviving primates' species of genus *HOMO.* Human are characterized by their hairlessness and bipedalism ability with high intelligence meaning that they have high level of motivation and self-awareness, ability to learn, form concept, understand, apply logic and reason. Human intelligence is thought to recognize pattern, plan, innovate, solve problems, make decisions, retain information, and use language to communicate.

Humans have large brain in compare to primates and advanced cognitive skills ie. Mental process or actions that acquires knowledge and understanding through thought, experiences and the senses. [1] Humans developed tools, forms complex social systems and civilizations.

Humans are socialistic in nature, with individual humans, able to form a multi-layered network of social groups – mainly families, corporations, institution and political states. Due to this social interaction among the humans capable to establish values, social norms, languages and traditions.

A human curiosity leads into development of science and technologies, philosophy, mythology, religion and artifacts of knowledge's. Humans also study about their own through the specialize domains such as anthropology, social science, history, psychology and medicines.

Healthy human brains can create prosperous societies. A person with a twisted mind cannot do any more good to the society or any living being than even a mere imagination.

The mind of the humans is that which thinks, imagines, remembers, wills and senses or is the set of faculties responsible for such phenomena. [2,3,4,] The mind is associated with human body and can experience perception, pleasure and pain, belief, desire, intention and have emotions.[5] Mental states fall into categories of conscious and sub-conscious, sensory or non sensory.[6]

Healthy body means healthy mind or mental health. It can be defined as "a state of emotional and psychological well-being in which an individual is able to use his or her cognitive and emotional capabilities, function in society, and meet the ordinary demands of everyday life".
Mental health encompasses basically emotional, psychological and social well being, cognition and behaviors. WHO mentioning that mental health is a state of well-being in which individual realize his or her abilities, can cope with the normal stress of life, can work productively and fruitfully and can contribute to his or her community. [7] Mental health of any individual determine their ability to handle stress, interpersonal relationship and decision making.[8]

Mental health emphasizes about an individual's ability to enjoy life and can balance between life activities and efforts to achieve psychological resilience.[9] One can define mental health on the basis of cultural differences, personal philosophy, subjective assessments, and competing professional theories.[10]
Sleep irritation, lack of energy, lack of appetite, thinking of harming oneself or others, self-isolating and frequently zoning out are the common sign of mental health difficulties. [11]
Why individual and society need a healthy mind?
It can be understand by defining mental health as "it is an individual's capacity to feel, think, and act in ways to achieve a better quality of life while respecting personal, social, and cultural boundaries. [12] Thus, impairments in any of these, may be the risk factor leading into mental disorder or mental illness of individual. [13]

Mental disorders can be defined as health conditions that affect and alter cognitive functioning, emotional responses, and behavior associated with distress and/or impaired functioning.[14, 15]
India is facing with high prevalence of mental health disorders among the population and the epidemiological studies revealed the rate for psychiatric disorders varying from 9.5 to 370 per 1000 people in

*(Continued on page 22)*

# MAN, MIND AND MEDICINE…….continue

*(Continued from page 21)*

India.[16]. Mental health conditions such as depression, anxiety disorders, and bipolar disorder, schizophrenia, and substance use disorders are commonly observed mental health disorders with majority of the population in India.

Depression is characterized by persistent sadness, hopelessness, and a loss of interest or pleasure in activities. It is observed that, 3.5% of deaths were attributable to anxiety or depression in India. [17] Depression can impact on an individual's mood, thoughts, behavior, and physical well-being.

An anxiety disorder means an individual experiencing excessive and persistent worry, fear, or anxiety that may interfere with daily functioning. In generalized anxiety disorder individual may involves with chronic and excessive worry about various aspects of their life. In panic disorder an Individual may be characterized with recurrent panic attacks.

Phobias involve an intense fear of specific objects, situations, or activities and obsessive-compulsive disorder (OCD) is found in with individual who is characterized by intrusive thoughts (obsessions) and repetitive behaviors (compulsions). Anxiety disorders may be characterizing with significant distress, avoidance behaviors, and impaired functioning found in 30 % adult's population. [18]

Bipolar disorder is characterized in an individual by alternating periods of elevated mood (mania or hypomania) and episodes of depression. In manic episodes, individuals may experience heightened energy levels, decreased sleep, racing thoughts, inflated self-esteem, impulsive behavior, and an exaggerated sense of self-importance. Similarly, in depressive episodes an individual may be are marked with sadness, loss of interest, fatigue, and changes in appetite and sleep patterns. Bipolar disorder can profoundly impact an individual's emotions, behavior, relationships, and overall functioning. The prevalence of bipolar disorder as per Global burden of disease study (GBDS) in India is 0.6% (for both males and females). [19]The male-to-female prevalence ratio was 0.8 (0.5–1.1) was found globally. [20]

Schizophrenia an individual may affect a person's perception of reality, thinking processes, emotions, and behavior. Schizophrenia can significantly impair an individual's ability to think, interact with others, and function in society. [21]

Mental disorder associated with drugs use is the interest of writing along with the other responsible factors including genetic, environmental, psychological, chronic diseases, personality traits. Substance use disorders involve the excessive and compulsive use of substances, such as alcohol or drugs, despite negative consequences and problems may include financial difficulties, legal issues, relationship conflicts, and physical health complications.[22]

Drugs use is responsible factor for mental disorders are including cannabis, [23] caffeine [24] and alcohol [25] lead into development of anxiety. [26] Cannabis, cocaine and amphetamines use are associated with psychosis and schizophrenia.[27]

For the management of mental disorder, a psychiatric medication is a major option and there are several main groups. Antidepressants use for the treatment of clinical depression, as well as often for anxiety and a range of other disorders. Anxiolytics (including sedatives) are used for anxiety disorders such as insomnia. Mood stabilizers are used primarily in bipolar disorder. Antipsychotics are used for psychotic disorders, notably for in schizophrenia and range of other disorders. Stimulants are commonly used, notably for attention deficit hyperactivity disorder (ADHD).[28]

A wide variety of pharmaceutical products including sedative – hypnotics and possessing dependence liability, are used in India having important medical use.

In a study of non-prescription and non-medical use of sedatives-hypnotics or use without a valid prescription by a Doctor. About 1.08% Indians (approximately 1.18 crore people) are current users of sedatives on national level. States with the highest prevalence of current sedative use are Sikkim (8.6%), Nagaland (5.4%), Manipur (4.3%) and Mizoram (3.8%). However, Uttar Pradesh (19.6 Lakh), Maharashtra (11.6 Lakh), Punjab (10.9 Lakh), Andhra Pradesh (7.4 Lakh) and Gujarat (7Lakh) are the top five states.[29] Commonly, misused sedatives are *Benzodiazepines*- Alprazolam, Chlordiazepoxide, Clonazepam, Clorazepate, Diazepam, Flunitrazepam,, Flurazepam, Lorazepam, Oxazepam, Temazepam, Triazolam, *z-drugs*- Zolpidem, , Zaleplon, Eszopliclone *Barbiturates* Amobarbital, Butalbital, Pentobarbital, Secobarbital, Phenobarbital. [30] According to the National Drug Dependence Treatment Centre, AIIMS, India is home to 7.7 million people with opioids use disorders, of whom 2.5 million use pharmaceutical opioids (Morphine, Dextropropoxyphene, Pethidine, Hydromorphone , Codeine , Hydrocodone, Oxycodone, Fentanyl, Methadone, Buprenorphine, Propoxyphene).

The Narcotic Drugs and Psychotropic Substances Act, 1985, is an Act that prohibits a person the production/ manufacturing/cultivation, possession, sale, purchasing, transport, storage, and/or consumption of any narcotic drug or psychotropic substance. The Drugs and Cosmetics Act, 1940 is an act which regulates the import, manufacture, distribution of safe, effective , standard drugs and cosmetics in India.

In conclusion, individual's mental health is the foundation for prosperity, happiness and development of family, societies and nation. It must be the concern of every citizen, societies, NGO'S, associations, organizations of India to organize awareness program on drug abuse among the adolescents, to encourage the National Action Plan for Drug Demand Reduction of the government of India. Enforcement agencies must regulate and prohibit the misuse of drugs and promote the medical use of psychiatric drugs (Sedatives-hypnotics and prescription opioids).

*Let's be together in support of* ***YES to Life and NO to Drugs.***

## References:

"Cognition". *Lexico*. Oxford University Press and Dictionar.com. Archived from the original on July 15, 2020. Retrieved 6 May 2020.

"Mind". *Encyclopedia Britannica*. Archived from the original on 9 May 2021. Retrieved 31 May 2021.

"Mind". *American Heritage Dictionary of the English Language*.

*(Continued on page 23)*

# MAN, MIND AND MEDICINE…….continue

*(Continued from page 22)*

Houghton Mifflin Harcourt. 2016. Archived from the original on 2021-06-29. Retrieved 2021-06-29.

"Mind". *Collins English Dictionary*. HarperCollins. 2014. Archived from the original on 2021-06-29. Retrieved 2021-06-29.

Kim, Jaegwon (2006). "1. Introduction". *Philosophy of Mind* (2nd ed.). Boulder: Westview Press. Archived from the original on 2021-06-02. Retrieved 2021-06-01.

Honderich, Ted (2005). "Mind, problems of the philosophy of". *The Oxford Companion to Philosophy*. Oxford University Press. Archived from the original on 2021-01-29. Retrieved 2021-06-01.

"Health and Well-Being". *World Health Organization*. Retrieved 2023-08-09.

"About Mental Health". *www.cdc.gov*. 2021-11-23. Retrieved 2022-04-11.

Snyder CR, Lopez SJ, Pedrotti JT (2011). *Positive psychology: the scientific and practical explorations of human strengths*. SAGE. ISBN 978-1-4129-8195-8. OCLC 639574840

"Mental Health". *medlineplus.gov*. Retrieved 2019-11-20.

"Mental Health". *medlineplus.gov*. Retrieved 2021-11-19.

Manwell LA, Barbic SP, Roberts K, Durisko Z, Lee C, Ware E, et al. (June 2015). "What is mental health? Evidence towards a new definition from a mixed methods multidisciplinary international survey". *BMJ Open*. 5 (6): e007079. doi:10.1136/bmjopen-2014-007079.

Galderisi S, Heinz A, Kastrup M, Beezhold J, Sartorius N (June 2017). "A proposed new definition of mental health". *Psychiatria Polska* (in Polish). 51 (3): 407–411. doi:10.12740/pp/74145.

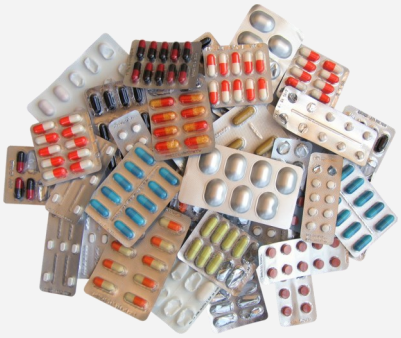
Manderscheid RW, Ryff CD, Freeman EJ, McKnight-Eily LR, Dhingra S, Strine TW (January 2010). "Evolving definitions of mental illness and wellness". *Preventing Chronic Disease*. **7** (1): A19. PMC 2811514.

Goldman HH, Grob GN (2006-05-01). "Defining 'mental illness' in mental health policy". *Health Affairs*. **25** (3): 737–49. doi:10.1377/hlthaff.25.3.737. PMID 16684739.

1. Math SB, Srinivasaraju R. Indian psychiatric epidemiological studies: learning from the past.. *Indian J Psychiatry.* 2010;52:0.
What is Depression? [ Jun; 2023 ]. 2023. https://www.psychiatry.org [Ref list]

What are Anxiety Disorders? [ Jun; 2023 ]. 2023. https://www.psychiatry.org [Ref list]

1. India State-Level Disease Burden Initiative Mental Disorders Collaborators The burden of mental disorders across the states of India: The Global Burden of Disease Study 1990-2017. *Lancet Psychiatry.* 2020;7:148–61.



2. Ferrari AJ, Stockings E, Khoo JP, Erskine HE, Degenhardt L, Vos T, et al. The prevalence and burden of bipolar disorder: Findings from the Global Burden of Disease Study 2013. *Bipolar Disord.* 2016;18:440–50.
What is Schizophrenia? [ Jun; 2023 ]. 2023. https://www.psychiatry.org [Ref list]

Jahan AR, *StatPearls [Internet]* https://www.ncbi.nlm.nih.gov/books/NBK570642/ Treasure Island (FL): StatPearls; Substance Use Disorder. [Google Scholar] [Ref list]

"Cannabis and mental health". *Royal College of Psychiatrists*. Retrieved 23 April 2013.

Winston AP, Hardwick E, Jaberi N (October 2005). "Neuropsychiatric effects of caffeine". *Advances in Psychiatric Treatment*. **11** (6): 432–39. doi:10.1192/apt.11.6.432

Fergusson DM, Boden JM, Horwood LJ (March 2009). *Archives of General Psychiatry*. "Tests of causal links between alcohol abuse or dependence and major depression".

1. Vilarim MM, Rocha Araujo DM, Nardi AE (August 2011). "Caffeine challenge test and panic disorder: a systematic literature review". *Expert Review of Neurotherapeutics*. **11** (8): 1185–95.
Picchioni MM, Murray RM (July 2007). "Schizophrenia". *BMJ*. **335** (7610): 91–5.

"Mental Health Medications". *National Institute of Mental Health*. Retrieved 6 May 2019.

1. Magnitude of Substances use in India (2019), Ministry of Social Justice and empowerment. Government of India. P.23-24.
Michael F. Weaver,Prescription Sedative Misuse and Abuse. Yale Journal of Biology and Medicine, 88 (2015), pp.247-256.

**Source: Dr. Ram Chandra Besra, Jhajkhand**

# A Critical Analysis of latest Homoeopathy Notification No. GSR 98(E) dated 02-02-2024

**NK Ahooja**

**Former State Drugs Controller,**

**FDA Haryana**

## Notification

In recent developments, the Ministry of Ayush issued **Notification No. GSR 98(E) dated 02nd February 2024**, proposing amendments to the Drug Rules 1945.

However, this move has sparked certain suggestions and objections.

This article aims to dissect and analyze the concerns raised against this notification, shedding light on key points that demand attention and reconsideration.

## The Context: Drugs Cosmetic and Medical Devices Bill 2023

- Draft Bill's Availability for Public Comment
- The draft bill of Drugs Cosmetic and Medical Devices Bill 2023 was publicly available for stakeholders' comments and is presently under consideration by the Parliament.

**Rules under the parent act, Drugs and Cosmetic Act, should not precede changes in the parent act itself.**

- Rules as Enablers of the Parent Act
- Rules are designed to give effect to the intent of the parent act, i.e., Drugs and Cosmetics Act.
- Alterations in rules during the parliamentary consideration of the parent act may disrupt the legislative harmony.
- Enabling Provisions in the Parent Act
- Every rule should have an enabling provision in the parent act, emphasizing that suggested changes should align with the parent act, which is currently under parliamentary scrutiny.
- Validity of Rules without Enabling Provision
- Rules lacking an enabling provision in the parent act are deemed null and void.
- Proposals for rule changes are baseless when the parent act is under parliamentary review.

## Specific Concerns Regarding Proposed Amendments

- Amendment in Rule 157: Class 2 Substitution
- The proposed substitution raises concerns about the qualification requirement for Ayurveda, Siddha, Sowa Rigpa, or Unani drug manufacturing.
- The suggested change is deemed against the principles of law and natural justice, posing a potential threat to pharmacy graduates' knowledge and job prospects.
- Bifurcation between Ayurvedic and allopathic pharmacy graduates is deemed inappropriate, considering the comprehensive syllabus covering pharmaceutical analysis, industrial pharmacy, pharmaceutics, and phytochemicals.
- Impact on Pharmacy Graduates
- The proposed amendment threatens to diminish job prospects for pharmacy graduates.
- B. Pharmacy is advocated as the sole qualification for manufacturing, testing, etc., of drugs of any type, and the proposed changes should not be entertained.

*(Continued on page 25)*

# Regulator's Guide: Continue……..

भारत का राजपत्र
The Gazette of India

*(Continued from page 24)*

## Crucial points for consideration

1 **Two crucial points for consideration:**

- **Delay in Amendments**

- Proposed amendments should not be considered until the parent Drugs Cosmetic and Medical Device Bill is passed by the Parliament.

- **Qualification Criteria**

- The qualification for drug manufacturing and testing should remain B. Pharmacy, as it encompasses the necessary knowledge for all types of drug-related activities.

## Conclusion

In conclusion, the objections and suggestions raised against Notification No. GSR 98(E) underscore the need for a thorough review and reconsideration.

The proposed amendments, particularly those affecting the qualification criteria, demand careful consideration to prevent adverse consequences for pharmacy graduates and maintain the integrity of the pharmaceutical industry.

**Source: NK Ahooja**

# Phensedyl Cough syrup worth lakhs seized from Dhanbad warehouse: Gujarat

A truck loaded with Phensedyl cough syrup was seized by Gujarat Police. The truck driver was interrogated and on his traces Gujarat Police reached Barwa Adda situated in Dhanbad city of Jharkhand on 11.03.2024.

In collaboration with Gujarat police and local Drugs administration, a raid was conducted on a warehouse located in Barwadda in the presence of the magistrate. Raid team comprised Sri Ranjeet Kumar Chowdhary, Drugs Inspector, Dhanbad -II and Sri Ghanashyam, Drugs Inspector, Dhanbad-III.

The raid team recovered approximately 26, 000 bottles of Phensedyl Cough Syrup from the warehouse which were being used as drug of abuse. The warehouse manager and other accused peoples ran away because of the news. The market value of seized drugs was estimated to be approximately Rs 65 lakhs. Phensedyl cough syrup was packed in rice sacks and cartoons.

FOOD & DRUGS CONTROL ADMN. FDCA GUJARAT STATE

Drugs Administration informed that a complaint case has been filed in the competent court against the warehouse manager Sri Upendra Singh and Sri Umesh Kumar Singh and the truck driver. This news is being seen among the public as a good message to the society about the good deeds of the drugs administration.

**Source: FDCA Gujarat**

# Drugs Testing Laboratory, Telangana has got NABL Certification

National Accreditation Board for Testing and Calibration Laboratories

## CERTIFICATE OF ACCREDITATION

## DRUGS CONTROL LABORATORY

has been assessed and accredited in accordance with the standard

## ISO/IEC 17025:2017

## "General Requirements for the Competence of Testing & Calibration Laboratories"

for its facilities at

A 84, VENGAL RAO NAGAR, HYDERABAD, TELANGANA, INDIA

in the field of

## TESTING

**Certificate Number:** TC-13317

**Issue Date:** 20/03/2024 **Valid Until:** 19/03/2026

This certificate remains valid for the Scope of Accreditation as specified in the annexure subject to continued satisfactory compliance to the above standard & the relevant requirements of NABL.
(To see the scope of accreditation of this laboratory, you may also visit NABL website www.nabl-india.org)

**Name of Legal Entity:** DRUG CONTROL ADMINISTRATION, GOVERNMENT OF TELANGANA

Signed for and on behalf of NABL

N. Venkateswaran
Chief Executive Officer

# Action Against Illegal Transport of Narcotic Drugs: Bihar

Drug trafficking continues to pose a significant threat to communities worldwide, with devastating consequences for individuals and societies. Recently, an incident in Darbhanga District, Bihar, shed light on the ongoing battle against the illegal transport of narcotic drugs. On the 16th of March 2024, a collaborative effort between the Drugs Control Department and local police led to a crucial raid near Said Nagar, Kali Mandir, Ekmi Road, Darbhanga.

During the raid, two individuals, namely Chandan Kumar and Rohit Kumar, were apprehended for transporting narcotics on a scooty without proper documentation. The primary investigation revealed their intent to misuse the drugs, raising concerns about the prevalence of substance abuse in the region.

The seized drugs included bottles of Codeine-containing syrup, with specific details such as brand names, batch numbers, and expiration dates. Following protocol, a First Information Report (FIR) was lodged at Laheria Sarai Police Station under the Narcotic Drugs and Psychotropic Substances (NDPS) Act 1985, marking a crucial step towards legal action against the perpetrators.

Leading the raid team was Sandeep Sah, a dedicated Drugs Inspector from Darbhanga, exemplifying the commitment of law enforcement agencies to combat drug-related crimes. Despite the challenges posed by drug trafficking, collaborative efforts between authorities and communities remain pivotal in curbing the illicit trade.

The incident underscores the urgent need for preventive measures, including stringent border security, international cooperation, and community awareness programs. While the legal framework provides a foundation for action, addressing the root causes of drug trafficking requires a multifaceted approach.

In conclusion, the raid against illegal transport of narcotic drugs in Darbhanga serves as a reminder of the persistent threat posed by drug trafficking. By fostering collaboration, raising awareness, and implementing preventive strategies, communities can work towards a safer and drug-free future.

**Source: Sandeep Sah, Drugs Inspector, Darbhanga, Bihar**

# Bihar DCA News March 2024

## Patna

On 11th March 2024, Patna team took action on fake factory running in the name of manufacturer of Kanpur. Company was involved in preparing Bhang Gola in the name of Charminar gold, Munakka claiming for stomach ache. Factory sealed by Drugs Inspector and arrested 12 persons with 2000 Kg Bhang and other machinery. As directed by SDC Uday Shankar and ADC Sachchidanand Prasad joint team members were DI Rajesh Kumar Sinha, Prabhat Kumar Choudhary, AYUSH DI Satyanarayan and Indrakant Kumar.

सेहत से खिलवाड़ • देवनगर में कानपुर की आयुर्वेद कंपनी के नाम पर बन रही थी नकली दवा

पेट की दवा के नाम पर बना रहे थे भांग का गोला; फैक्ट्री सील, संचालक समेत 12 मजदूर गिरफ्तार

2000 किलो भांग, चार मशीनें, नकली दवा और अन्य सामान जब्त

चारमीनार गोल्ड मोनवका बन रही थी

फैक्ट्री का लाइसेंस नहीं

यूपी से लाए गए थे मजदूर

## Gaya

On 14th March 2024, Gaya Team raided the unlicensed medicine shop situated at Atri, Gaya and seized the huge quantity of medicines. Prosecution before court is under process. Team Members were DI Shashibhushan Kumar, Sunil Kumar and Wasim Akhtar.

## Darbhanga

On 16th March 2024, Dharbhanga Drug Inspector Saneep Sah with local police officer Sheo Jyoti Kumar raided the premises where codeine containing cough syrups were stored. During raid team found the ban fixed dose drugs combination containg CPM and Codeine. On dated 5th March 2024, Codeine was also seized by DI Shambhu Nath Thakur and arrested one person at Darbhanga.

## Vaishali

Under the scheme of strengthening of Drugs Control Regulatory system, on 13th March 2024, newly constructed Drugs Control Administration Office at Hajipur, Vaishali is handed over to officers of Drugs Control Adminsitartion. Now functional at new building of Sadar hospital, Hajipur, Vaishali

**Source: Sandeep Sah, Drugs Inspector, Darbhanga, Bihar**

# Kerala's Bold Move to Ensure Drug Quality

## Drug Quality

The drug control department (DCD) in Kerala is gearing up for a game-changing initiative – 'Operation Double-Check.' to Ensure Drug Quality.

This strategic move involves all drug inspectors in the districts, aiming to ensure the drug quality imported from other states and to unveil the sources of drug procurement by corporate and discount pharmacies.

### Need for Operation Double-Check

The decision to launch Operation Double-Check stems from secret information received by the regulatory body.

Numerous sources have hinted at unauthorized drugs entering Kerala, raising serious concerns about drug quality.

A highly-placed source within the department highlighted the urgency to address this issue, emphasizing the need to verify if drugs are procured from genuine manufacturers.

### Targeting Discount Pharmacies

The initial focus of Operation Double-Check will be on discount pharmacies.

Drug inspectors will meticulously trace their drug procurements to ensure they are sourced from authorized dealers or genuine manufacturers.

Simultaneously, state laboratories will conduct quality checks on samples collected from medical shops, ensuring a harmonious balance between chasing the source of purchase and testing drug quality.

### Transparent and Ethical Procurement Mechanism

**Sujith Kumar**, the Drug Controller of Kerala, emphasized the department's intent to establish a transparent and ethical procurement mechanism for all drug dealers.

The department receives complaints alleging that many circulating drugs are not from genuine suppliers, making it challenging for inspectors to detect the supply channels.

This initiative aligns with the nationwide effort to curb substandard and spurious drug rackets.

### Nationwide Surge in Illegal Drug Activities

The surge in substandard and spurious drug rackets is not unique to Kerala.

Recent incidents, like the arrest of individuals in Delhi and Telangana for manufacturing and supplying spurious drugs, underscore the magnitude of the issue.

Kerala, being a hub for drugs from all over India, faces increased scrutiny.

Marketing companies, especially those procuring medicines from north India, have come under the scanner.

### Scrutiny on Marketing Companies and Discount Pharmacies

The Drug Controller stressed the importance of transparency in the drug procurement system.

While traders have the right to conduct businesses, the sources of procuring medicines must be disclosed.

This disclosure is critical, considering the procurement system is a major determinant of drug availability.

The DCD aims to minimize the circulation of spurious or not-of-standard-quality drugs in Kerala, with stringent actions promised against offenders.

### Post-GST Quality Concerns and the Evolving Supply Chain

The Drug Controller shed light on the quality issues emerging in the Post-GST period.

The disrupted supply-chain system allows anyone to purchase medicines from anywhere, making it challenging to regulate the industry.

Previously, a well-defined system, starting from manufacturers to retailers, aided officials in tracking drug origins and movements.

The enforcement officials will now introduce a separate wing to monitor discount pharmacies and medical shops offering discounts.

### Industry Response and Future Strategies

AN Mohan, president of the All Kerala Chemists and Druggists Association, welcomed the DCD's decision for Operation Double-Check.

He assured that the association, committed to society, would act as quality watchdogs, providing data on the procurement and supply of medicines to the department.

The All India Organisation of Chemists and Druggists will discuss strategies to counter the threat of discount offerings and corporate pharmacies in an upcoming executive council meeting.

**Source: The Health Master**

# Telangana: Illegal sale of drugs, 3 arrested under NDPS Act

## NDPS

In the heart of Telangana, a recent joint operation conducted by the North Zone Task Force, Begumpet police, and Drug Inspector, Begumpet, **Drugs Control Administration, Telangana** (DCA Telangana) has brought to light a concerning issue – the illicit trade of habit-forming drugs (**NDPS**).

This article delves into the details of this NDPS matter, exposing the illegal activities and the subsequent legal actions taken against the culprits.

## The Joint Operation

The coordinated effort between the North Zone Task Force, Begumpet police, and Drug Inspector, Begumpet, **Drugs Control Administration, Telangana** (DCA Telangana) showcases the collaborative approach required to combat drug-related crimes effectively.

The synergy between these entities played a crucial role in uncovering and addressing the illicit drug trade within the region.

## The Culprits and the Location

The focus of the operation was M/s. Mahaveer Medical Hall in Rassoolpura, Begumpet, where three individuals were apprehended for their involvement in the illegal sale of Codeine phosphate syrup, Tramadol injections, and Ultracet tabs.

These substances, known for their habit-forming nature, were being dispensed at exorbitant rates.

## Illegal Sale of Codeine Phosphate Syrup

**Codeine phosphate syrup**, a widely used medication, had found its way into the illicit market.

The article explores how this drug, when sold without proper authorization and at inflated prices, poses a significant risk to the community.

DCA Telangana

## Tramadol Injections on the Black Market

**Tramadol** injections, another substance seized during the operation, have become a target for those seeking to exploit the vulnerabilities of individuals struggling with addiction.

This section sheds light on the implications of the illegal sale of Tramadol injections.

## Ultracet Tabs: A High-Risk Commodity

The investigation also uncovered the sale of **Ultracet** tabs, a combination of tramadol and acetaminophen.

The article examines the risks associated with the unauthorized distribution of this potent medication.

## Lack of Purchase Bills Raises Red Flags

One alarming aspect of the operation was the absence of purchase bills for the drugs seized.

The lack of documentation raises questions about the legitimacy of the transactions and highlights the need for stricter regulatory measures.

## Handover to Begumpet Police

The three individuals involved in the illegal

*(Continued on page 31)*

# Telangana: Illegal sale .....continue

(Continued from page 30)

drug trade were promptly handed over to Begumpet police.

This section outlines the seamless transition from the joint operation to law enforcement, emphasizing the importance of swift action in such cases.


## Police Action: FIR and Violations

Begumpet police wasted no time in booking a case against the accused and issuing a First Information Report (F.I.R).

The article explains the charges brought against the perpetrators, focusing on the violation of Section 8 (c) of the NDPS Act.

## Section 8 (c) of NDPS Act

A detailed exploration of Section 8 (c) of the **NDPS Act** provides readers with insights into the legal framework governing the unauthorized sale of habit-forming substances.

This section educates the audience on the specific clause invoked in this case.

## Punishable Offenses under Section 22 of the NDPS Act

Understanding the consequences of the offenses, this part of the article sheds light on the punishable aspects of Section 22 of the **NDPS Act**.

It emphasizes the severity of engaging in illegal drug trade activities.

## Submission of FIR Copy for Information

In an effort to keep fellow officers informed, the article discusses the submission of the FIR copy for wider dissemination.

This move aims to enhance collaboration among law enforcement agencies in addressing similar matters.

## Utilizing FIR Information in Duties

Officers can leverage the information provided in the FIR copy during their duties.

This section underscores the practical utility of such documentation in the daily responsibilities of law enforcement personnel.

## The Scope of the Issue

The concluding part of the article reflects on the broader implications of the NDPS matter at **Telangana**.

It prompts readers to consider the prevalence of such illegal activities and the collective responsibility in curbing them.

**Source: The Health Master**

# DCA, Telangana seized huge stock of Narcotic Drugs during a joint operation

## Press Release

**Drugs Control Administration, Telangana carried out a joint operation along with:**

- TSNAB (Telangana State Anti-Narcotics Bureau),
- Prohibition & Excise Department,
- Commissioner's Task Force, Hyderabad,
- Kushaiguda Police, and
- Jagtial District Police, and busted the illegal diversion of Narcotic and Psychotropic Drugs by Dr. G. Madanmohan, an ENT Surgeon at Mamatha ENT Hospital in Jagtial.

Dr. G. Madanmohan illegally diverted Narcotic drugs from the Operation Theatre and sent them to Hyderabad through courier/parcel, thereby supplying them to a drug addict in Sainikpuri.

The details are as follows:

Based on credible information regarding illegal possession of narcotic drugs, officials from the Drugs Control Administration, along with TSNAB (Telangana State Anti-Narcotics Bureau), Prohibition & Excise Department, Commissioner's Task Force, Hyderabad and Kushaiguda Police carried out a raid at a residential building located in Sri Saibaba Officers Colony, Sainikpuri.

During the raid, officials detected huge stocks of **Narcotic Drugs,** including 'VERMOR-15' (Morphine Sulphate Injection IP 15 mg/ml), 'Rumorf' (Morphine Sulphate Injection IP 15 mg/ml), 'Rumorf' (Morphine Sulphate Injection IP 10 mg/ml), 'Rumorf' (Morphine Sulphate Injection IP 15 mg/ml) 'VERMOR-10' (Morphine Sulphate Injection IP 10 mg/ml), Rumorf-CR-30 Tablets (Morphine Sulphate Controlled Release Tablets), and **Psychotropic drugs** Ozatcel 30 (Pentazocine Injection), 'Mezolam' (Midazolam Injection IP 10 mg), 'LORI' (Diazepam Injection 5 mg/ml), 'Librax' Tablets (Chlordiazepoxide & Clinidium Bromide Tablets), Bupregesic Injections (Buprenorphine Hydrochloride Injection), and Buprigesic Patch (Buprenorphine Transdermal Patch) at the house of a drug addict. Officials seized the stocks.

**List of drugs seized during the raid at Sainikpuri is under the article**

*(Continued on page 33)*

# DCA, Telangana seized .....continue

*(Continued from page 32)*

Upon inquiry, it was revealed that Dr. G. Madanmohan of Mamatha ENT Hospital in Jagtial supplies them through parcels via courier/parcel to Hyderabad, and their watchman collects the parcel and delivers it to the drug addict.

Dr. G. Madanmohan is an ENT surgeon who operates a hospital named Mamatha ENT Hospital in Jagtial. The hospital-attached pharmacy, named 'Maanvitha Pharmacy,' is managed by Oraganti Raju. The pharmacy holds NDPS License issued by the Drugs Control Administration, Telangana for the purchase of NDPS Drugs and for issuing them to the doctor for utilization of narcotic drugs during surgical procedures.

Dr. G. Madanmohan illegally diverted the Narcotic drugs and Psychotropic Drugs from the Operation Theatre of his hospital and supplied them through parcels to Hyderabad, thus providing them to a drug addict in Sainikpuri.

Drugs Control Administration officials carried out a raid at 'Maanvitha Pharmacy' located in Manasa ENT Hospital, Gollapally Road, Ashok Nagar, Jagtial and detected several discrepancies in the stock registers maintained regarding Narcotic Drugs. Officials, with the assistance of Jagtial District Police, apprehended Dr. G. Madanmohan.

Upon inquiry, Dr. G. Madanmohan revealed that he had been supplying Narcotic Drugs to the drug addict for the past two years. Dr. G. Madanmohan was arrested by Kushaiguda Police, and a case has been registered under the NDPS Act vide FIR No. 197/2024 at Kushaiguda Police Station.

The drug license held by 'Maanvitha Pharmacy,' situated in Manasa ENT Hospital on Gollapally Road, Ashok Nagar, Jagtial, will be canceled by the Drugs Control Administration, Telangana.

Officers from Drugs Control Administration viz. Sri. G. Ramdhan, Joint Director, DCA, Hyderabad, Sri. B. Govind Singh, Drugs Inspector, Secunderabad and Smt. Ch. Swapna, Drugs Inspector, Jubilee Hills, Officers from Prohibition and Excise Department Sri. Jaganmohan Reddy, Excise Inspector, Begumpet Excise Station, Officers from Police Department viz. Sri. Shiva Naidu,

*(Continued on page 34)*

# DCA, Telangana seized .....continue

*(Continued from page 33)*

Deputy Superintendent of Police, TSNAB, Sri. Venkateswarlu, Inspector of Police, TSNAB, Sri. Gnanadeep, Sub-inspector of Police, Commissioner's Task Force, Hyderabad, North Zone, Sri. Veeraswamy, Inspector of Police, Kushaiguda Police Station and Sri. N. Upender Yadav, Sub-inspector of Police, Kushaiguda Police Station and their staff are among the officers who carried out a raid **at Sainikpuri**.

Officers from Drugs Control Administration viz. Sri. M. Srinivasulu, Assistant Director, Karimnagar, Sri. N. Narasiah, Assistant Director, Nizamabad, Sri. V. Upender, Drugs Inspector, Jagtial and Sri. P. Karthik Bharadwaj, Drugs Inspector, Karimnagar and Officers from Police Department Sri. Ayaz Khan, Assistant sub-inspector of police, Jagtial District Police and their staff are among the officers who carried out a raid **at Jagtial**.

The abuse of narcotic drugs poses significant health risks, impacting individuals physically, mentally, and emotionally. Addiction is a prevalent consequence, characterized by a compulsive need to seek and use drugs despite adverse effects.

Overdose, a potentially fatal outcome, occurs when the body is overwhelmed by the quantity of drugs consumed, leading to life-threatening consequences.

Morphine injection addiction is highly dangerous, leading to physical dependence, tolerance, slow breathing, respiratory depression, severe drowsiness. Morphine injection addiction carries a high risk of coma and death due to respiratory depression and overdose.

Narcotic drug abuse leads to serious health risks, including addiction, overdose, and various complications such as respiratory, cardiovascular problems and mental health disorders.

**V.B. KAMALASAN REDDY, IPS**
**DIRECTOR GENERAL**

# DCA, Telangana seized .....continue
## Drugs seized during the raid

| Sl. No. | Name of the Drug Seized | Quantity |
|---|---|---|
| 1 | 'VERMOR-15' 1ml ampoules (Morphine Sulphate Injection IP 15 mg/ml) | 50 ampoules |
| 2 | Rumorf-CR-30 Tablets (Morphine Sulphate Controlled Release Tablets) | 30 Tablets |
| 3 | 'VERMOR-10' 1ml ampoules (Morphine Sulphate Injection IP 10 mg/ml) | 30 ampoules |
| 4 | Bupregesic Injection 1 ml ampoules (Buprenorphine Hydro-chloride Injection) | 25 ampoules |
| 5 | 'LORI' (Diazepam Injection 5 mg/ml) | 9 ampoules |
| 6 | 'Rumorf' 1ml ampoules (Morphine Sulphate Injection IP 15 mg/ml) | 10 ampoules |
| 7 | 'Librax' Tablets (Chlordiazepoxide & Clinidium Bromide Tablets 5mg+2.5mg) | 46 tablets |
| 8 | Buprigesic Patch 5 (5 mcg/hr) (Buprenorphine Transdermal Patch) | 2 patches |
| 9 | OZATCEL 30 Injection (Pentazocin Injection IP 30mg/ml) | 2 ampoules |
| 10 | 'Mezolam' 10 ml vial (Midazolam Injection IP 10 mg) | 7 vials |
| 11 | NEX400 1ml ampoule (Naloxone Injection IP) | 3 ampoules |
| **Used Injections detected during the raid** | | |
| 12 | 'VERMOR-10' 1ml ampoules (Morphine Sulphate Injection IP 10 mg/ml) | 200 ampoules |
| 13 | 'Rumorf' 1ml ampoules (Morphine Sulphate Injection IP 10 mg/ml) | 10 ampoules |
| 14 | 'Rumorf' 1ml ampoules (Morphine Sulphate Injection IP 15 mg/ml) | 10 ampoules |
| 15 | 'VERMOR-15' 1ml ampoules (Morphine Sulphate Injection IP 15 mg/ml) | 30 ampoules |
| 16 | 'Mezolam' 10 ml vial (Midazolam Injection IP 10 mg) | 4 vials |

# Unlicensed manufacturing of drugs busted in Delhi

The Drugs Control Department, Government of NCT of Delhi as a part of its endeavor to provide quality medicines to consumers keeps a watch on the to unearth clandestine activities related to manufacture and sale of not of standard quality and Spurious drugs in Delhi.

On 11.03.2024, an information was received regarding some clandestine activity related to drugs is being carried out at Flat No 1101, Block -2, Eleventh Floor, CSP Units DLF Capital Greens, 15 Shivaji Marg, Moti Nagar, New Delhi 110015. Accordingly, a joint team comprising of Sh. Rohit Bajpai ADC, Sh. Deepak Sharma ADC (Intelligence), Sh. Sandeep Kumar Sharma DI, Sh. Vishal Sachan DI & Sh. Sunit Sethi, DI of Drugs Control Department Delhi along with the officials of Crime Branch, Delhi Police (led by Inspector Kamal Kumar) immediately conducted a joint raid at the said premises.

Two persons namely Viphil Jain & Suraj Shat were found involved in the manufacturing for sale/ distribution of Spurious anticancer drugs without holding any requisite Drugs manufacturing licenses at that flat. They were found manufacturing for sales and distribution following drugs, along with other drugs:

- Nivolumab 10 mg/mL (OPDYTA), labeled as Manufactured and Packaged By: Bristol-Myers Squibb Holdings Pharma, Ltd. Liability Company, Manati, Puerto Rico 00674, USA (Nivolumab is a monoclonal antibody which is used in cancer treatment).
- Pembrolizumab Injection (Keytruda) 100 mg/4ml labeled as Manufactured By: M/s Schering-Plough

Labo NV Belgium (Pembrolizumab injection is used to treat skin cancer)

- Fluconazole Injection USP 2mg/ml (Forcan), labeled as CIPLA Ltd, C-116B, Road No 8, Vishwakarma Industrial Area, Jaipur 302013 at : SP-918, Phase III, Bhiwadi 301019 (Fluconazole injection is used to treat serious fungal infections)

The other packing material, labeled vials, printed literature, rubber pack seals etc. were also recovered during the raid. The accused were using disposable syringes to fill innocuous substance into the vials which were manually sealed and sold to unscrupulous dealers as high value anti-cancer drugs. Both the persons were arrested by Crime branch Delhi Police & all the consignment of Spurious drugs along with machine & equipment were seized. The cost of these drugs in open market is estimated to be around four crores. Samples of these drugs have been collected for testing and have been sent to the testing laboratory, reports are awaited. Further investigations in the matter are in progress to unearth the firm(s)/person(s) involved in this racket.

**Source: Deepak Sharma, ADC, NCT of Delhi**

# Journey of OTC Drugs Regulation in India

## OTC Drugs

In a significant move to enhance the accessibility of over-the-counter drugs (OTC drugs), the Drugs Technical Advisory Board (DTAB) has proposed the formation of a sub-committee.

This committee is tasked with scrutinizing the conditions determining a drug's OTC status, along with the development of a comprehensive mechanism for such categorization.

The Ministry of Health, aligning with this initiative, issued a draft amendment in the Schedule K of the Drugs Rules, 1945, on May 25, 2022.

## The Draft Amendment

The proposed amendment lists approximately 16 drugs earmarked for exemption under Schedule K.

These drugs are deemed fit for retail sale over the counter without the prescription of a Registered Medical Practitioner (RMP).

Among the specified conditions, a crucial point is the stipulation that the maximum duration of treatment or use should not exceed five days.

If symptoms persist, patients are advised to consult an RMP.

### *Key Conditions for OTC Exemption*

The conditions set in the draft encompass various aspects, such as the maximum recommended doses for five days and the provision that the pack size should not surpass the stated doses.


These precautions are crucial to maintaining consumer safety and well-being.

## DTAB's Deliberation

In its recent meeting in January 2024, the DTAB discussed the draft notification and considered individual applications from pharmaceutical companies.

Notable among these were requests from Intermed Laboratories Private Limited for diclofenac diethylamine transdermal patch 200 mg, Reckitt Benckiser Private Limited for acetylsalicylic acid effervescent 500 tablets, and Glenmark Private Limited for dextromethorphan HBr lozenges 50 mg, mometasone furoate nasal spray 50 mcg.

### *Sub-Committee Formation*

DTAB, acknowledging the intricacies involved, recommended the establishment of a sub-committee.

This committee is tasked with a detailed examination of the conditions influencing a drug's OTC status and the formulation of a mechanism for the consideration of drugs under this category.

*(Continued on page 38)*

# Journey of OTC Drugs …..continue

*(Continued from page 37)*

## DCC's Earlier Endeavors

The **Drugs Consultative Committee** (DCC) had previously appointed a sub-committee under the chairmanship of NK Ahooja, drugs controller of Haryana.

This sub-committee submitted a report emphasizing the urgent need to define OTC drugs and lay down specific provisions for their regulation.

### *OTC Drugs Classification*

The sub-committee proposed the inclusion of a clear definition for **OTC drugs** in the Drugs & Cosmetics Rules 1945.

It advocated for the incorporation of basic characteristics of OTC drugs, along with their classification into OTC-1 and OTC-2.

Factors considered for classification include evidence of safety, therapeutic index, accessibility, non-habit forming nature, supply chain mechanism, and socioeconomic conditions of the country.

### *Regulatory Recommendations*

Apart from classification, the sub-committee recommended regulations on switching prescription drugs to OTC status, new OTC drug approval, distribution, sale, and advertisement of OTC drugs.

These comprehensive guidelines aim to streamline the OTC drugs landscape in the country.

## DCC's Validation

The recommendations of the subcommittee were considered in the 57th meeting of the DCC held on August 8, 2019.

The **DCC** recommended suitable amendments in the **Schedule K** of the Drugs and Cosmetics Rules, 1945, incorporating necessary provisions for **OTC drugs**, subject to specified conditions.

### *DTAB's Continued Advocacy*

The matter was revisited in the 87th meeting of **DTAB** in November 2021.

Following this, the list of 16 drugs was published as a draft notification in May 2022.

The Board emphasized the need to adopt best practices concerning the dispensing of drugs by various professionals.

**Source: The Health Master**

# Cracking Down on Antibiotic Misuse: Karnataka Drug Dept

## Antibiotics

In a proactive measure to combat **antibiotic resistance** and safeguard public health, the **Karnataka drugs control department** is intensifying its surveillance of antibiotic medicine sales.

The enforcement team is diligently working to ensure that medicines falling under the ambit of **Schedule-H** and **Schedule-H1** of the Drugs and Cosmetics Act are dispensed only with a valid prescription across all pharmacy outlets in the state's 31 districts.

## The Enforcement Initiative

### Surprise Checks on Pharmacy Outlets

The **state drugs control department's** enforcement wing is conducting surprise checks on pharmacy outlets, meticulously examining whether records are maintained regarding the sale of **antibiotics** as per official directives.

This stringent approach aims to curb unauthorized sales and enforce compliance with the regulations.

### Combating Unauthorized Antibiotic Sales

Taking a resolute stance against the unauthorized sale of antibiotics by both medical shops and hospital pharmacies, the department aims to ensure that antibiotics, classified as prescription drugs under **Schedule-H** and **Schedule-H1**, are dispensed exclusively under the supervision of a qualified pharmacist and with a valid prescription from a registered medical practitioner (RMP).

**Related news: Drugs Control Dept's fight against Antimicrobial Resistance:**

**Karnataka**

## Upholding Public Health

### The Commitment to Antibiotic Resistance Prevention

Karnataka drugs controller **Bhagoji T Khanapure** emphasized the commitment to public health, particularly in the context of preventing **antibiotic resistance** (AMR).

The enforcement team's vigilance in monitoring pharmacy outlets underscores the dedication to the cause.

According to **Khanapure**, "Our commitment is to keep antibiotic resistance at bay, and our team ensures **antibiotics** are sold only with a valid prescription."

### Legal Consequences for Violators

In an effort to underscore the seriousness of the matter, violators of the regulations will face legal consequences.

This strict approach signifies the authorities' determination to tackle antibiotic misuse and its potential consequences.

*(Continued on page 40)*

# Cracking Down on Antibiotic ....continue

*(Continued from page 39)*

## India's Battle Against Antibiotic Resistance

### A Global Challenge

India, like many countries worldwide, is grappling with the issue of **antibiotic resistance.**

The state regulator underscores the importance of proper prescription and supervision in antibiotic distribution to prevent misuse, overuse, and the development of antibiotic resistance.

### Extending Concerns to Multiple Sectors

The concerns regarding **antimicrobial resistance** (AMR) go beyond human healthcare to encompass animal healthcare and soil health.

Antimicrobial resistance poses a threat across the entire spectrum of microorganisms, including bacteria, viruses, fungi, and parasites.

This resistance compromises the effectiveness of drugs, leading to significant challenges in public health, veterinary medicine, and agricultural practices.

## Multidimensional Approach to AMR Prevention

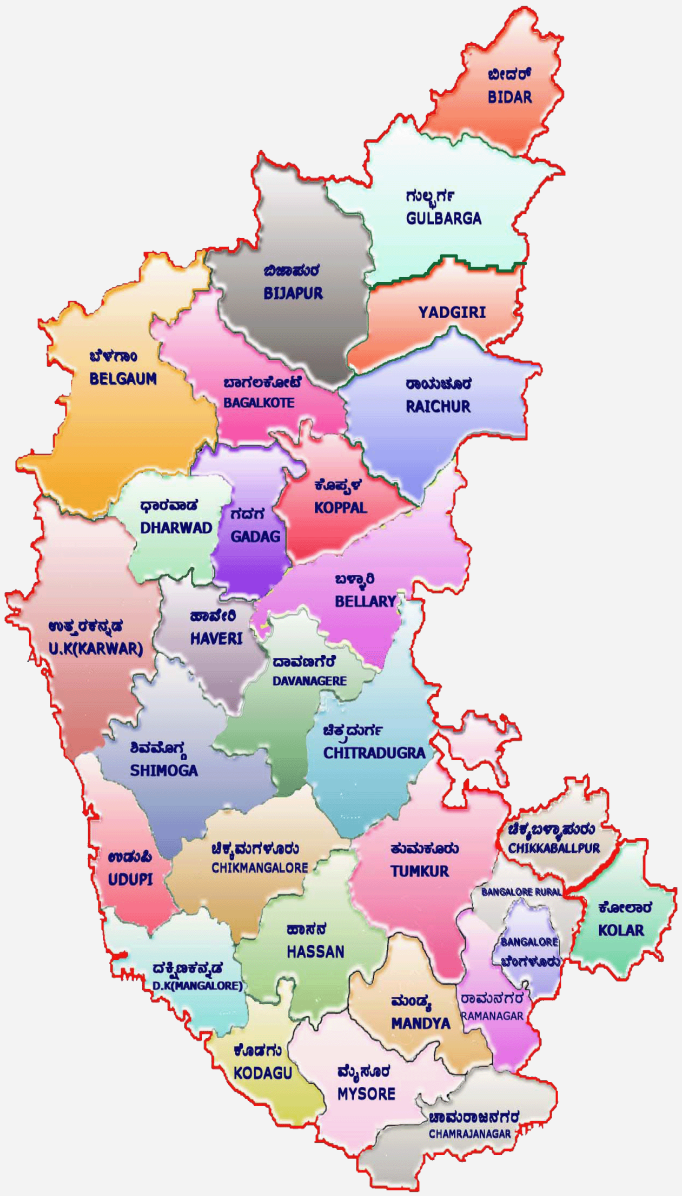
### Collaborative Efforts

Preventing antimicrobial resistance is a complex task that requires a multidimensional approach

**Khanapure** highlighted the need for collaboration involving medical practitioners, healthcare support staff, regulators, industry, and the public.

The **drugs control department's** proactive measures, such as ensuring no antibiotic sale without a prescription, contribute to building a sense of responsibility among pharmacists and the public in preventing antimicrobial resistance.

**Source: The Health Master**



# IPC releases draft guidelines to include Disinfectants & Antiseptics in IP

## Guidelines

The Indian Pharmacopoeia Commission (IPC) has recently unveiled a pivotal draft proposal addressing the guidelines for disinfectants and antiseptics in the Indian Pharmacopoeia (IP).

This comprehensive document strives to establish robust standards governing the selection, application, and regulation of these vital pharmaceutical agents.

Manufacturers, regulatory authorities, healthcare professionals, and stakeholders are encouraged to contribute their insights and comments on this proposal before the April 15, 2024 deadline.

The IPC stresses that stakeholder engagement is paramount for refining the guidelines, tentatively set to be incorporated into the **IP 2026** edition, effective July 2026.

## 1. Importance of Guidelines

The IPC underscores the significance of maintaining cleanliness and sterility in pharmaceutical manufacturing environments to prevent microbial contamination of products.

It outlines the necessity of implementing sound cleaning and sanitization programs to ensure the quality and safety of pharmacopoeial articles.

## 2. Draft Proposal Overview

A closer look at the draft proposal reveals its emphasis on various aspects of disinfectants, antiseptics, and sterilants.

This includes their classification based on chemical types, efficacy testing methods, and application procedures in sterile pharmaceutical manufacturing areas.

The proposal also underscores the regulatory compliance and safety considerations associated with the use of these agents.

## 3. Stakeholder Collaboration

The IPC advocates for stakeholder collaboration in developing effective cleaning and sanitization programs in the pharmaceutical industry.

The goal is to ensure that the final guidelines align with the needs of both the industry and regulatory agencies in India.

## 4. Role of Antiseptics

The IPC's draft proposal highlights the critical role of antiseptics in hand and surgical site disinfection, especially in hospital settings.

Effective antiseptic use has proven to reduce bacterial counts on the skin, significantly lowering the risk of hospital-acquired infections.

*(Continued on page 42)*

# IPC releases draft guidelines ……continue


*(Continued from page 41)*

## 5. Recommended Antiseptics

**Common antiseptics recommended for such purposes include:**

- 4% chlorhexidine,
- 10% povidone-iodine,
- 3% hexachlorophene,
- 70% isopropyl alcohol, and

**0.5% chlorhexidine in 95% alcohol.**

## 6. Factors in Disinfectant Selection

Selecting disinfectants for pharmaceutical manufacturing environments involves careful consideration of factors such as:

- Types of microorganisms to be controlled,
- Spectrum of activity,
- Concentration,
- Application method, and
- Contact time.

The IPC emphasizes the importance of adhering to standards supported by regulatory authorities.

## 7. Safety Considerations

The IPC further emphasizes safety considerations for operators applying disinfectants, highlighting the need to prevent contamination of pharmaceutical products.

Proper planning, including disinfectant rotation and measures to maintain residual bactericidal activity, is crucial to uphold hygiene standards and product integrity.

## 8. Regulatory Framework

Under the framework of the Drug and Cosmetic (D&C) Act 1940 and rules 1945, along with IS 1061:2017 standards, chemical disinfectants marketed in India are required to adhere to specific regulations.

## 9. Mandated Information

Manufacturers are mandated to provide detailed product information, including use dilution, types of microorganisms targeted, and necessary contact time.

## 10. FDA Regulation

Certain liquid chemical sterilizers intended for critical or semi-critical medical devices are closely regulated by the Food and Drug Administration (FDA).

**Source:** The Health Master

# Pharma Transparency: The Need for Clearer Eye Drops Packaging

## 1. Eye Drops

In the realm of pharmaceuticals, a critical shift may be on the horizon – a transition to transparent bottles for **eye drops**.

The clarity of these essential medical solutions is under scrutiny, prompting discussions and proposed amendments to the Drugs and Cosmetics Rules, 1945 by the **Drug Controller General of India** (DCGI).

## 2. Significance of Transparent Packaging

The packaging of pharmaceuticals plays a vital role in ensuring the safety and efficacy of the products.

For **eye drops**, transparency becomes particularly crucial, allowing consumers to assess the clarity of the solution before administering it.

## 3. Regulatory Initiatives

The **DCGI** has taken a proactive approach by calling a meeting with pharma lobby groups to address the packaging concerns surrounding eye drops.

Proposed amendments to the existing regulations could reshape the industry's practices.

## 4. Issues with Opaque Packaging

Opaque plastic vials or bottles have been the traditional choice for packaging eye drops.

However, concerns have arisen regarding the potential for contamination, leading to a reevaluation of this practice.

## 5. Historical Testing Results

Historical testing results of **eye drop** samples have raised alarms.

Particulate matter and contamination issues were prevalent in samples packed in opaque plastic vials, prompting a reconsideration of packaging materials.

## 6. DCGI's Proposal

The **DCGI** aims to address these concerns by amending the **Drugs and Cosmetics Rules, 1945**.

The proposed changes focus on advocating for the use of transparent plastic vials or bottles for eye drop formulations.

## 7. Meeting with Pharma Lobby Groups

To delve deeper into the issue, a meeting has been scheduled with pharma lobby groups.

This collaborative effort aims to gather insights from key industry players and find common ground for implementing transparent packaging.

## 8. DCC's Deliberation

The **Drugs Consultative Committee** (DCC), a technical body of experts, previously discussed the matter.

The committee recommended a consultation meeting with ophthalmic product producers to further explore the feasibility and implications of transparent packaging.

## 9. Contamination Concerns

Opaque plastic bottles have shown a higher

*(Continued on page 44)*

# Pharma Transparency.....continue

*(Continued from page 43)*

susceptibility to bacterial contamination, particularly at the bottle tip.

This contamination poses risks to patients, as they may unknowingly use **eye drops** with potential bacterial presence.

## 10. Importance of Transparent Bottles

Ensuring transparency in eye drop packaging is deemed critical for users.

Transparent bottles not only allow consumers to check for contamination but also provide visibility into the remaining quantity, enhancing user awareness.

## 11. Industry Response

Pharmaceutical companies currently favor non-transparent plastic bottles.

The industry's response to the proposed changes is pivotal, as it involves adapting to new packaging norms that prioritize consumer safety and awareness.

## 12. Moving Towards Transparency

The industry may need to embrace a paradigm shift towards transparent packaging, aligning with the evolving regulatory landscape and the pressing need for enhanced safety measures in pharmaceuticals.

## 13. Advantages of Transparent Packaging

Transparent bottles for eye drops offer several advantages, including better visibility, reduced contamination risks, and improved consumer confidence.

Embracing these benefits could lead to a positive transformation in the pharmaceutical packaging sector.

## 14. Challenges in Implementation

While the benefits are apparent, the transition to transparent packaging may present challenges.

This section explores potential obstacles and discusses strategies for overcoming them.

## 15. Consumer Empowerment

The ultimate goal of transparent packaging is to empower consumers.

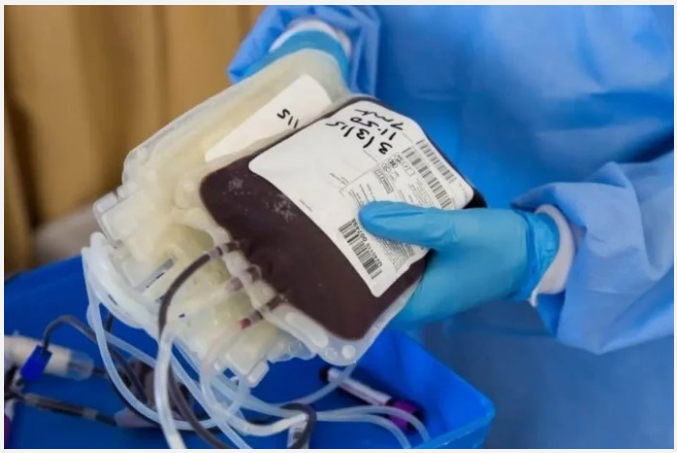
By providing them with the tools to assess the clarity and safety of **eye drops**, the industry can enhance user trust and contribute to overall healthcare transparency.

**Source:** **The Health Master**

# Five booked for holding Blood Donation Camp without permission

## Blood Donation Camp

The city of Kanjurmarg recently witnessed an unsettling event as the local police booked five individuals associated with a Solapur-based trust. These individuals stand accused of organizing a **blood donation camp** on



February 24 without the necessary permissions.
Shockingly, 28 individuals donated blood under the impression that they were contributing to a noble cause.
In this article, we delve into the details of this deceptive incident, uncovering the alleged wrongdoings and exploring the consequences for the trust members involved.

## The Accused and Their Tactics

### *1. Identifying the Culprits*

The accused, namely Samadhan Mane-Deshmukh, Kiran Patil, Sharad Harnmare, Shankar Patil, and Suhas Patil, allegedly organized the **blood donation camp**.

### *2. Bait and Switch*

Police officials reported that the accused enticed donors by claiming to represent a blood bank in Pune.
Moreover, they sweetened the deal by promising donors smartwatches as a token of appreciation.

## The Complainant's Perspective

### *3. The Tip-off*

Prashant Aswar, a drug inspector with the **FDA**, received information about the unauthorized **blood donation camp**.
The tip-off came from a government officer who raised concerns about the lack of necessary permissions.

### *4. The Investigation Begins*

Upon receiving the information, Aswar visited the camp site and discovered that the individuals leading the camp were not certified medical professionals.
Furthermore, the donors were being offered smartwatches, raising suspicions about the legitimacy of the operation.

## Unraveling the Deception

### *5. False Claims Exposed*

Aswar, during his investigation, found Samadhan Mane-Deshmukh at the registration counter.
Deshmukh identified himself as a public relations officer with the Muktai Blood Centre of Solapur and insisted that the camp was directed by Sumit Jethe.

### *6. Discrepancies Uncovered*

Deshmukh presented a license for the Solapur -based trust, but a cross-check with the on-site staff revealed discrepancies.
This prompted Aswar to alert the relevant authorities about the potential fraud.

## Legal Actions Taken

### *7. Criminal Charges Filed*

The Kanjurmarg police have registered a case against the accused under section 420 for cheating and relevant sections of the **Drugs and Cosmetics Act.**

### *8. Suspending the Camp*

Prompt action by the FDA official led to the immediate suspension of the **blood donation camp**, preventing further fraudulent activities.

**Source: The Health Master**

# Unveiling the Illegal Pharma Unit in Uttarakhand

## Illegal Pharma Unit

In a shocking revelation that has sent shockwaves across the pharmaceutical industry, a groundbreaking joint operation, named '**Operation JAI**,' orchestrated by the **Drugs Control Administration**, Telangana (DCA), the Hyderabad Police Commissioner's Task Force, and the Malakpet police, successfully unearthed **Illegal Pharma Unit** in Uttarakhand.

The operation uncovered a web of deceit, with the illegal pharma unit being accused of producing spurious and counterfeit drugs distributed across various states, including **Telangana**.

## The Genesis of 'Operation JAI'

On February 27, the Malakpet police conducted a search operation that led to the seizure of **27,200 capsules** falsely labeled as 'MPOD-200,' masquerading as an antibiotic.
Shockingly, tablets purported to be Cefpodoxime Proxetil and Lacto Bacillus, with a face value of **₹7.34 lakh**, were discovered.
These counterfeit drugs were falsely attributed to 'Meg Lifesciences,' a non-existent company supposedly situated in Khasra Himachal Pradesh's Sirmour.
The arrest of Aravapalli Satyanarayana, caught red-handed selling the spurious drugs, unraveled the intricate network.

## Unraveling the Network

During interrogation, Satyanarayana pointed the finger at Gandla Ramulu of Meerpet, who was subsequently arrested.
Ramulu admitted to sourcing the spurious drugs from Vishad Kumar of Kotdwar, Uttarakhand.

Vishad, in turn, disclosed that he manufactured these drugs at 'Nectar Herbs and Drugs' in Uttarakhand alongside Sachin Kumar.

Shockingly, the orders for these counterfeit drugs were being placed through WhatsApp calls, adding a technological twist to the **illegal drug trade.**

## Raids in Uttarakhand

With this critical information, a coordinated search operation was launched in Uttarakhand, involving **local drug authorities from Uttarakhand.**
The manufacturing location of the spurious drugs was traced to Sigaddi in Kotdwar.

A surprise search on February 29 uncovered a stash of counterfeit drugs, including Cefixime Tablets IP 200 mg falsely labeled as 'Omnicef-O 200' tablets.

Additionally, these fake drugs bore the misleading branding of 'manufactured by Aristo Pharmaceuticals Pvt Ltd.' The prime suspects, Sachin and Vishad, were apprehended during the raid.

## The Seizure

The magnitude of the **illegal** operation became apparent as authorities seized **38,350 tablets** (3,835 strips) of counterfeit 'Omnicef-O 200,' along with **60.27 kg** of unnamed orange tablets, **65.27 kg** of unnamed white tablets, and **33.45 kg** of branded cartons.

The total face value of the confiscated stocks amounted to a staggering **₹44.33 lakh**.
The raid at 'Nectar Herbs and Drugs' in Uttarakhand marked a significant victory against the rampant production and distribution of counterfeit pharmaceuticals.

**Source: The Health Master**

# FDA Maharashtra: Crackdown on Illicit Cosmetic Manufacturing

## FDA Maharashtra

In a resolute move, **Maharashtra Food and Drug Administration** (FDA Maharashtra) Commissioner **Abhimanyu Kale** spearheaded a raid on the premises of Raj Products in Mumbai, intensifying efforts to combat illicit activities in the cosmetic industry.

## FDA Maharashtra's Commitment

**Commissioner Kale**, speaking on the raid, reaffirmed the **FDA Maharashtra'**s unwavering commitment to regulatory compliance and public safety. He emphasized the agency's dedication to maintaining industry integrity through stringent enforcement measures.

## Uncovering Unauthorized Cosmetic Production

Initiated based on confidential information, the operation unveiled that Raj Products, under Anand Patel's ownership, was manufacturing cosmetics without the necessary licenses. The company's production of "Prince Enriched Coconut Hair oil" raised significant concerns.

## Illegal Production Methods and Materials

The illicit manufacturing involved blending coconut oil and light liquid paraffin, packaged in pre-printed High-Density Polyethylene (HDPE) containers.

This section details the unauthorized use of materials like light liquid paraffin and HDPE in cosmetic production.

## Swift FDA Maharashtra Action

Promptly responding to the violation of the Drugs and Cosmetics (D&C) Act 1940, Drugs Inspector **P B Aswar** seized raw materials, finished products, empty containers, and machinery during the raid, amounting to a substantial value.

FDA MAHARASHTRA

FOOD AND DRUG ADMINISTRATION

## Collaborative Enforcement Efforts

Joint Commissioner (Vigilance) FDA Maharashtra, **Rahul Khade**, and Assistant Commissioner (HQ-IB) FDA Maharashtra, **U.G. Bagmare**, actively guided the operation, highlighting the collaborative efforts of enforcement agencies to ensure comprehensive action.

## Message to Rogue Manufacturers

**Commissioner Kale** asserted that the raid sends a robust message to rogue manufacturers, emphasizing the **FDA Maharashtra**'s zero-tolerance stance towards non-compliance with regulatory frameworks.

## Legal Proceedings and Ongoing Investigations

Legal proceedings have been initiated against Raj Products, and ongoing investigations aim to hold accountable those responsible for the violations, underscoring the FDA Maharashtra's commitment to ensuring industry accountability.

**Source: The Health Master**

# Humorous Dose

A man goes into a pharmacy and asks the pharmacist if he can give him something for the hiccups.

The pharmacist promptly reaches out and slaps the man's face.

"What did you do that for?" the man asks.

"Well, you don't have the hiccups anymore, do you?"

The man says, "No, but my wife out in the car still does!"

😄 😄 😄

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

# Best Wishes On Promotion

**The DCOIWA family extends its best wishes for the future endeavors of the following officers who have recently assumed their new positions following their well-deserved promotions.**

**Mr. R. Chandrashekhar (DCOIWA Life member) has been promoted as Joint Drugs Controller General India, CDSCO**

**Mrs. A. Visala has been promoted as Joint Drugs Controller General India, CDSCO**

# Best Wishes On Promotion

**The DCOIWA family extends its best wishes for the future endeavors of the officers of FDA Maharashtra who have recently promoted as Joint Commissioners.**

**Promotions at FDA Maharashtra :**

1. **Mr. Hukare promoted as Joint Commissioner Pune Division.**
2. **Mr. Shaikh sahib promoted as Joint Commissioner Sambhaji nagar Division**
3. **Mr. Milind Patil promoted as Joint Commissioner Nashik Division**
4. **Mr. Gahane promoted as Joint Commissioner Head Quarters**
5. **Mr.Supe promoted as Joint Commissioner Kokan Division**
6. **Mrs. Harsha Ahale promoted as Joint Commissioner Amaravati Division**

## Congratulations to newly selected Drugs Inspectors: Telangana

## Congratulations to newly selected Drugs Inspectors: Telangana

| 18 Drugs Inspectors Selected - Telangana State DCA | | | | |
|---|---|---|---|---|
| S.No | Name | Contact Number | Zone | |
| 1 | Mounika Bejjarapu | 7989984493 | Zone 2 |  |
| 2 | Ettam Naresh Reddy | 9912980179 | Zone 2 |  |
| 3 | S Viswanath Reddy | 8125232429 | Zone 2 |  |
| 4 | Ambedkar Pottapenjara | 9948191228 | Zone 2 |  |
| 5 | Paila Sravanthi Reddy | 8309334251 | Zone 2 |  |
| 6 | Pedishetty Renuka | 9502343590 | Zone 2 |  |
| 7 | Saka Vinay | 8374166627 | Zone 2 |  |
| 8 | Jogu Sowjanya | 9010429106 | Zone 2 |  |
| 9 | Praveen kumar Thota | 8328207035 | Zone 2 |  |

## Congratulations to newly selected Drugs Inspectors: Telangana

| | | | | |
|---|---|---|---|---|
| 10 | Medichelme Surendranath | 8464821298 | Zone 2 |  |
| 11 | Musipatla Mahesh Babu | 9652408524 | Zone 2 |  |
| 12 | Induri Srikanth | 8555857986 | Zone 2 |  |
| 13 | Ramavath Geethanjali | 8519989317 | Zone 2 |  |
| 14 | Patheparapu Chandrakala | 8501981986 | Zone 1 |  |
| 15 | Madugula Shyam Sunder | 7981201764 | Zone 1 |  |
| 16 | P Shravan kumar | 8143304767 | Zone 1 |  |
| 17 | S UmaRani | 8688709676 | Zone 1 |  |
| 18 | Gurram.Aswani | 8125255291 | Zone 1 |  |

## Congratulations on promotion of Mrs. A Visala, CDSCO

**The DCOIWA family extends its best wishes for the future endeavors of Mrs A Visala who have been recently promoted as Joint Drugs Controller General India, CDSCO.**

## Congratulations to newly selected Drugs Inspectors: Telangana

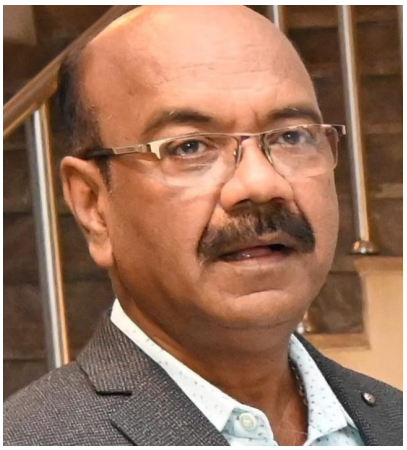
**B. Mounika, topper of 2024 batch Telangana drugs inspectors selections received appointment order on the hands of Hon'ble Chief Minister of Telangana Shri A. Revanth Reddy at Hyderabad. DCOIWA congratulates her (4th march 2024).**

# Best Wishes On Retirement

**The DCOIWA family congratulates the following officers on their well-deserved retirement! Thier dedication and service have made a lasting impact on our department. Best wishes for a joyful retirement filled with new adventures and relaxation.**

**Mr. Amresh Tumbagi, (DCOIWA Life member) has been retired Addnl. State Drugs Controller Karnataka**

**Mr. W.H. Patton (DCOIWA Life member) has been retired as Addnl. Drugs Controller, Nagaland**



**Mr. Hemant Shrivastava (DCOIWA Life member) has been retired and Assistant Drugs Controller, Chhattisgarh**

# CDSCO: NSQ List—February 2024 Page 1

List of Drugs, Medical Devices, Vaccines and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded for the Month of February– 2024.

| | |
|---|---|
| Total no. of samples received | - 676 |
| Total number of samples tested | - 1167 |
| Total number of samples declared as of Standard Quality | - 1018 |
| Total number of samples declared as Not of Standard Quality | - 58 |
| Total number of samples declared as Spurious | - 02 |
| Total number of samples declared as Misbranded | - NIL |

| S.No | Name of Drugs/medical device/cosmetics | Batch No. | Date of Manufacture | Date of Expiry | Manufactured By | Reason for failure | Drawn By (From state/CDSCO Zone) | From (Name of Laboratory) |
|---|---|---|---|---|---|---|---|---|
| 1 | Acepik - P (Aceclofenac and Paracetamol Tablets) | NKT230962A | 05/2023 | 04/2025 | Nexkem Biotech Pvt. Ltd., Plot No. 64, HPSIDC, Industrial Area, Baddi, Distt. Solan (H.P.) - 173 205. | Disintegration | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 2 | Amoxycillin Oral Suspension I.P. (Medmoxil 125) | XMSD-001 | 03/2023 | 08/2024 | Laborate Pharmaceuticals India Ltd., 51, Indl, Area, Paonta Sahib (H.P.) | Stability | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 3 | Calcium Carbonate and Vitamin D3 Tablets IP (Calcigiant 500 Tablets) | NLT-17023 | 05/2023 | 04/2025 | Nutra Life Healthcare Pvt. Ltd., Plot No. 44-45, Shiv Ganga Industrial Estate, Lakeshwari, Bhagwanpur, Roorkee, Distt. | Assay of Vitamin D3 | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 4 | Ofloxacin Dispersible Tablets IP 100 mg (Oflab 100 DT) | C21O062001 | 05/2022 | 04/2024 | Pharmaceuticals Ltd., A-28/3 MIDC, Chikalthana, Aurangabad-431006 | Uniformity of Dispersion | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 5 | Calcium and Vitamin D3 Tablets IP (MAHACAL -500) | KSWAC014 | 05/2023 | 04/2025 | Hanuchem Laboratories, Plot No. 16-17, Sector - 5, Indl. Area, Parwanoo, Dist. Solan 173 220 (H.P.) | Assay of Vitamin D3 | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 6 | Serratiopeptidase Tablets (Serrizym Tablet) | AT035M | 07/2023 | 06/2025 | Arnav Research Laboratories, 435, G.I.D.C. 2, Dediyasan, Mehsana, Gujarat 384002 | Assay | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 7 | Montelukast Sodium and Levocetirizine Hydrochloride Tablet IP (XL-Mont) | TXL012007 | 11/2022 | 10/2024 | DWD Pharmaceuticals Ltd., 308/5, Village & Post: Poicha (Rania), Tal Savli, Dist. Vadodara 391780, Gujarat, India | Desription | Drugs Inspector, Ranchi, Jharkhand | Central Drugs Laboratory, Kolkata |
| 8 | Propofol Injection IP 500 mg/50 ml (Hyprovan 500 Injection) | L3352301A | 06/2023 | 05/2025 | Protech Telelinks, Mauza Ogli, Suketi Road, Kala Amb. Dist. Sirmour - 173030 (H.P.) | Assay of Propofol | Drugs Inspector, Bilaspur, Himachal Pradesh | Central Drugs Laboratory, Kolkata |
| 9 | Heparin Sodium Injection IP 25000 IU/5ml | 22HE16 | 10/2022 | 09/2024 | SAI Parenterals Limited, D1 & D4, Survey No. 280, Phase-V, IDA, Jeedimetla, Hyderabad 500 055. | Description, Extractable Volume, Particulate Matter and Assay | Drugs Inspector, Bikaner, Rajasthan | Central Drugs Laboratory, Kolkata |

## CDSCO: NSQ List—February 2024 Page 2

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 10 | with Glimepiride & Voglibose Tablets (Metaglim-V2) | T-230859 | 08/2023 | 07/2025 | 85, Madhopur Hazarathpur, Roorkee -247667, Uttarakhand | Assay of Glimepiride | CDSCO, Rishikesh | Drugs Laboratory, Kolkata |
| 11 | Clarithromycin Tablets IP 250 mg | OT-231393 | 10/2023 | 09/2025 | Orchid Bio-Tech Limited, 65, Peerpura-Delhi Highway, Roorkee-247667 (U.K.) | Dissolution | CDSCO, Rishikesh | Central Drugs Laboratory, Kolkata |
| 12 | Rabeprazole Sodium & Domperidone Capsules (Deep SR Capsules) | OC-23349 | 11/2023 | 10/2025 | Orchid Bio-Tech Limited, 65, Peerpura-Delhi Highway, Roorkee - 247667 (U.K.) | Dissolution of Rabeprazole & Domperidone | CDSCO, Rishikesh | Central Drugs Laboratory, Kolkata |
| 13 | Glimepiride & Meftormin Hydrochloride Prolonged Release Tablets IP (Glimsid-2MF) | T-231020 | 10/2023 | 09/2025 | Vilin Bio Med Ltd., Unit-II, Khasra No.85, Madhopur, Hazarathpur, Roorkee-247667, Uttarakhand. | Dissolution & Assay of Glimepiride | CDSCO, Rishikesh | Central Drugs Laboratory, Kolkata |
| 14 | Liquid Formaldehyde 40% w/v (Formallin) | FS-228A | 08/2022 | 07/2025 | Pharm Asia Drug, 20-21, Panchal Compound, Survey No. 78/1, PH No. 17, New 45, Gram Lasudia Mori, Indore - 452 010 (M.P.) | Methyl Alcohol & Assay of Formaldehyde 40%w/v | CDSCO, North Zone | Central Drugs Laboratory, Kolkata |
| 16 | Hydrogen Peroxide Topical Solution IP 6% w/v (20 Volume) | HP23-021 | 02/2023 | 01/2025 | SGS Pharmaceutical (P) Ltd., E-13/1, 20-21, Panchal Compound, Survey No. 78/1, PH No. 17, New 45, Gram Lasudia Mori, Indore - 452 010 (M.P.) | Identification, Acidity, Non-volatile matter and Assay (Spurious) | CDSCO, North Zone | Central Drugs Laboratory, Kolkata |
| 17 | L-Asparaginase 10000 IU (L-ASGEN) | BASL2205YA | 03/2022 | 02/2024 | Beta Drugs Ltd., Kharuni Lodhimajra Road, Vill. Nandpur, Baddi, Dist. Solan, Himachal Pradesh 173205 | Particulate Matter (subvisible) | O/o. The Drugs Inspector, Cuttack, Odisha. | Central Drugs Laboratory, Kolkata |
| 18 | Amikacin Injection IP 500 mg (Amikatas 500 mg) | RV3044 | 08/2023 | 07/2025 | Ronam Healthcare Pvt. Ltd. Village-Kalujhanda, Tehsil-Baddi, Distt. Slolan (H.P.) 174103 | Description & Particulate Matter | O/o. The Drugs Inspector, Cuttack, Odisha. | Central Drugs Laboratory, Kolkata |
| 19 | Neostigmine Injection IP 0.5 mg/ml | V23034 | 01/02/2023 | 31/01/2025 | Vital Healthcare Pvt. Ltd., Plot No. H10 and H10/1, MIDC Satpur, Nashik. | pH and Assay of Neostigmine | CDSCO, West Zone, Mumbai | Central Drugs Laboratory, Kolkata |
| 20 | Tranexamic Acid Injection I.P. (Tranexica) | SAI-14764 | 03/2022 | 02/2024 | Sunvet Healthcare, Vill. Shambhuwala, Paonta Road, Distt. Sirmour (H.P.) - 173001 | pH | DCA, Vijayawada, Andhra Pradesh | Central Drugs Laboratory, Kolkata |
| 21 | Paracetamol Tablets IP 500 mg (Pyricool | 23444042 | 11/2023 | 10/2026 | Alkem Health Science, A unit of Alkem Laboratories | Dissolution | CDSCO, East Zone, | Central Drugs Laboratory, |

# CDSCO: NSQ List—February 2024 Page 3

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Namchi, Sikkim - 737137 | | | |
| 22 | Ciprofloxacin Hydrochloride Tablets IP 500 mg | 2331044 | 07/2023 | 06/2026 | Aurio Pharma Laboratories Pvt. Ltd., 26/1/1, S.H.K.B Sarani (Jawpur Road), Dumdum, Kolkata- 700 074 | Dissolution | CDSCO, East Zone, Kolkata | Central Drugs Laboratory, Kolkata |
| 23 | Oseltamivir Oral Suspension I.P. 12 mg | URDP1153 | 05/2023 | 10/2024 | Unicure India Ltd., Plot No. 46(B) / 49B, Vill. Raipur, Bhagwanpur, Roorkee, Distt. Haridwar, Uttarakhand | Description | CDSCO, East Zone, Kolkata | Central Drugs Laboratory, Kolkata |
| 24 | Ambroxol,Guaiphenesin & Terbutaline Syrup (Bromex Expectorant) | BXE064 | 01/09/2023 | 31/05/2026 | Hygeia Pharmaceuticals MFG (P) Ltd., 608, Dwarir Road, Dhamaitala Dakshin Jagaddal, Pin - 700 151 | Assay of Ambroxol Hydrochloride and Terbutaline Sulphate | CDSCO, East Zone, Kolkata | Central Drugs Laboratory, Kolkata |
| 25 | Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate, Sodium Citrate and Menthol Syrup (SUNGESIC-C) | 002 | 01/09/2023 | 31/08/2025 | Sunny Industries Private Limited, 23/3/1B, R.N. Nandan Lane, Kolkata 700 025 | Description & Assay of Paracetamol | CDSCO, East Zone, Kolkata | Central Drugs Laboratory, Kolkata |
| 26 | Deferasirox | 82231480 | 02/07/2023 | 01/07/2027 | Glenmark Lifesciences Ltd., Plot No. Z-103/I, Sez Phase II, Dahej, Dist. | 4 Hydrazino benzoic acid | CDSCO, Ahmedabad | Central Drugs Laboratory, |
| 27 | Miconazole Nitrate and Fluocinolone Acetonide Ointment (Zole - F) | SXE1800A | 08/2023 | 07/2026 | Sun Pharmaceuticals Ind. Ltd., Kh. No. 1335-1340, Near EPIP- I, Vill- Bhatoli Kalan, Baddi, Distt. Solan, H.P. 173205 | Assay | CDSCO, Ahmedabad | Central Drugs Laboratory, Kolkata |
| 28 | Trihexyphenidyl Hydrochloride Tablets IP 2 mg (Ridyl) | AR-132 | 06/2023 | 05/2025 | Apex Formulations Pvt. Ltd., 1276, Rajpur, Ahmedabad-Mehsana Highway, Dist. Mehsana, Gujarat. | Assay | CDSCO, Ahmedabad | Central Drugs Laboratory, Kolkata |
| 29 | Levosalbutamol Sulphate, Ambroxol Hydrochloride, Guaiphenesin and Menthol Syrup 60 ml Syrup (HISTARED-LS) | L23K015 | 11/2023 | 10/2025 | Fanal Pharmaceuticals LLP, 67, Surbhi Radhe Industrial Zone, Survey No. 251, At. Khambha, 360311, Gujarat, India | Description & Assay of Levosalbutamol | CDSCO, Ahmedabad | Central Drugs Laboratory, Kolkata |
| 30 | TERBUTALINE SULPHATE, BROMHEXINE HCl & GUAIPHENESIN SYRUP (NEFDYL-X) | WHL-01715 | Nov-2023 | Oct-2025 | Warner Hindusthan Pvt. Ltd.,. 24-85/7, Sy.No.548 & 551, Laxmi Narayana Nagar Colony, New IDA, Uppal, Hyderabad-39 (TS) | Assay of Bromhexine Hydrochloride | CDSCO Hyderabad | CDTL, Hyderabad |
| 31 | BROMHEXINE HYDROCHLORIDE SYRUP 4mg/5ml | 31413 | 01-Aug-2023 | 31-Jul-2025 | Zenith Drugs Pvt. Ltd., 72/5, Muradpura (Orangpura) Dhar Road, Near Kalaria, Indore 453001 (MP) India | pH and Assay | CDSCO, Sub Zone, Indore | CDTL, Hyderabad |

## CDSCO: NSQ List—February 2024 Page 4

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 32 | POVIDONE-IODINE SOLUTION BP (VIDON) | EVO310 | 01-Jun-2023 | 31-May-2026 | PVT.LTD Plot No. 4, Gut No. 66, H.No. 827-830, Khupi Village, Near Kudus, Tal. Wada, Dist. Palghar, 421312, Maharashtra, India. | pH | CDSCO, West Zone, Mumbai | CDTL, Hyderabad |
| 33 | Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Syrup (Zist-D) | HRL-070 | Oct-23 | Sep-25 | Household Remedies Pvt. Ltd., Plot No.6/35, Dewan And Sons Aliyali, Palghar- 401 404. | Microbial Limit test | CDSCO, West Zone, Mumbai | CDTL, Mumbai |
| 34 | Pantoprazole Gastro-resistant Tablets IP (Pantojohn - 20) | T-2210131 | Oct-22 | Sep-25 | Johnlee Pharmaceuticals Pvt Ltd., By Aagya Biotech Pvt. Ltd., 1.5, Manglour-saharanpur road, Manglour- 247656, Roorkee, Haridwar. | Dissolution in buffer stage | CDSCO, West Zone, Mumbai | CDTL, Mumbai |
| 35 | Atorvastatin and Clopidogrel Capsules (10mg/75mg) | MC221173 | Dec-2022 | Nov-2024 | Mascot Health Series Pvt. Lt., Plot No. 79,80,Sector-6A, IIE, Sidcul, Haridwar-249403 | Dissolution of Atorvastatin Calcium calculated as Atorvastatin | CDSCO, North Zone Ghaziabad | RDTL, Chandigarh |
| | Mavacoxib Tablets | | | | MICRO LABS LIMITED UNIT-III, | | CDSCO, | RDTL, |
| 37 | Calcium Carbonate, Vitamin D3 and L-Lysine Suspension (Oscaid Suspension) | RL22070 | Aug-2022 | Jul-2024 | RACHIL PHARMA.., 18-19, Phase-1, Ind.Area, Sansarpur Terrace, Distt : Kangra (HP)-176501 | Description, Identification and Assay of Vitamin D3 | O/o CMO Bilaspur District-Bilaspur H.P.-174001 | RDTL, Chandigarh |
| 38 | Cefodoxime Proxetil and Potassium Clavulanate Tablets | MBT-22012 | Jun-2022 | Sep-2023 | Magnatek Enterprises, Plot No. 74 C (II) HPSIDC Ind. Area Baddi, Distt. Solan (H.P.) 1732025 | Assay of Potassium Clavulanate Diluted calculated as Clavulanic Acid | O/o State Drugs Controller, H.Q. Baddi, Distt. Solan, HP-173205 | RDTL, Chandigarh |
| 39 | Ofloxacin and Ornidazole Tablets IP (Normal -OZ TABLETS) | 122257 | Dec-2022 | Nov-2024 | Biologics Inc., Suketi Road, Kala-Amb, Distt. Sirmour (H.P.)-173030 | Dissolution of Ofloxacin and Ornidazole | State FDA Qatilgah Kargil-194103 (UT Ladakh) | RDTL, Chandigarh |
| 40 | Cefuroxime Axetil Tablets IP 500 mg | JAK-20 | May-2023 | Arp-2025 | Agron Remedies Pvt. Ltd., Sarverkhera, Moradabad Road, Kashipur-244713 (Uttarakhand) | Dissolution and Assay of Cefuroxime Axetil calculated as Cefuroxime | CDSCO Sub-Zone, Jammu | RDTL, Chandigarh |
| 41 | Ambroxol, Terbutaline Sulphate, Guaiphenesin and Menthol Syrup (Tricodex A Syrup) | SRLK230054 | Nov-2023 | Oct-2025 | SYSTOLE REMEDIES PVT. LTD. Vill. Ogli, Kala Amb, Teh. Nahan, Distt. Sirmour (H.P.)-173030 | Assay of Terbutaline Sulphate | CDSCO , Baddi | RDTL, Chandigarh |
| 42 | Ambroxol hydrochloride, Terbutaline Sulphate, Guaiphenesin and Menthol Syrup | NARL-0038 | Nov-2023 | Oct-2025 | M Sea Pharmaceuticals (P) Ltd., Surajpur, Paonta Sahib, Sirmour Himachal | Assay of Menthol | CDSCO , Baddi | RDTL, Chandigarh |

## CDSCO: NSQ List—February 2024 Page 5

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 43 | Ambroxol Hydrochloride, Levosalbutamol and Guaiphenesin Syrup (Saivent-LX Syrup) | MAG-S-1972 | Oct-2023 | Sep-2025 | Laboratories Ltd., Vill. Guruwala, P.O. Bhagani Sahib, Teh. Paonta Sahib, Distt. Sirmour (H.P.)-173025 | Assay of Ambroxol Hydrochloride and Levosalbutamol Sulphate calculated as Levosalbutamol | CDSCO Baddi | RDTL, Chandigarh |
| 44 | Ambroxol Hydrochloride, Levosalbutamol Sulphate and Guaiphenesin Syrup (KOFVON LS Syrup) | OL-032309 | Mar-2023 | Feb-2025 | Sickcure Pharmaceuticals, Plot No. 52A, Industiral Area, Gondpur, Tehsil-Paonta Sahib, Distt. Sirmour (H.P.) 173025 | Ethylene Glycol (EG) is exceeding the permissible limit | CDSCO Baddi | RDTL, Chandigarh |
| 45 | Ambroxol Hydrochloride, Terbutaline Sulphate, Guaiphenesin and Menthol Syrup (AVTUS-TG SYRUP) | BL-36 | Jul-2023 | Jun-2025 | Boffin Biotech Pvt. Ltd., Vill. Behral, Paonta Sahib, Distt. Sirmour-173025 (H.P.) | Assay of Menthol | CDSCO Baddi | RDTL, Chandigarh |
| 46 | Chlorpheniramine Maleate, Dextromethorphan Hydrobromide and Phenylephrine Hydrochloride Syrup (Expotus-D Syrup) | LSF-B0075 | Apr-2023 | Mar-2025 | Spen Formulations Pvt. Ltd., Plot No-123, Industrial Area, Mehatpur, Distt. UNA-174315 (H.P.) | Assay of Chlorpheniramine Maleate, Dextromethorphan Hydrobromide and Phenylephrine Hydrochloride | CDSCO Baddi | RDTL, Chandigarh |
| 47 | Dextromethorphan Hyhdrobromide, Phenylephrine Hydrochloride and Chlorpheniramine | GL2301001 | Jan-2023 | Dec-2024 | Roseate Medicare, Village Anji, PO Barog, Distt. Solan, | Identification and Assay of Chlorpheniramine Maleate and Assay of | CDSCO Baddi | RDTL, Chandigarh |
| 48 | Terbutaline Sulphate, Guaiphenesin, Ambroxol Hydrochloride and Menthol Syrup (Xpert-S Syrup) | 6530 | Feb-2023 | Jan-2025 | ESTRA PHARMACEUTICALS, Fatehgarh Churian Road, Amritsar Br. | Assay of Ambroxol Hydrochloride and Menthol | CDSCO Baddi | RDTL, Chandigarh |
| 49 | LEVOCETIRIZINE HYDROCHLORIDE & MONTELUKAST SODIUM TABLETS I.P. (Cetliv-M) | MDHMT-436 | Mar-2023 | Feb-2025 | M Sea Pharmaceuticals (P) Ltd. (A GMP ISO 9001: 2015 CERTIFIED CO., Surajpur, Paonta Sahib, Sirmour (H.P.)- 173001 | Dissolution of Montelukast | Assistant Director (Food & Drugs) Mizoram | RDTL, Guwahati |
| 50 | Levocetirizine Dihydrochloride and Montelukast Sodium Tablets IP | 23112703 | Mar-2023 | Feb-2025 | MERCURY LABORATORIES LIMITED., Unit No.2, Halol Baroda Road, Village: Jarod. Tal: Waghodia, Dist: Vadodara- 391510 | Dissolution of Montelukast | Inspector of Drugs, Assam | RDTL, Guwahati |
| 51 | DICLOFENAC SODIUM INJECTION I.P. 75mg/3ml | I213109 | Jul-2023 | Jun-2025 | ANG Lifesciences India Ltd., Village Malkumajra, Nalagarh Road, Baddi, Distt. Solan-173205 (H.P.) | Description | Inspector of Drugs, Assam | RDTL, Guwahati |
| 52 | Montelukast Sodium and Levocetirizine Hydrochloride Tablets IP (Montas- L) | MAT22030 | Jun-2022 | May-2024 | Tirupati Medicare Limited, Nahan Road, Paonta Sahib, Dist. Sirmour, Himachal Pradesh - | Dissolution of Montelukast | Inspector of Drugs, Sikkim | RDTL, Guwahati |

# CDSCO: NSQ List—February 2024 Page 6

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 53 | Pheniramine Maleate Tablet I.P. (APVIL) | RT220422 | May-2022 | Apr-2025 | Ridley Life Science Pvt. Ltd.,, D-1651, DSIDC, Indl. Complex, Narela, Delhi- 110040 | Description | Inspector of Drugs, Assam | RDTL, Guwahati |
| 54 | Pheniramine Maleate Tablet IP (APVIL) | RT220512 | Jun-2022 | May-2025 | RIDLEY LIFE SCIENCE PVT. LTD., D-1651, DSIDC Indl. Complex, Narela, Delhi-110040 | Description | Inspector of Drugs, Assam | RDTL, Guwahati |
| 55 | Levocetirizine Hydrochloride & Montelukast Sodium IP Tablets (Raremont-LC) | TSF-B1689 | Apr-2023 | Mar-2025 | Spen Formulations Pvt. Ltd., Plot No-123, Industrial Area, Mehatpur, Distt. UNA- 174315 (H.P.) | Dissolution and Assay of Montelukast | Inspector of Drugs, Assam | RDTL, Guwahati |
| 56 | Serratiopeptidase Tablets IP 10 mg (Serrarid-10) | RT220358 | Apr-2022 | Mar-2024 | RIDLEY LIFE SCIENCE PVT. LTD, D-1651, DSIDC, Indl. Complex, Narela, Delhi-110040 | Disintegration & Description | Inspector of Drugs, Meghalaya | RDTL, Guwahati |

| S.No | Name of Drugs/medical device/cosmetics | Batch No. | Date of Manufacture | Date of Expiry | Manufactured By | Reason for failure | Drawn By (From state/CDSCO Zone) | From (Name of Laboratory) | Remarks |
|---|---|---|---|---|---|---|---|---|---|
| 57 | Telmisartan Tablets 40 mg and Amlodipine 5 mg Tablets IP (Telma AM) | 05230355 | 03/2023 | 02/2026 | Glenmark Pharmaceuticals Ltd., Village Kishanpura, Baddi-Nalagarh Road, Tehsil Baddi, Distt. Solan (H.P.) | Assay & Dissolution of Telmisartan & Amlodipine | CDSCO, North Zone | Central Drugs Laboratory, Kolkata | The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug. Thus, the product is purported to be spurious, however, the same is subject to outcome of further investigation. |
| 58 | Telmisartan Tablets I.P. 40 mg (Telma 40) | I8220890 | 12/2022 | 11/2025 | Glenmark Pharmaceuticals Ltd., Samlik Marchak, Industrial Growth Centre, East Sikkim, Sikkim - 737135 | Dissolution | CDSCO, North Zone | Central Drugs Laboratory, Kolkata | The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug. Thus, the product is purported to be spurious, however, the same is subject to outcome of further investigation. |

Click to Download the pdf file of NSQ list February 2024

Click here for all NSQs Lists

# Important

**GSR No. 216(E) dt 18-03-2024 Pack size of drugs in multiple of 7**

**Download the notification**

---

**63rd meeting of DCC held on 30-01-2024**

**Download the minutes of 63rd DCC meeting**

---

**90th meeting of DTAB held on 25-01-2024**

**Download the minutes of 90th DTAB meeting**

---

**Govt notifies Patent (Amendment) Rules, 2024**

**Download Patent (Amendment) Rules, 2024**

---

**IPC releases draft guidelines to include Disinfectants & Antiseptics in IP**

**Download the draft guidelines**

---

**CDSCO's Revised Guidance on Biological Products**

**Download the revised guidelines**

---

**Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024**

**Download the UCPMP 2024**

---

**DCGI circular dt 09-02-2024 Regulatory Guidelines for sampling by Drugs Inspectors of Centre and States**

**Download the CGI circular dt 09-02-2024**

# FAQs

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

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




# Pharmaceuticals

# Important Notifications

भारत का राजपत्र
The Gazette of India

## Important Notifications

Compiled by
Rakesh Dahiya
FDA Haryana

## For notifications on following topics Click below links

# Upcoming Events

## April-2024

### Medical Fair India:

**Date: Mar 13-15, 2024**

**Location: Bombay Exhibition Centre (BEC), Mumbai, India.**

**Description:** Medical Fair India for hospitals, health centers, and clinics acts as a platform for making connections and nurturing business relationships. With participation from over 20 countries, Medical Fair India provides an opportunity to position your brand among competitors and increase your level of visibility. This trade platform gives leading manufacturers of medical devices, equipment, consumables, hospital furniture, surgical instruments, components, laboratories, IVD, Diagnostics, and infrastructure a chance to showcase their latest innovations, products, and services on an international platform.

**Click for more details**

### Indian Fharma Fair

**Date: Mar 15-16, 2024**

**Location: Sharaton Grand Palace Indore, Omaxe City 1 Bypass Road Mayakhodi Indore (MP), India.**

**Description:** Indian Fharma Fair (IFF) is a one stop junction to every pharmaceutical company or professional who wishes to expand business through various channels of franchise and distribution on one hand and wholesalers and professionals from purchase department of hospitals who seek to buy bulk quality materials at reasonable rates.

**Click for more details**

## May-2024

### COSMOBEAUTY SEOUL-2024

**Date: May 29–31, 2024**

**Location: Seoul, S. Korea.**

**Description:** COSMOBEAUTY SEOUL was first held in 1987 and has been growing as Korea's most renowned beauty-exhibition, which provides a professional business platform and the latest beauty trends in Korea.

We continue to support all domestic and international business owners in beauty field and help them find a gateway to both the Korean Beauty Market and Global industry

**Click for more details**

*(Continued on page 66)*

# Upcoming Events

*(Continued from page 65)*

## July-2024

### IPC 2024

**Date: July 05-07, 2024**

**Location: Hitex City, Hyderabad, India.**

**Description:** The Indian Pharmaceutical Congress (IPC) 2024, which is the 73rd edition of the event, is slated to be held in Hyderabad from July 5 to 7, 2024. The venue is the HITEX city. This is the sixth time Hyderabad is hosting the event which is being organised by the Indian Pharmaceutical Association (IPA)

## August-2024

### DCOIWA Annual Congress-2024

**Date: August 10-11, 2024**

**Location: Mumbai, India.**

**Description:** 2nd Annual Congress cum workshop is going to be held on August 10–11, 2024.

DCOIWA (DRUGS CONTROL OFFICERS (I) WELFARE ASSOCIATION) will be organising its second annual congress to unite and organize the working and retired Drugs Control Officers from Indian States, Union Territories, and CDSCO, with the object of coordinating their activities for the establishment of social justice and regulating the relations of the officers with government agencies. Around 1000 delegates (Drugs Control Officers including State Drug Controllers) across the nation may attend the congress.

## Important links

PG Portal

CDSCO

SUGAM Portal

Online System for Medical Devices

State FDAs Portal

NPPA

Jan Aushadhi

Pharmexcil

FSSAI

eCourts

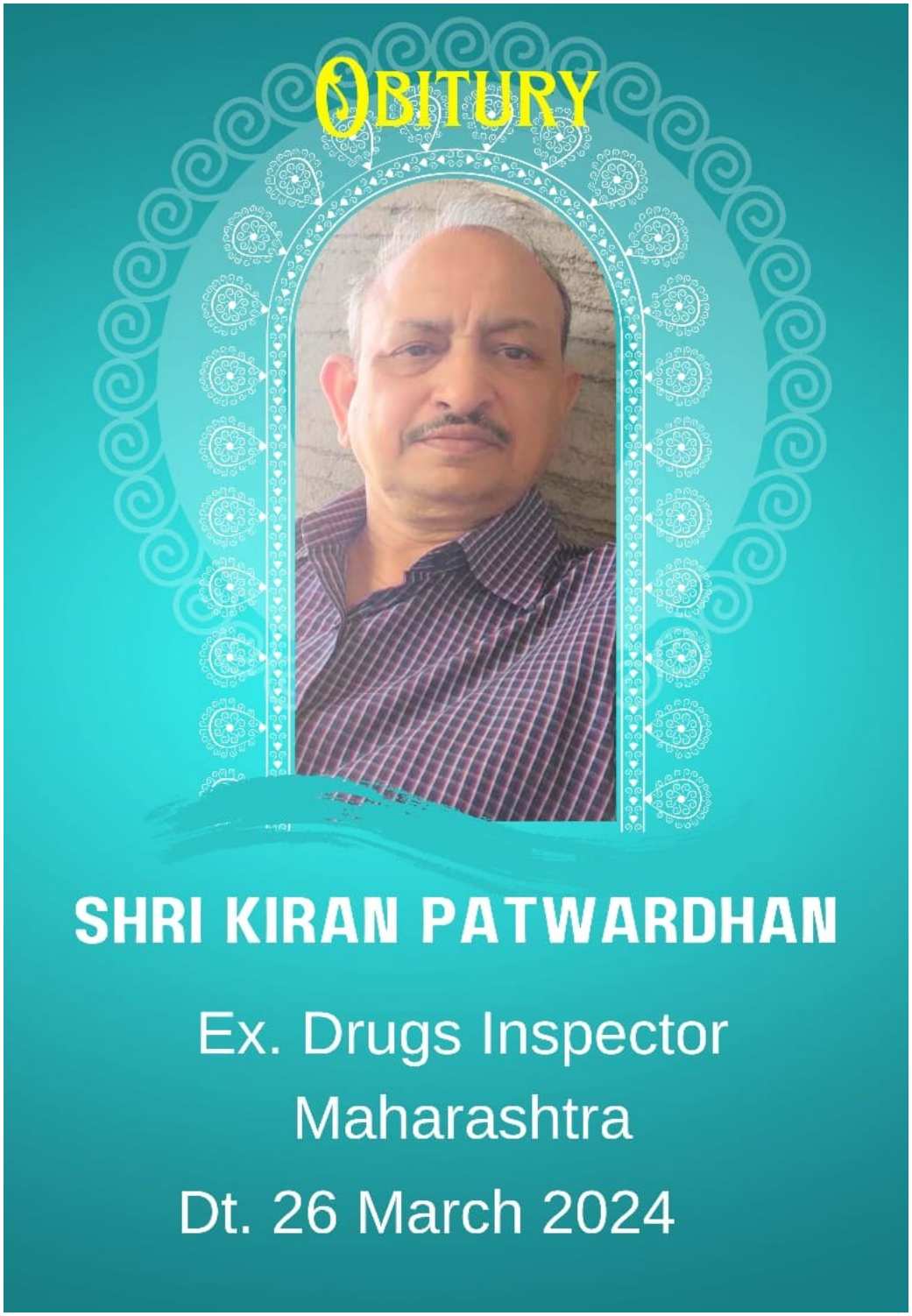
Pharma Sahi Daam

National Medical Commission

Clinical Establishment

Pharmacy Council of India

# Obituary




**It is with profound sadness that we extend our deepest condolences on the untimely passing of Shri Kiran Patwardhan, Ex. Drugs Inspector, Maharashtra, who left us on March 26, 2024. Our thoughts and prayers are with his family during this difficult time. Shri Kiran's dedicated service and contributions to the field of drug control will be remembered with great respect. May his soul rest in peace, and may his family find strength and solace in the cherished memories they shared with him. The DCOIWA family stands in solidarity with them, offering our heartfelt sympathy and support.**

# 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**

**DISCLAIMER**

This e-newsletter is released solely for educational and informational purposes, and is distributed free of charge to DCOIWA members, regulators, and pharmacy professionals. The content and opinions expressed in DCOIWA Newsletter are those of the authors of the particular article / research paper and do not necessarily reflect the views of DCOIWA or any its members. DCOIWA does not take any responsibility whatsoever for any inaccuracy thereto or loss caused therefrom. The editor and affiliated parties are not liable for any damages incurred as a result of the use of the contents of this newsletter. Material from DCOIWA Newsletter my be reproduced without permission provided the source is acknowledged.

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