ISSUE No. 64

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jan. 2025 - Jun. 2025

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Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

It is with great pleasure that we present the 64th edition of the Pharma Web Newsletter, covering the period from Jan to Jun 2025. This issue is packed with valuable content, including program highlights and insightful presentations by distinguished experts from the pharmaceutical industry:

- **Development of Sustainable Quality Culture in Pharma Industry - Dr. Tom Thomas Puthiaparampil, PhD.,** Quality Head – India, SYNER-G BioPharma Group
- **Regulatory Compliance Challenges – Revised Schedule M MSME Perspective - Shri. Harish K Jain,** National President – Federation of Pharma Entrepreneurs & Director - Embiotic Laboratories Pvt. Ltd

Additionally, this edition features a collection of **Gazette Notifications** related to amendments in the Drugs & Cosmetics Act and Rules, as well as key circulars from the DCGI concerning drugs and pharmaceuticals. We've also curated significant news articles from national publications, providing a well-rounded perspective on recent developments in the pharmacy sector. Furthermore, pertinent Parliamentary Questions and Answers relevant to our profession are included to keep you informed of legislative updates.

We extend our sincere gratitude to **M/s. Delvin Formulations, M/s. Medopharm, and M/s. Tablets (India) Ltd.** for their unwavering support through advertisements, which play a vital role in sustaining this publication.

A special acknowledgment goes to **M/s. Fourrts (India) Laboratories Pvt. Ltd.** for their invaluable contributions to *Pharma Web* advertising and their dedication to nurturing talent in the field through the meritorious awards granted to B.Pharm students of *The Tamilnadu Dr. MGR Medical University*, Guindy, Chennai. Their commitment to fostering excellence in our profession is truly commendable.

We trust this newsletter will serve as a useful resource for our pharmaceutical professionals. Your feedback and suggestions for improvement are always welcomed and greatly appreciated.

With Best Regards,

R. NARAYANASWAMY

Chief Editor

ARTICLES

Development of Sustainable Quality Culture in Pharma Industry

by
Dr. Tom Thomas Puthiaparampil, PhD
Quality Head – India, SYNER-G BioPharma Group

This topic was presented during the 10th Pharmac South Exhibition conducted in Chennai on 5th July 2025

Introduction

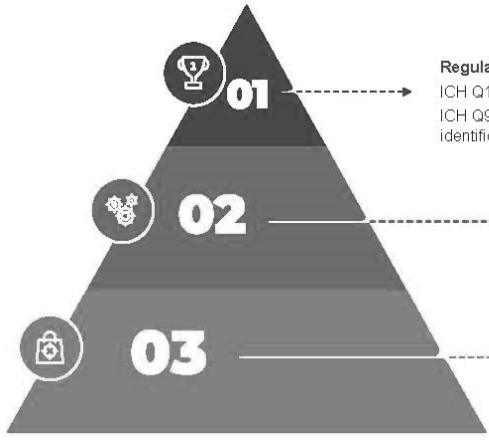
Quality Culture
The collective values, beliefs, attitudes, and behaviors that organizations adopt to produce safe, effective, and high-quality products consistently. It goes beyond regulatory compliance, embedding quality into every aspect of operations.

Sustainable and Compliance-Driven Culture
Crucial in the pharmaceutical industry, as it has a direct impact on patient safety, regulatory adherence, product integrity, and business continuity.

Sustainable Quality Culture:

- Drives regulatory compliance
- Enables the production of safe and effective medicines
- Ensures patient safety
- Builds regulatory trust, allowing smoother market access and fewer disruptions

Integrative Framework for Building a Quality-Driven Culture

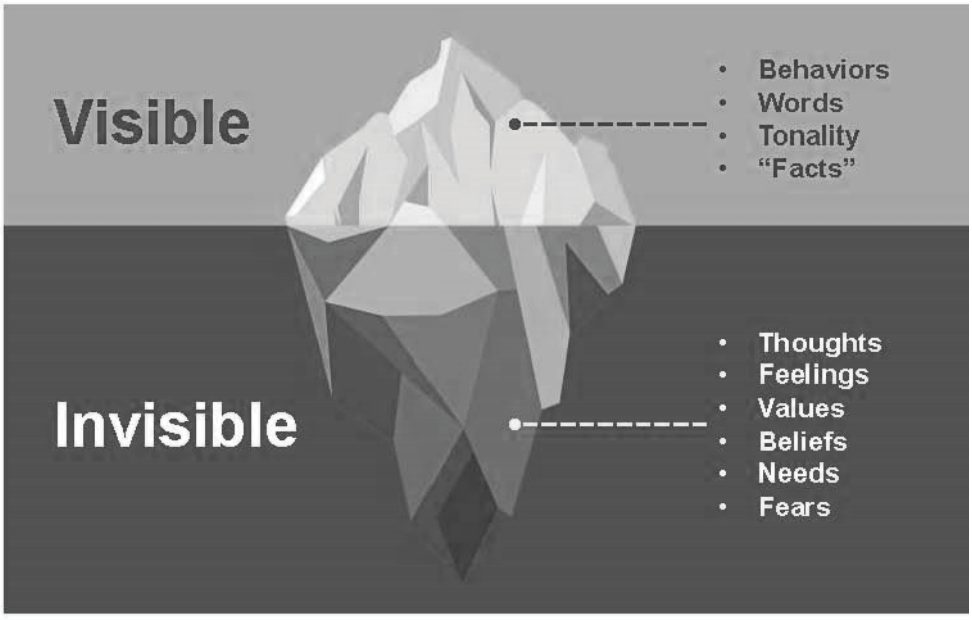


Regulatory Guidance
ICH Q10: Emphasizes senior management's role in fostering quality culture.
ICH Q9: Supports in developing a good quality culture by proactive risk identification and mitigation strategies

Organizational Enablers
Organizational Structure: QA remains independent and empowered.
Business Decisions on Quality: QA actively contributes to strategic choices.

Operational Behaviors
Actions Over Words: Demonstrated commitment, not just intent.
Investment in Quality: Allocating resources for sustained quality outcomes.
Work Standards: The work you accept defines your culture

Quality Culture



Why Quality Culture Matters?

- High-risk industry with zero tolerance for failure
- Increasing global regulatory scrutiny
- Influence on product quality, safety, efficiency
- Builds trust with stakeholders
- Prevents data integrity issues
- Reduces quality failures and recalls
- Enhances patient safety
- Drives long-term business sustainability

Characteristics of a Strong Quality Culture

- Leadership Commitment
- Employee Empowerment
- Open Communication
- Continuous Improvement
- Risk-based Decision-making
- Alignment of values, behavior and process

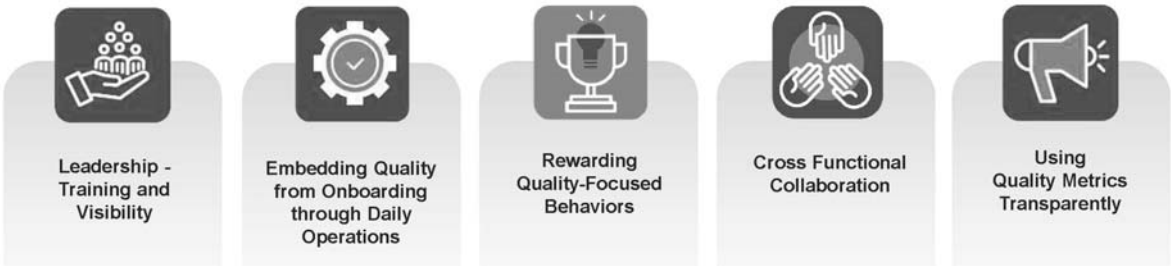
Quality Risk Management (Q9)

Pharmaceutical Development (Q8)

Pharmaceutical Quality System PQS (Q10)

Development and Manufacture of Drug Substances (Q11)

Key Strategies to Develop Quality Culture



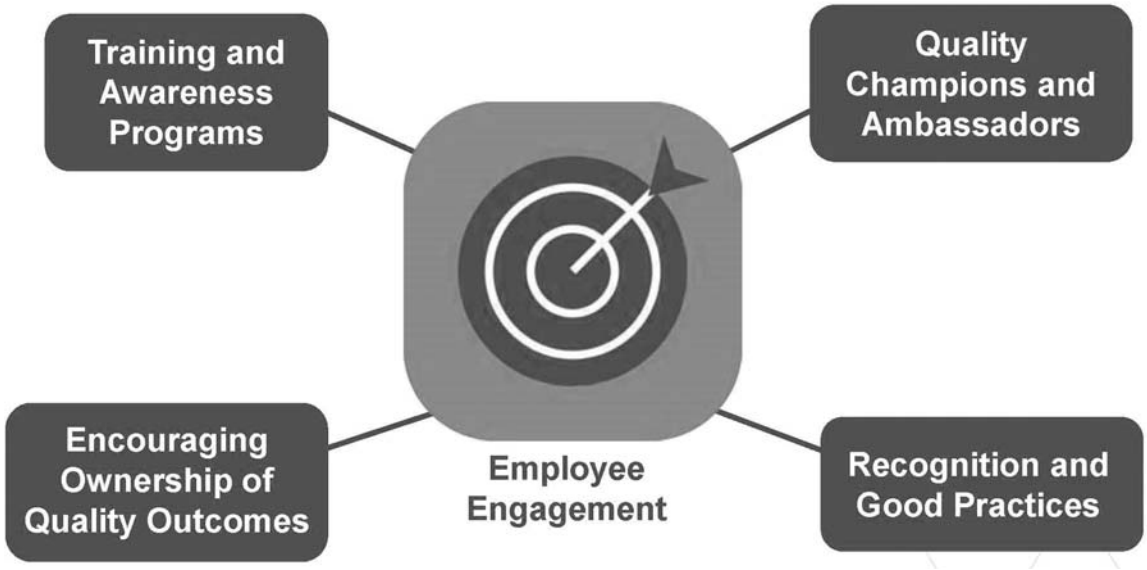
Strategies to Develop Sustainable Quality Culture

Leadership and Vision

5V Model Leader
Vision — Quality vision, strategy, unifying goals, plan mantra-share with entire organization
Vigilance — Accountability, follow through, etc.
Visibility — Presence/Gemba walk, priority actions and reactions
Voice — Passion, credibility, clarity, motivation
Values — Ethics, model behaviors, humility

A leader should lead by example, able to coach and mentor their team, and help to build a learning organization

Employee Engagement Strategies



Current Challenges to Industry

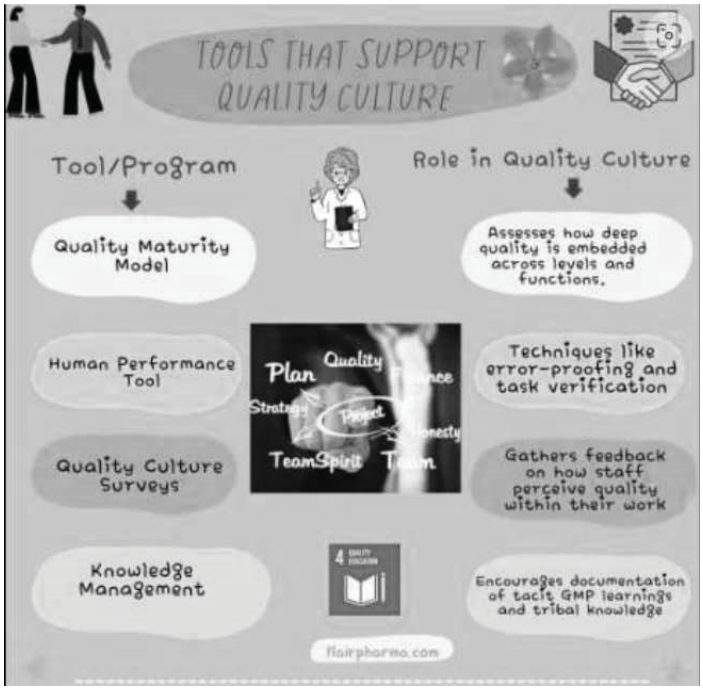
- Resistance to Change
- Siloed departements
- Inconsistent Training
- Focus on compliance over quality
- Increased regulatory expectations

Measurement of Quality Culture

Use of tools like:

- Quality Culture Assessment Surveys (e.g., PDA, ISPE)
- KPI-based metrics (deviation trends, CAPA effectiveness)
- Behavioral indicators (speaking up culture, audit readiness)
- Benchmarking against industry standards

Quantitative Tools	Qualitative Tools
CAPA Trends	Culture Surveys (MHRA/ISPE models)
Deviation Rates	Observations, Assessments
Audit Findings	Interviews and Focus Groups



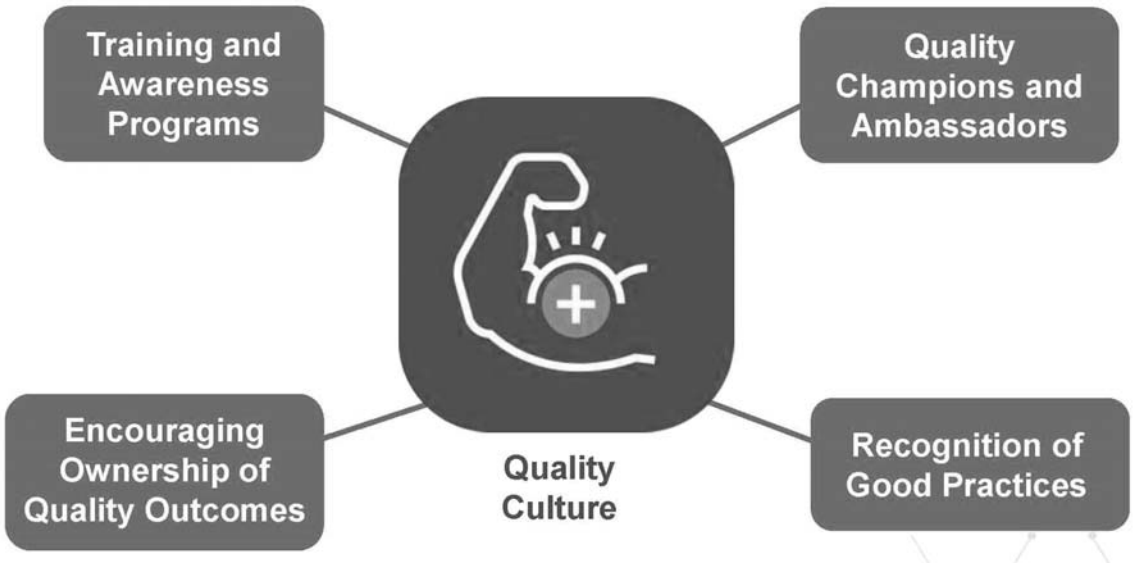
Quality Metrics Framework

- Culture Index Score
- RFT Scores
- Time to Closure of CAPAs
- Measurement of Training Effectiveness

Impact on Compliance

- Better Inspection Outcomes
- Reduction in Regulatory Observations
- Improved Regulatory Trust and Transparency
- Increased Inspection Readiness
- Lowered Risk of Warning Letters and Import Alerts
- Fewer Product Recalls and Batch Rejection
- Improved Product Quality and Patient Safety
- Stronger Data Integrity

Measures for Building Quality Culture



Sustaining the Quality Culture in the Long Term

Continued Trainings and Effective Communication

Periodic Reassessment and Benchmarking

Embedding Culture into SOPs and Policies

Succession Planning

Conclusion

Sustainable Quality Culture is not Optional — it's Strategic

Culture Drives Compliance, Efficiency, and Innovation

Invest in People, Process, and Leadership

Future Outlook

Role of Digital Transformation and AI in Sustaining Quality Culture

Growing Emphasis on Human Performance and Behavior Science

Regulatory Compliance Challenges – Revised Schedule-M MSME Perspective

by
Shri. Harish K Jain
National President – Federation of Pharma Entrepreneurs &
Director - Embiotic Laboratories Pvt. Ltd

This topic was presented during the 10th Pharmac South Exhibition conducted in Chennai on 5th July 2025

Challenges:

1. New Drug Definition under NDCT Rules 2019 –Proposal regarding Enteric coated, Antibiotics
2. Export NOC by CDSCO
3. 92ndDTAB proposal for immediate suspension of license in case of NSQ
4. NPPA –TMR issue
5. Regular upgradation of Pharmacopeia Monograph
6. Additional Product Permission –Process & Product development report submission
7. Issues related to implementation of Revised Schedule M

NDCT Rules 2019:

"New drug" means,—

(i) a drug, including active pharmaceutical ingredient or phytopharmaceuticaldrug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority with respect to its claims; or

(ii) a drug approved by the Central LicencingAuthority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

NDCT Rules 2019:

(iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

(iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central LicencingAuthority; or

(v) a vaccine, recombine recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, 4 [cell or stem cell derived product], gene therapeutic product or xenografts, intended to be used as drug;

NDCT Rules 2019:

Explanation : The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licencing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be New Drugs

1. DCGI Circular DT 24.2.2025 (Enteric coated Tablet/Capsules)
2. 64thMeeting of DCC DT 19.6.2024
3. 92ndDTAB DT 28.4.2025: DTAB recommended that all the antimicrobialsshall alwaysbe deemed to be considered as New Drug under the definition of "New Drug" under New Drugs and Clinical Trials Rules, 2019 in public interest. Accordingly consequential changes may be made in the Rules.
4. Big Question: Whether NDCT Rules are Prospective or Retrospective ?
5. Contradiction with Rule 122E ??

Export NOC:1.

1. Applicable for Unapproved/Banned/New Drugs for export purpose

Earlier NOC was issued by CDSCO/SLA (20thAug 2018 to 14thMay 2024) based on Purchase order of Customer.

DCGI Circular DT 30thApr 2024 –NOC by CDSCO on SugamPortal from 15thMay 2024

Unapproved ?? –Available in India licensed by SLA but not approved by DCGI –Dosage form, Strength, FDC etc..

Unapproved API ?? -Ex: MinoxidilSulphate(salt of approved API)

Export NOC:

Issue arisen due to BBC report on alleged export of Tapentadol& Carisoprodolin some part of Nigeria

1. Approved by SRA like USA, EU, Canada, Japan, Australia, Switzerland, India
2. Approved by Importing (Destination) Country… How to obtain data ?? Ex: Afghanistan ??
3. Bulk Drug listed in I.P, BP, USP, JP, EP
4. Issues where the importing country lacks mature or functional regulatory authority –How to get details ??
5. Other countries like China, Bangladesh, Vietnam etc.. are supplying even if importing country did not approve
6. Unapproved NDPS Drug: NRA approval of importing country is Mandatory.
7. Ambiguity & confusion will remain till final satisfactory regulation is framed. Till then ?? What ?? Other countries will take away market ??

92ndDTAB-Immediate Suspension of License in case of NSQ :

The Board was apprised about the issue. The board noted that it is very important that once a drug is declared NSQ, the license of such product shall be suspended immediately in public interest unless a satisfactory corrective action and preventive action (CAPA) is submitted by such manufactures.

After detailed deliberation, DTAB recommended for the appropriate amendment in the Drug Rules in this regard and the suspension product license should be revoked only after route cause analysis and corresponding CAPA has been implemented.

1. NSQ is Batch or the Product ?
2. Fast moving products (Tender) –even one batch NSQ will stop whole business
3. Act has provision to challenge NSQ report
4. Opportunity to be heard –Natural Justice ??

NPPA –TMR Issue :

Recently this issue was discussed again with all Associations

Product & Process Development : For Product License

Required as per Revised Schedule M

Guidance document by CDSCO

Guidance Document

Title: Guidance Document for submission of application for obtaining Manufacturing License by the Applicant based on Dossier based licensing of Drugs

Document No. CDSCO/DBA/V.01

Central Drugs Standard Control Organisation
Directorate General of Health Services,
Ministry of Health and Family Welfare
Government of India

Purpose:

To provide guidance to Indian manufacturer for submission of application to concerned State Licensing Authority and CDSCO Zonal/Sub-Zonal Offices for grant/renewal of manufacturing License, as the case may be.

Scope:

The guidance document is applicable to the manufacturer for the submission of application for grant of license and also to the regulatory authorities for reviewing the submitted application as per provided checklist. It is not applicable for AYUSH drugs, cosmetics and medical devices.

Introduction:

Dossier based approval is a process commonly used to assess and approve application. Instead of making decision based on the individual evaluation, a dossier based approach allows for more structured and comprehensive evaluation of relevant information contained in a dossier submitted by the applicant.

This includes application Form, supportive documents, test reports, certificates and any other required materials. Once the dossier is received, it is reviewed by the concerned authorities for making decision. The evaluation criteria is based on the various provisions provided under Drugs and Cosmetics Act and Rules thereunder. Based on the review, a decision is to be made, whether to approve, reject or request for further clarification from the applicant.

The dossier based approval process promotes the transparency and ensures fairness in the decision making process. The dossier based approach is more efficient than the individual evaluation as it streamlines the process and reduces the need for redundant assessment. The dossier based approach is very helpful when objective and consistent evaluation is required.

agreement/MIDC approval, approval of other Government Authorities and other facility related information.

Part B is w.r.t submission of various technical information about the applied drug products like Stability data, process validation data, analytical method validation/verification data etc.

The checklist so developed will help the applicant to submit the dossier in the uniform manner across the country and will bring the credibility and predictability in the regulatory system.

All the State regulatory authorities are expected to implement the checklist in their respective States in order to achieve the objective of uniform submission of documents for obtaining the license which is as under:

Checklist for grant/renewal of manufacturing license of drug products:

Checklists No	Item Description
	Part A – Firm/facility related details
1	Covering letter
2	Specific Power of Attorney in favour authorized signatory for submitting application on behalf of the company
3	Site Plan and layout of the building with the name, address, scale, measurements of the area as per Schedule –M Requirement
4	Self-attested copies of documents pertaining to the possession of premises such as, Register ownership /rent /lease/allotment letter /Possession Letter, Tax Receipt, (Documents should be Registered with appropriate Authority)
5	Consent to establish from State pollution control Board.
6	List of Directors, Partners, Trustees, alongwith ROC Copy Registered Partnership deed, Trust deed
7	List of Competent Technical Staff with their qualification, Registration, Experience, previous FDA Approvals, Etc.
8	Appointment/Acceptance Letter of Competent Technical staff of manufacturing Section.
9	Appointment/Acceptance Letter of Competent Technical staff of Testing Section.
10	Section wise List of plant and Machineries
11	NOC of department of industrial safety & Health
12	HVAC installation and validation Certificate
13	Water System installation and validation Certificate
14	Site Master File
15	Constitution details of firms
16	List of SOPs/STPs
17	Self-declaration of technical person
18	Self-declaration of Directors
	Part B - Product specific details
19	Copy of valid Test license in Form 29
20	Source of bulk drugs along with current regulatory status with copy of Form 46A/ 45A/CT-19/CT-22 (if obtained)
21	Certificate of Analysis of the bulk drugs/drug substance
22	Master Manufacturing Formula
23	Manufacturing Procedure
24	Product Development report with Excipient compatibility and forced degradation study
25	Process validation report
26	Finished product specification including impurity profile
27	Finished Product Method of Analysis
28	Finished product Analytical method validation report
29	Finished Product Certificate of Analysis for three consecutive batches/three validation batches
30	Stability study data report as per requirements mentioning batch size. (should be presented in tabular form with details of Batch No, Batch size, Date of Manufacturing, Date of initiation, Packaging details)

GUIDANCE DOCUMENT FOR GRANT OF MANUFACTURING LICENC...

31	Comparative Dissolution Release Profile with the Approved formulation (in case of oral dosage form)
32	Comparative evaluation of pharmaceutical equivalence with international brand(s) or approved Indian brands, if applicable
33	Draft specimen of the label and carton
34	Bio Equivalence protocol and report
35	Justification on Bio equivalence study waiver, if requested
36	Details of the approval of the New Drug in the country. In case of new drugs, copy of approval of new drug from CLAs in favour of the applicant in Form 48/CT-23
37	Form 10 issued by CDSCO where required
38	Form 51 Undertaking
39	Challan of Fees Paid To Be Upload
40	Any Other Document
41	Application in prescribed legal form (e.g. Form 24, Form 27, Form 27-D, 27DA, etc.)

Note:

1. For obtaining permiss on for additional items on approved category, the applicant will be required to submit details as mentioned at serial no. 19 to 41 only.
2. If applicant is submitting, not applicable (NA) against any above mentioned documents, the same needs to be justified adequately.

Important requirements of these guidelines as per Part B

1. Product development report with excipient compatibility and forced degradation study
2. Process validation report
3. Analytical method validation report
4. Stability study Data
5. Comparative dissolution profile
6. BE Protocol & report

Revised Schedule M - Challenges for MSMEs

The 1941 Sulfathiazole Disaster and the Birth of Good Manufacturing Practices

JOHN P. SWANN

History Office, Food and Drug Administration, Rockville, Maryland

PDA J Pharm Sci and Tech **1999**, *53* 148-153

ABSTRACT: The beginning of modern standards for good manufacturing practices can be traced to an incident that began in December 1940, when the Winthrop Chemical Company of New York put on the market sulfathiazole tablets contaminated with phenobarbital. Hundreds of deaths and injuries resulted. FDA's investigation into Winthrop's sulfathiazole production and the agency's efforts to retrieve the Winthrop drug remaining on the market revealed numerous control deficiencies in the plant and serious irregularities in the firm's attempt to recall the tainted tablets. The incident prompted FDA to require detailed controls in sulfathiazole production at Winthrop and throughout the industry, an approach that became the basis for production control standards for all pharmaceuticals.

Issues:

- Contamination during Manufacturing
- Poor Quality Control

Rectification Steps taken by USFDA:

- Revision of FDA procedures to require disclosure of additional data on manufacturing facilities, control procedures, and processing of the finished product
- Pharmaceutical factory inspections devoted to an examination of facilities, including "adequacy of supervision over key equipment such as tablet machines;" manufacturing control procedures, for example, "the method of identifying and segregating a finished batch prior to completion of laboratory tests;" and laboratory controls, such as the extent of testing raw materials and finished products.

Schedule M:

First Amendment : F.1-60/61-D DT 12.7.1962-Requirement on Premises & Plant and equipments

Elaborate Schedule M : GSR 735 (E) DT 24.8.1988 –based on WHO TRS 567 of 1975

Last Revision was made Vide GSR 894 (E) DT 11.12.2001, which was made effective from 30.6.2005 for existing units –based on WHO TRS 923 of 1992

Revised Schedule M:

Draft was Published Vide GSR 999(E) DT 5.10.2018 –based on WHO GMP TRP 961-Principle of Quality has to be built into the product and not merely by testing

Final Notification was issued vide GSR 992 (E) DT 28.12.2023 –Triggered by incidents in Gambia, Uzbekistan etc.

Revised Schedule M:

Part I: Good Manufacturing Practices for Pharmaceutical Products -Main Principles

1. Pharmaceutical Quality System
2. Quality Risk Management (QRM)
3. Good Manufacturing Practices for Pharmaceutical products
4. Sanitation & Hygeine
5. Qualification & Validation
6. Complaints & Adverse reactions
7. Product recalls
8. Change Control
9. Production under loan license or contract and contract analysis and other activities
10. Self Inspection, quality audits and suppliers audits and approval

Revised Schedule M:

11. Personnel
12. Premises
13. Equipment
14. Materials
15. Reference standards
16. Waste materials
17. Documentation
18. Good practices in production
19. Good practices in quality control
20. Computerized systems

Appendix –I : Site master file

Revised Schedule M:

Part I: Main Principles

Specific Requirements:

Part II: Sterile Products
Part III: Hazardous Products (Hormones, Cytotoxic, Steroids)
Part IV: Biological Products
Part V: Radio Pharmaceuticals
Part VI: Phytopharmaceuticals
Part VII: Investigational Products for CT Humans
Part VIII: Oral Solid Dosage Forms (Tablets/Capsules)
Part IX: Oral Liquids
Part X: Topical/External Products
Part XI: Metered Dose Inhalers
Part XII: API
Part XIII: Requirements of Plant & Equipment

Specific Requirements for manufacture …….

Note: GMP for Pharmaceutical products: Main Principles as given in Part I shall be complied with, mutatis mutandis, for ……. In addition to these requirements, the following specific requirements should also be followed, namely

mutatis mutandis: Indicates that whilst it may be necessary to make some changes to take account of different situations, the main point remains the same.

01. Pharmaceutical Quality System (PQS) with QRM

Requirement 1: PQS with QRM

Old Schedule M

No formal PQS or QRM system.

Revised Schedule M

Mandated PQS incorporating QRM tools like FMEA, HACCP.

Why it's Tough / Nearly Impossible

Setting up a PQS means changing how the entire company works.
Needs trained staff, clear procedures (SOPs), regular reviews, tools like FMEA or HACCP. Small companies often lack the people or experience to handle all this.

02: Computerized Systems with Audit Trails (ALCOA + Compliance)

Requirement 2: Computerized Systems with Audit Trails

Old Schedule M

Manual/limited electronic records allowed.

Revised Schedule M

Validated systems with audit trails, access control, backups, change logs.

Why it's Tough / Nearly Impossible

Requires special, expensive GxP-compliant software.
Needs validation, secure access, regular backups.
Small companies often lack the IT setup or experts.

03. Environmental Monitoring in Non-Sterile Areas

Requirement 3: Environmental Monitoring

Old Schedule M

EM mandatory only for sterile zones.

Revised Schedule M

Viable and non- viable monitoring required in all production areas.

Why it's Tough / Nearly Impossible

Requires air quality monitoring tools, microbiology lab, trained staff.
Significant changes in setup, equipment, and operations for non- sterile units.

04: Real-Time Continuous Particulate Monitoring

Requirement 4: Real-Time Monitoring

Old Schedule M

Periodic sampling (manual).

Revised Schedule M

Continuous online monitoring with alert and alarm limits.

Why it's Tough / Nearly Impossible

Costly and complicated systems needing regular calibration, validation, alarms, data recording. Most factories need major upgrades.

05. Annual Product Quality Review (APQR/PQR)

Requirement 5: APQR/PQR

Old Schedule M

Not required.

Revised Schedule M

Comprehensive annual review of deviations, complaints, OOS, and stability trends.

Why it's Tough / Nearly Impossible

Hard to manage without digital systems and trained QA staff.

06: Change Control System (Structured)

Requirement 6: Change Control System

Old Schedule M

Only basic documentation of changes.

Revised Schedule M

Formal system with QRM- based evaluation, impact assessment, approval workflow.

Why it's Tough / Nearly Impossible

Needs dedicated tracking software, staff training, approvals from different teams.

07. Validation of All Equipment, Utilities, Cleaning, and Processes (IQ/OQ/PQ)

Requirement 7: Validation

Old Schedule M

Selective and basic validation.

Revised Schedule M

Comprehensive validation, including cleaning, hold times, utilities.

Why it's Tough / Nearly Impossible

Needs detailed planning, third- party experts, costly validation software.

08: Contract Manufacturing and Testing - Defined Responsibilities

Requirement 8: Contract Manufacturing and Testing

Old Schedule M

Not clearly defined

Revised Schedule M

Defined QA/QC roles, audit rights, agreements for Contract Giver and Acceptor.

Why it's Tough / Nearly Impossible

Extra storage space, temperature control, clear labeling, tracking software needed.

09. Pharmacovigilance and Recall System

Requirement 9: Pharmacovigilance and Recall

Old Schedule M

Complaints handling optional

Revised Schedule M

Mandatory ADR reporting risk-based recall procedures, regulatory notification

Why it's Tough / Nearly Impossible

Needs trained PV staff, IT systems, SOPs, 24x7 preparedness.

10: Sample Retention for API and Excipients

Requirement 10: Sample Retention

Old Schedule M

APIminimal; excipient: no defined requirement.

Revised Schedule M

API retain 1 year after expiry; Excipient: 2 years.

Why it's Tough / Nearly Impossible

Extra storage space, temperature control, clear labeling, tracking software needed.

11. Specialized GMP Requirements for New Categories (Biologics, Radiopharma, MDIs, Phytopharma)

Requirement 11: Specialized GMP Requirements

Old Schedule M

Not Covered

Revised Schedule M

Detailed guidelines for separate categories, including layout, containment, staff qualification.

Why it's Tough / Nearly Impossible

Requires redesign of facilities, hiring expert consultants, significant investment.

12: Packaging Materials Traceability & Control

Requirement 12: Packaging Materials Traceability & Control

Old Schedule M

No specific traceability; spot checks only.

Revised Schedule M

Unique IDs for every batch of printed or primary packaging; obsolete packaging must be destroyed and logged.

Why it's Tough / Nearly Impossible

Proper systems for labeling scanning, recording, and handling required.

13. Master Formula & Batch Record Details

Requirement 13: Master Formula & Batch Record

Old Schedule M

Basic batch records

Revised Schedule M

Extensive documentation processing times, equipment Ids, yields, operator initials, deviation notes

Why it's Tough / Nearly Impossible

Needs electronic systems, staff training, regular checks for record accuracy and completeness

14: WHO-TRS Guidance Adoption

Requirement 14: WHO-TRS Guidance Adoption

Old Schedule M

Not referenced.

Revised Schedule M

Manufacturer must consider WHO TRS documents for HVAC, water systems, validation.

Why it's Tough / Nearly Impossible

Requires understanding of international quality standards, expert help to redesign systems.

15. Detailed Personnel Requirements

Requirement 15: Detailed Personnel Requirements

Old Schedule M

No explicit Organizational structure.

Revised Schedule M

Maintain organization chart; define roles for key personnel; implement visitor procedures and training.

Why it's Tough / Nearly Impossible

Proper HR systems, regular training programs, and a culture of documentation needed.

16: Airlocks with HEPA Filters for Material & Personnel Transfer

Requirement 16: Airlocks with HEPA Filters

Old Schedule M

General hygienic practices.

Revised Schedule M

Separate material and personnel airlocks with Class D HEPA filters; pass-box requirements between zones.

Why it's Tough / Nearly Impossible

Major facility layout changes, investment in HVAC systems, significant APEX and planning

INFORMATION

M. Pharm & Pharm. D Scholarships 2024-25 Awardes by TNPSW Trust

Profile of 1st Rank

PHARMACEUTICS

Name: Mr. Jawathu. A

Project Title: Phyto-Nano Fabrication and Evaluation of Novel Polyherbal Cream and its Anti-Psoriatic Activity in Rats

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Dr. Arjunan Karupaiah

PHARMACEUTICAL CHEMISTRY

Name: Ms. D. Melphiya

Project Title: Reactivation of Mutated MAPK1 Gene through Zinc metal Chaperones for Triple Negative Breast Cancer Therapy .

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. S. Jubie

PHARMACEUTICAL ANALYSIS

Name: Mr. H. Mohammed Idrees

Project Title: Stability Indicating UPLC Method Development and Validation for the Quantitation if Rupatadine Fumarate and Characterization of its Degradation Products

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. P.G. Sunitha

PHARMACOLOGY

Name: Mr. Raghul L R V

Project Title: Identification & Evaluation of Therapeutic Potential of Highly Selective Estrogen Receptor – Beta (ER-ß) Phytoestrogen in Testosterone and N-Methyl N-Nitroso Urea (MNU) Induced Prostate Cancer Model.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Divakar. S

PHARMACOGNOSY

Name: Ms. T. Tanamani Jenifer

Project Title: Comparative Phytochemical Profile of Wedelia chinesis (Osbeck) Merr. & Eclipta alba (Linn.) Hassk and Anti-Cholelithiatic Effect of Wedelolactone Loaded Phytosome in Balb/C Mice.

College: College of Pharmacy, Madras Medical College, Chennai

Guide's Name: Dr. R. Vadivu

PHARMACY PRACTICE

Name: Ms. Sneha. R

Project Title: Effect of S-Adenosyl Methionine Precusor versus Vitamin supplements in treatment of Hyperhomocysteinemia in patients with ischemic stroke – A Prospective Cohort Study.

College: Sri Ramachandra Faculty of Pharmacy, SRIHER, Chennai

Guide's Name: Dr. S. Karthik

PHARM D

Name: Ms. Jaishree. M, Mr. Abishek. M, Mr. Sri Harish Kumar. S

Project Title: Effect of N-Acetylcysteine in Reducing Post-operative Cognitive Dysfunction After Anaesthesia in Elderly Patients Undergoing Day Care Surgery.

College: SRM College of Pharmacy, SRMIST, Chennai

Guide's Name: Dr. M. G. Rajanandh

EVENTS

Pharma Knowledge and Training Institute (Finishing School)

11th Training

on

Industrial Orientation Training for Production and Quality Management Personnel

The 11th Training program for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held at Trust premises in Spencer Plaza, Anna Salai, Chennai from **3rd Feb to 20th February 2025.** The total 40 trainees from C.L. Baid Metha College of Pharmacy, Chennai, GRD College of Pharmcy, Tiruvallur, Surya School of Pharmacy, Vilupuram, PSG College of Pharmacy, Coimbatore, Sankaralingam Bhuvaneshwari College of Pharmacy, Sivakasi, RKP College of Pharmacy, Krishnagiri, G.P. Pharmacy College, Jolarpet, Vijay Vidyalaya College of Pharmacy, Dharmapuri, & College of Pharmacy, Madurai Medical College, Madurai, students were trained in this training program.

The students were given training both theoretically and practical on the subject of **"Industrial Orientation Training on Production and Quality Management Personnel".** The following subjects were taught as theory and practical during this training programme.

Theoretical Training Programme

- Regulatory Requirement of Pharma industry in India and Good manufacturing Practice under "Revised Schedule M"
- Role of Govt. Labs and its procedure
- Ethics on Pharmaceutical Marketing
- Plant Design & Site Master File
- cGMP's for manufacturing including entry & exit procedures
- ICH guidelines for production & Quality Control of Pharmaceuticals
- IQ, OQ, PQ and DQ of equipment of Production & QC, Validation, Qualification and calibration
- Market complaints, CAPA, OOS and OOT etc., What is containment? Essential steps to control contamination, handling of deviation, Risk Assessment
- Change control, Deviation control and the importance
- Quality by Design (QbD)
- Regulation and Opportunities in Medical Devices
- Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc Different types of equipment used for their manufacture, Ingredients used and in-process tests to be carried during their production. Packing of the above products
- Basic Calculations in Quality Control, Dilutions and Statistical Analysis, Qualitative Analysis, Quantitative Analysis & Elemental Analysis

- Air Systems, Water Systems, their sampling and testing
- Calibration of QC equipments, Reference Standards and Working Standards, Reference / retention samples storage
- Rules and Regulations of Import and Export, New Drug Approvals
- Documentation and records in Production and QC
- Standard Operating Procedures
- Sampling of Raw Materials, Packing materials, In- process Materials and Finished products

- Stability Testing, Accelerated and Real Time Studies, Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability
- Artificial Intelligence in Pharmaceuticals
- Analytical method validation
- Regulation & Manufacturing Process of Vaccines
- Different types of Oral Liquid Dosage Forms such as Liquids, Syrups, Suspensions & Emulsions etc. Facilities required and their methods of manufacture, in process tests to be carried out during their manufacture
- Microbiology - An Introduction, Microbiology for non-sterile preparations
- Overview of the Pharmaceutical Industry and job opportunities for the Pharmacy graduates
- Testing of Pharmaceutical Analytical Instruments (TLC, HPLC, HPTLC, Spectrophotometer, GC, ect.)
- Manufacturing Process & requirements Parenteral Preparations

- Dissolution & its Importance, Methods used in Dissolution Testing
- Batch Manufacturing Records, Batch Packing Records and importance of online recording. Basics of production planning & Inventory Control
- Preparation and Standardization of Herbal Formulations
- Tablets (Processes involved in the production of Tablets such as size reduction, sieving, granulation, compression, coating etc., Various components of a Tablet with examples of different materials used &, In process tests to be carried during production of Tablets)
- Types of tablets such as Plain Tablets, Press Coated Tablets, Tablet in Tablet, Film Coated Tablets, Enteric Coated tablets, Delayed Release tablets etc, their advantages , How to control and rectify (in case of failure) weight variation, Disintegration time, Hardness, Friability, Dissolution etc during production , Different types of Coating of Tablets, Materials used for coating & coating process
- Preventive maintenance, Predictive maintenance & Break down maintenance
- Soft Skill
- The above subjects were taught by well experienced senior level pharma industry manufacturing and quality assurance technical personnel through power point presentation.
- One day program was conducted on Chromatography analysis like HPLC, GC, LCMS Spectrophotometer, etc., at M/s. SPINCO Biotech, Perungudi, Chennai with practical training.

Practical Training

M/s. Fourrts (India) Laboratories Pvt. Ltd., Plant 1 & Plant 2, Chennai, M/s. Apex Laboratories Pvt. Ltd.,Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Sai Mirra Innopharm Pvt. Ltd., Ambattur, Chennai M/s. The Madras Pharmaceuticals, OMR, Chennai, M/s. Tablets (India) Ltd., Tondairpet, Chennai and M/s. Ordain Healthcare Global Pvt Ltd., offered their facilities for practical training to the trainees for 5 days.

Evaluation

All the trainees were evaluated after each of the lecture programme as well as on the final date of completion of the programme on the basis of the evaluation 3 top scored trainees were awarded with cash prize, during the valedictory function.

ValedictoryFunction

The Valedictory function was held on 20th February 2025. The Chief Guest of the function was Dr. S. V. Veeramnai, Chairman of our Trust and M/s. Fourrts (India) Labs Pvt Ltd., and Mr. M. N. Sridhar, Director of Drugs Control, Tamil Nadu, was the guest of Honour. Mr. R. Narayanaswamy, Mr. N. Sreenivasen, Mr. K. Pandiayn, were the guests of the valedictory. Dr. R. Ilavarasan, Director, PKTI Welcomed the gathering and explained about the 11th training program. Certificates were distributed all the trainees.

All the trainees expressed their views that such program enhance their knowledge and more useful for their carrier in Pharma profession.

International Symposium on Dissolution and Drug Development

The Indian Pharmaceutical Association – Tamil Nadu State Branch (IPA-TNSB) and SOTAX India Pvt. Ltd., Mumbai successfully organized a one-day **International Symposium on Dissolution and Drug Development** on **23rd January 2025** at the **Madras Medical College Auditorium**, Rajiv Gandhi Government General Hospital, Chennai.

The symposium brought together leading experts in pharmaceutical sciences to share insights on cutting-edge advancements in dissolution techniques and drug delivery.

The event was inaugurated by **Thiru. M. N. Sridhar**, Director of Drugs Control, Tamil Nadu, in the presence of distinguished guests including **Dr. S. V. Veeramani**, Chairman, Pharmexcil; **Thiru. J. Jayaseelan** (IDMA & IPA); **Dr. M. Kavitha**, Vice Principal, Madras Medical College; and **Mr. M. Yousuf,** Secretary, TANIPA Trust.

Prof. Dr. R. Radha, Professor & Head, College of Pharmacy, Madras Medical College, welcomed the gathering. **Prof. Padma V. Devarajan**, President, SPDS, provided an overview of the Society for Pharmaceutical Dissolution Science (SPDS) and the day's program.

A highlight of the event was the **felicitation of Dr. Vinod Shah,** a renowned pharmaceutical consultant and distinguished alumnus of Madras Medical College, in recognition of his global contributions to drug development. The introduction and felicitation were led by **Dr. L. Ramasamy,** Founder and Chairman, SOTAX India Pvt. Ltd.

The vote of thanks was delivered by **Mr. T. Sathish,** Honorary Secretary, IPA-TNSB

The scientific sessions explored a wide spectrum of topics, including nanotechnology in medicine, advanced pharmacokinetics, and innovative dissolution testing methodologies. Eminent speakers such as **Prof. Imre Klebovich**, **Prof. Dr. Romana Zelko**, and **Mr. Suhas Yewale** enriched the program with international perspectives and research-driven discussions.

The symposium concluded with a **live demonstration of the USP 4 dissolution apparatus**, followed by a lively Q&A session and a networking lunch. The event marked a significant step forward in fostering collaboration and innovation in pharmaceutical sciences.

HEARTFELT CONDOLENCES

Dr. T. K. Ravi

DOB: 03.11.1964
DOD: 28.01.2025

Dr. T. K. Ravi, Principal and Head of the Department of Pharmaceutical Analysis at Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore. A stalwart in the field of pharmaceutical education and research, Dr. Ravi dedicated over 37 years to shaping future pharmacists with passion, integrity, and excellence. Guided over 100 postgraduate and doctoral scholars and published more than 150 research papers in peer-reviewed national and international journals.

Honored with prestigious awards including:

Distinguished Alumni Award – College of Pharmaceutical Sciences, Manipal (2000)

Professional Excellence Award – Tamil Nadu Dr. M.G.R. Medical University (2011)

Best Pharmacist of the Year – Indian Pharmaceutical Association, TN Branch (2015)

Global Educator Award – Association of Pharmaceutical Scientist and Educators (2023)

Principal of the Year – APTI Tamil Nadu (2024)

Held several leadership roles such as:

President, Indian Pharmaceutical Association (Coimbatore Branch)

Vice President, Indian Association of College of Pharmacy

Executive Council Member, Pharmacy Council of India (2008–2013)

Governing and Senate Member, Tamil Nadu Dr. M.G.R. Medical University

He will be remembered not only for his scholarly achievements but also for his unwavering commitment to the growth of the pharmaceutical sciences. Our thoughts and prayers are with his family, colleagues and students during this time of great loss.
May his soul rest in peace.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 30th January, 2025

S.O. 558(E).— In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby appoints Dr. Pronab Dhar, Head of the Division of Biological Standardization, Indian Veterinary Research Institute, Izatnagar to be the Government Analyst, with immediate effect, for whole of India in respect of all classes of drugs specified below, namely:-

(1) Anti-sera for veterinary use.
(2) Vaccines for veterinary use.
(3) Toxoids for veterinary use.
(4) Diagnostic Antigens for veterinary use.

[F. No. X.11035/129/2024-DR]
RAJIV WADHAWAN, ADVISER (Cost).

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 12th March, 2025

S.O. 1158(E).—Whereas the Central Government is satisfied that the use of drug formulations containing Chloramphenicol or Nitrofurans drugs are likely to involve risk in any food producing animal rearing system whereas safer alternatives to the said drugs are available;

And, whereas, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the import, manufacture, sale and distribution of all formulations containing Chloramphenicol or Nitrofurans drugs for use in any food producing animal rearing system;

Now, therefore, in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940, and after consultation with the Drugs Technical Advisory Board, the Central Government hereby prohibits the import, manufacture, sale and distribution of the following drugs, for use in any food producing animal rearing system, with immediate effect, namely -

" (1) Chloramphenicol and its formulations; and
(2) Nitrofurans and its formulations. ".

[F. No. X.11035/127/2024-DR]
NIKHIL GAJRAJ, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2025

G.S.R. 127(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 10(E), dated the 4th January, 2025, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of seven days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on 04th January, 2025; And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government.

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), with the consideration that consultation with Drugs Technical Advisory Board shall be held as per the provisions of the said Act, the Central Government hereby makes the following rules, further to amend the Drugs (Amendment) Rules, 2023, namely:-

1. Short title and Commencement:- (1) These rules may be called the Drugs Amendment Rules, 2025.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs (Amendment) Rules, 2023, in rule 6, in the Table, in the entry against 'Small and Medium manufacturers', under column (2) after the words "Twelve months from the date of publication of these rules", the following proviso shall be inserted, namely :-

"Provided that the small and medium manufacturers with turnover less than two hundred and fifty crores may seek extension of the timeline for implementation and for that purpose shall make an application to the Central Licence Approving Authority in Form 'A' annexed to this notification, within a period of three months from the date of publication of this notification, along with a plan of upgradation and for such manufacturers, the timeline for implementation shall be extended till 31st day of December, 2025".

[F. No. X.11014/2/2017-DRS]
RAJIV WADHAWAN, Adviser (Cost)

FORM A

Application for seeking extension of compliance with Revised Good Manufacturing Practices (GMP) under Schedule-M of the Drugs Rules, 1945

Sl.No.	Item	Details
1	Name and address of the manufacturer	
2	Turnover (year April,2023-Mar ch, 2024)	
3	Details of the licence in all forms,- (i) Licence number (ii) Validity	
3	Sections held	
4	Whether holding World Health Organisation Good Manufacturing Practices (WHO-GMP)/Certificate of Pharmaceutical Product (CoPP), If yes, the validity of the certificate	
5	Details of gap analysis (section wise) (i) Plant, (ii) Equipment, (iii) Lab equipment (iv) HVAC system, (v) Utilities, (vi) Technical staff, (vii) Documentation (viii) Others	
6	Plan or strategy for compliance with the revised GMP (item wise as per the gap analysis at Sl. No. 5) Starting on or before 31.03.2025	
7	Extension of time required for compliance (not beyond 31st day of December, 2025)	
8	Justification of the time required for compliance	

Undertaking

I undertake that I have carried out the gap analysis and propose to initiate upgradation within three months from the date of this application and comply with the revised Schedule-M requirements as per the plan submitted at Sl.no.6. above.

Date:

Place: Signature

(Director/Partner/Proprietor/Authorised Signatory)

Footnote : The Principal rules were published on the Official Gazette vide notification number G.S.R. 922(E), dated the 28th December, 2023.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 12th March, 2025

S.O. 1159(E).—In exercise to the powers conferred by sub-sections (1) and (2) of section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) hereinafter referred to as 'the Act' and in supersession of the notification of the Government of India in the Ministry of Health & Family Welfare, Number S.O. 4326(E) dated the 18th October, 2021, except as respects things done or omitted to be done before such supersession, the Central Government hereby reconstitutes the Drugs Technical Advisory Board consisting of the following members, namely: -pect of the Medical Devices as specified against their names in column (4) of the said table, namely :-

Serial Number.	Name/Official designation of the Member.	Status in Drugs Technical Advisory Board.	Section of the Drugs and Cosmetics Act, 1940 under which appointed, nominated or elected.
(1)	(2)	(3)	(4)
1.	The Director General of Health Services, New Delhi.	Chairman ex- officio	Appointed under clause (i) of sub section (2) of section 5 of the Act.
2.	The Drugs Controller, India, New Delhi.	Member ex- officio	Appointed under clause (ii) of sub section (2) of section 5 of the Act.
3.	The Director, Central Drugs Laboratory, Kolkata.	Member ex- officio	Appointed under clause (iii) of sub section (2) section 5 of the Act.
4.	The Director, Central Research Institute, Kasauli.	Member ex- officio	Appointed under clause (iv) of sub section (2) section 5 of the Act.
5.	The Director, Indian Veterinary Research Institute, Izatnagar, Bareilly, Uttar Pradesh.	Member ex- officio	Appointed under clause (v) of sub section (2) section 5 of the Act.
6.	The Chairman, National Medical Commission, India.	Member ex- officio	Appointed under clause (vi) of sub section (2) section 5 of the Act.
7.	The President, Pharmacy Council of India.	Member ex- officio	Appointed under clause (vii) of sub section (2) section 5 of the Act.
8.	The Director, Central Drugs Research Institute, Lucknow.	Member ex- officio	Appointed under clause (viii) of sub section (2) section 5 of the Act.
9.	Director, Directorate of Food and Drugs Administration, Goa.	Member	Nominated under clause (ix) of sub section (2) section 5 of the Act.
10.	State Drugs Controller, Drugs Control Administration, Himachal Pradesh.	Member	Nominated under clause (ix) of sub section (2) section 5 of the Act.
11.	Dr. Atul Kumar Nasa, Member, Executive Committee, Pharmacy	Member	Elected under clause (x) of sub section (2) section 5 of the Act.

12.	Dr. Vijay Oza, Member, Post Graduate Medical Education Board, National Medical Commission.	Member	Elected under clause (xi) of sub section (2) section 5 of the Act.
13.	Shri Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance.	Member	Nominated under clause (xii) of sub section (2) of section 5 of the Act.
14.	Dr. Jerin Jose Cherian, Scientist- E, Indian Council of Medical Research.	Member	Elected under clause (xiii) of sub section (2) of section 5 of the Act.
15.	Dr. Bhavesh Vyas, Assistant Professor, Department of Pharmacology, Narendra Modi Medical College, Ahmedabad, Gujarat.	Member	Elected under clause (xiv) of sub section (2) of section 5 of the Act.
16.	Dr. R.N. Gupta, National President, Indian Pharmaceutical Association.	Member	Elected under clause (xv) of sub section (2) of section 5 of the Act.
17.	Government Analyst, Drugs Control Laboratory, Vijayawada, Andhra Pradesh.	Member	Nominated under clause (xvi) of sub section (2) of section 5 of the Act.
18.	Government Analyst, Government Public Analyst Laboratory, Lucknow, Uttar Pradesh.	Member	Nominated under clause (xvi) of sub section (2) of section 5 of the Act.

2. The Drugs Controller (India) shall be the Member-Secretary of the Board.

[F. No. X.19012/2/2009-DFQC(Pt.)]

NIKHIL GAJRAJ, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th March , 2025

S.O. 203(E).—In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rule, 1945, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare numbers S.O. 4271(E), dated the 26th November, 2019, S.O.2191(E), dated the 15th May, 2023 and G.S.R. 91(E), dated the 2nd February 2024 published in Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), except as respects things done or omitted to be done before such supersession, the Central Government hereby appoints the persons specified in column (2) of the Table below as Government Analysts at the National Institute of Biologicals, Plot No. A-32, Sector 62, Institutional Area, Noida, Uttar Pradesh - 201309 for the whole of India in respect of the classes of drugs specified against their names in column (3) of said Table, namely:—

Serial No.	Name of Government Analyst	Medical Device (s)
(1)	(2)	(3)
1	Dr. Akanksha Bisht	In-vitro Diagnostic Medical Devices
2	Dr. Rajesh Kumar Sharma	
3	Dr. Richa Baranwal	
4	Dr. Varun Singh	Biochemical Kits
5	Dr. Gauri Misra	Molecular Diagnostic Kits
6	Dr. Ashwini Kumar Dubey	
7	Ms. Kanchan Ahuja	Blood Grouping Reagents.
8	Dr. Pankaj Kumar Sharma	
9	Dr. Meena Kumari	Blood Products, including recombinant origin.
10	Ms. Y. Madhu	
11	Dr. Manoj Kumar	
12	Mr. Tara Chand	
13	Ms. Sudha V Gopinath	
14	Dr. Charu Mehra Kamal	Recombinant products
15	Ms. Gurminder Bindra	
16	Dr. Sanjay Mendiratta	
17	Ms. Shalini Tewari	
18	Dr. Subhash Chand	Monoclonal Antibodies
19	Dr. Ratnesh Kumar Sharma	
20	Dr. Saurabh Sharma	
21	Dr. Harish Chander	
22	Dr. Jyoti Sharma	

Serial No.	Name of Government Analyst	Medical Device (s)
(1)	(2)	(3)
23	Dr. Hemant Kumar Verma	Enzymes and Hormones, including recombinant origin
24	Mr. N. Nanda Gopal	
25	Ms. Rashmi Shrivastava	
26	Mr. Harit Kasana	Vaccine and Antisera.
27	Mr. Jaipal Meena	
28	Dr. Manjula Kiran	
29	Mr. Neeraj Malik	

[F.No. X.11035/128/2024-DR]
RAJIV WADHAWAN, Advisor(Cost)

FileNo.: DC-DT-13011(11)/2/2024-eoffice

Government of India

Ministry of Health & Family Welfare

Directorate General of Health Services
Central Drugs Standard Control Organization
(Veterinary Division)

FDA Bhawan, Kotla Road,
New Delhi-110 002, India,

To, 20 FEB 2025

All the State/UT Drugs Controllers

Subject:- Prohibits to manufacture, sale and distribution and use of drug "Nimesulide and its formulation for animal use" with immediate effect-reg.

Sir,

As you aware, reports have appeared from time to time about the use of drug formulations containing Nimesulide are likely to involve risk to animals and vulture population in the country.

Hon'ble High Court of Delhi in the hearing vide order dated-01.09.2023 of case W.P. (C) 7493/2022&CM APPL. 22886/2022 Gaurav Kumar Bansal Vs Union of India directed to furnish the reason as to why the drug 'Nimesulide' has not been banned.

Accordingly, Ministry of Health and Family Welfare Government of India has taken up the matter and issue NOTIFICATION vide S.O. 5633(E) 30th December, 2024 New Delhi.

In light of recent measures as above, you are requested to sensitize your inspectorate staff to keep strict vigil on manufacture, sale and distribution of drug in the country and take all regulatory measures to ensure that drug is not illegally manufactured/sold and its misuse in the animals is prevented.

Details of action taken in the matter may please be forwarded to this office for further action.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:

1. PS to JS (R) Ministry of Health and Family Welfare
2. DGHS
3. MOEF & CC
4. Bombay Natural History Society (BNHS)
5. IVRI
6. DAHD

File No. ND-13020/2/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization (HQ)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi -110002
Dated 24 FEB 2025

To,

All State/UT Drugs Controllers

Subject:- Gastro Resistant Tablets/Capsules, Delayed Release Tablets/Capsules as "New Drugs" as per Rule 2, (1)(w) of the New Drugs and Clinical Trials Rules, 2019-Reg.

Sir/Madam,

As per the definition of "New Drug" specified in Rule 2(1)(w) of the New Drugs and Clinical Trials Rules, 2019, a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority shall always be deemed to be a new drug.

The issues relating to uniform implementation of this rule regarding Gastro-resistant Dosage forms / Delayed-release Dosage forms (Enteric Coated Tablets/Capsules) across the country was deliberated in 64th meeting of the Drugs Consultative Committee (DCC) held on 19-06-2024.

After detailed deliberation, the committee recommended to issue a Circular to all the States/UTs regarding the interpretation of Gastro-resistant Tablets/Capsules /Delayed release Tablets/Capsules (Enteric Coated tablets/ capsules) as "New Drug" as per Rule 2 (1) (w) of the New Drugs and Clinical Trials Rules, 2019, for uniform implementation across the country.

Accordingly, all the State/UT Drugs Controllers are requested to ensure uniform implementation of the Rule 2 (1) (w) of the New Drugs and Clinical Trials Rules, 2019 that modified or sustained release form of a drug including Gastro-resistant Tablets/Capsules /Delayed release Tablets/Capsules (Enteric Coated Tablets/Capsules) or novel drug delivery system shall always be deemed to be new drug as per the provisions of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:
1.All Stakeholder through CDSCO website.
2.All Zonal/ Sub-Zonal Offices of CDSCO.
3. CRU Section of CDSCO (HQ)

F.No.10171/DCGI/10/2024-eoffice
Government of India
Directorate General of Health Service
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road,
New Delhi-110002

24 FEB 2025

Sub: Submission of Clinical Trial Site Addition and change of Principal Investigator applications through SUGAM portal -Reg.

In continuation to notice vide F.No.1017/DCG(I)/10/2024-eoffice dated 26.12.2024 on the subject sited above, the submission of applications for addition of Clinical Trial Site and change of Principal Investigator are now also functional on online system of SUGAM Portal (www.cdsconline.gov.in) for clinical trials of Biological products (Vaccine and rDNA). Applicants seeking for approval of Clinical Trial Site Addition and change of Principal Investigator applications for all the clinical trials may apply through the online portal.

The applicant should submit application through SUGAM along with the checklist of documents along with the approval of the ethics committee. The proposed addition of clinical trial sites is deemed to be approved if no objection is received from the CDSCO within 30days of the receipt of the application and the proposed change of Principal Investigator is deemed to be approved by the CDSCO from date of receipt of application subject to the condition that application is complete as per the checklist

(Dr.Rajeev Singh Raghuvanshi)
Drugs Controller General(India)

To,

1.All stakeholders through CDSCO website

2.CDAC team

File No: IT/Sch M ex/ONDLS/2025/002
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan. Kotla Road,
New Delhi-110002

Circular 24 MAR 2025

On line application for extension of time to comply with revised Sch M on ONDLS portal-regarding

It is informed that Department of Health and Family Welfare has published a notification vide G.S.R. 127(E) dated 11th February 2025 regarding seeking extension of the timeline for implementation and for that purpose shall make an application to the Central Licence Approving Authority in Form 'A' annexed to the notification, within a period of three months from the date of publication of this notification, along with a plan of upgradation for the small and medium manufacturers with turnover less than two hundred and fifty crores may, the timeline for implementation shall be extended till 31st day of December, 2025.

In this regard, the Central Drugs Standard Control Organization (CDSCO) has developed an online system for submitting application through the ONDLS Portal (www.statedrugs.gov.in).

The applicant/ Manufacturer seeking extension of the timeline has to register on the ONDLS portal and thereafter submit an application. No hard copy of the application for seeking extension of the timeline for implementation will be considered.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To
All Pharma Industry Association
Copy to: The PS to ADV (Cost)

F. No. DC-DT-15011(11)/63/2024
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

Dated: 27.03.2025

Office Memorandum

Subject: Exemption of sampling & testing of orphan drugs at CDSCO Port offices - Regarding.

This office has received representations from the various associations and importers of Drugs organizations involved in the import and marketing of life saving orphan drugs in the country. "Orphan drug" is defined as per clause (x) of rule 2 of New Drugs & Clinical Trial Rules 2019, means a drug intended to treat a condition which affects not more than five lakh persons in India.

Various challenges encountered drug sampling and testing of orphan drugs at various port office of CDSCO have been brought to the notice, such as small volume, high cost, requirement of specialized testing equipments and unavailability reference standards & testing methods at testing laboratories. These challenges may lead to delay the availability of such lifesaving orphan drugs to needy patients. Procedure for sampling & testing during import of drugs at various port offices of CDSCO has been defined in the Guidance Document for Zonal, Sub-zonal & Port Offices (Revision: 01, 2024) dated 12.09.2024.

Considering the various representations received in the matter and to stream line the procedure for release of orphan drugs it has been decided that such consignment shall be released by the CDSCO Port offices on the basis of legal undertaking submitted by the importer stating that required quantity of sample shall be forwarded to the concerned laboratory and test report shall be submitted to respective port office within 15 days of receiving from the laboratory.

Yours faithfully

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General of India

To:
1. All Zonal and Sub-zonal offices of CDSCO
2. All Port offices (Air/Sea) of CDSCO
3. All Stake holders through CDSCO Website (for information)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th April, 2025

S.O. 1717(E).— Whereas, the Central Government is satisfied that the use of the drug fixed dose combination of Chlorpheniramine Maleate + Phenylephrine Hydrochloride is likely to involve risk to children below four years of age and whereas safer alternatives to the said drug are available.

And whereas, the matter was examined by Subject Expert Committee appointed by the Central Government and the said Committee recommended that all formulations of fixed dose combination of Chlorpheniramine Maleate IP + Phenylephrine Hydrochloride should not be used in children below four years of age and accordingly manufacturers should mention warning “fixed dose combination shall not be used in children below four years of age" on the label and package insert or promotional literature of the drug.

And whereas, the Drugs Technical Advisory Board also examined the said fixed dose combination and recommended that all formulations of the fixed dose combination of Chlorpheniramine Maleate + Phenylephrine Hydrochloride should be prohibited for use in children below four years of age under section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940) and for manufacture, sale and distribution of the said fixed dose combination subject to the condition, that manufacturers shall mention a warning that “fixed dose combination shall not be used in children below four years of age” on the label and package insert or the promotional literature of the drug.

And whereas, on the basis of the recommendations of the said Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of restriction, the manufacture for sale, sale and distribution for human use of the said drug in the country;

Now, therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby restricts the manufacture, sale or distribution of all formulations of fixed dose combination of Chlorpheniramine Maleate + Phenylephrine Hydrochloride subject to the following condition, that the manufacturers shall mention the warning “fixed dose combination shall not be used in children below four years of age” on the label and package insert or the promotional literature of the drug.

2. This notification shall come into force on the date of its publication in the Official Gazette.

[F. No. X.11035/132/2024-DR]
RAJIV WADHAWAN, Adviser (Cost)

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi the 16th May,2025.

S.O. 2208 (E).—In exercise of the powers conferred by section 6 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with clause (a) of sub-rule (1) of rule 19 of the Medical Devices Rules, 2017 and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare number S.O. 3758 (E), dated the 10th August, 2022 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), except as respects things done or omitted to be done before such supersession, the Central Government hereby authorises Dr. Rakesh Kumar Rishi, Director In-charge of Central Drugs Laboratory, Kolkata, to sign statutory certificates of test or evaluation of samples of Medical Devices sent by Courts of Law under sub-section (4) of section 25 of the said Act or in Form MD-30 of the Medical Device Rules, 2017, as the Director In-charge of the said laboratory, for the whole of India with effect from the date of publication of this notification in the Gazette of India till the regularly appointed person takes charge of the post or until further orders, whichever is earlier.

[F. No. X.11014/2/2025-DR]
RAJIV WADHAWAN, Adviser (Cost).

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 22nd May, 2025

S.O. 2298(E).— Whereas, the Central Government is satisfied that the use of drugs formulations containing any antimicrobials or group of antimicrobials and their formulations as listed below in animals are likely to involve risk to Humans.

And, whereas, safer alternatives to the said drugs for animal use are available;

And, whereas, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the Import, manufacture, sale, and distribution of any antimicrobial medicinal products as listed below for animal use;

Now, therefore in exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the draft notification is hereby published after consultation with the Drugs Technical Advisory Board for information of all persons likely to be affected thereby, and notice is hereby given that

the said draft notification shall be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft notification are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 545 A Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdivmohfw@ gov.in.

Following antimicrobials and group of antimicrobials and their formulations for animal use: -

1. Antibiotics
i. Ureidopenicillins
ii. Ceftobiprole
iii. Ceftaroline
iv. Siderophore cephalosporins
v. Carbapenems
vi. Penems
vii. Monobactams
viii. Glycopeptides
ix. Lipopeptides
x. Oxazolidinones
xi. Fidaxomicin
xii. Plazomicin
xiii. Glycylcyclines
xiv. Eravacycline
xv. Omadacycline

2. Antivirals
i. Amantadine
ii. Baloxavir marboxil
iii. Celgosivir
iv. Favipiravir
v. Galidesivir
vi. Lactimidomycin
vii. Laninamivir
viii. Methisazone/ Metisazone
ix. Molnupiravir
x. Nitazoxanide
xi. Oseltamivir
xii. Peramivir
xiii. Ribavirin
xiv. Rimantadine
xv. Tizoxanide
xvi. Triazavirin
xvii. Umifenovir
xviii. Zanamivir

3. Antiprotozoals
I. Nitazoxanide

[F. No. X.11035/125/2024-DR]
RAJIV WADHAWAN, Adviser (Cost)

सत्यमेव जयते

File No: IT/COPP/ONDLS/2025/001
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan. Kotla Road,
New Delhi-110002

Dated 25 JUN 2025

To

All State/UTs Drugs Controllers

Sub: Grant of WHO-GMP COPP through ONDLS portal-reg.

Sir/Madam,

As you are aware that the ONDLS portal has been developed by CDAC in coordination with States for processing of application and online licensing of Sale/Manufacturing license, Blood Centre license and Grant of manufacturing License and Large Volume Parenterals. Recently, CDAC has also developed online portal for submission and processing of the application for grant of WHO-GMP (COPP) on the ONDLS Portal. Step wise procedure for registration with the ONDLS portal is annexed.

In view of the above, you are requested to direct the Manufacturing units under your jurisdiction to submit application for the approval of WHO GMP (COPP) through ONDLS portal from **15.07.2025**. It may be noted that physical files will not be entertained for approval of grant of manufacturing License and WHO-GMP (COPP) from **15.07.2025**. Further, CDAC may be contacted at uttamkumar@cdac.in or ondlssupport-noida@cdac.in & CDSCO(it-cell@cdsco.nic.in) for any assistance regarding ONDLS portal.

This is for your information and necessary compliance.

Yours faithfully

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:

1. All Zonal and Sub Zonal office with direction not to accept the application in hard copy after the deadline mentioned above.

Procedure for application of WHO/COPP Certificate

Before applying for grant of WHO GMP/COPP Certificate to state authorities, the license and product details must be approved on ONDLS portal. The following steps are required for approval of product before filing COPP application by the applicant:

1) Manufacturing site registration
2) After registration of manufacturing site, details of the technical staff which are currently on license should be registered.
3) Add all license product through old license management data
4) Add license basic data through old license management data
5) Submit license data to the concern state drug regulatory
6) state drug regulatory approved the license data, New number will be generated against old license number.
7) You can file the application once the data is approved.

File No: IT/Misc/Sugam/2025/002
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan. Kotla Road,
New Delhi-110002

Dated

28 APR 2025

NOTICE /CIRCULAR

Subject: Introduction of Tooltips for legal forms in SUGAM and Medical Device Online Portals to Assist Stakeholders-regarding

It is hereby informed that, in order to improve the user experience and facilitate submission of data in the applications, tooltips for legal forms have been activated on the SUGAM and Medical Device Online portals. These tooltips are designed to provide helpful guidance on the specific requirements for each field in the various application forms submitted to CDSCO for approval. By offering clear instructions on expected inputs, this feature aims to minimize errors and facilitates the quality of submissions.

We encourage stakeholders to utilize this functionality while filling the application on both portals. The tooltips can be accessed by simply hovering over the information icon or help text next to each field.

This initiative reflects CDSCO's ongoing commitment to promoting transparency, ease of doing business, and regulatory compliance. For any questions or technical assistance, stakeholders can reach out to the respective portals' helpdesk.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,
All Stakeholders/Applicants of Pharmaceutical and Medical Device Industry

File No.: MED/52/2024-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Device Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002,
Dated:
09 APR 2025

NOTICE

Subject : Provision for auto-generated Market Standing Certificate and Non-Conviction Certificate for licenced medical device - Reg

In order to promote ease of doing business and to simplify the regulatory procedure, the current online application workflow for grant of Market Standing Certificate (MSC) and Non-Conviction Certificate (NCC) for medical devices licensed by Central Licensing Authority is upgraded in the Online System for Medical devices with a new workflow for auto-generated MSC and NCC certificate.

In this regard, all the current MSC and NCC applications received by CDSCO in the old workflow will be automatically rejected by the system.

In view of the above, it is requested that all concerned stakeholders shall re-submit fresh MSC and NCC application from the date of issuance of this notice.

(Dr.Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To,

1. All stakeholders through CDSCO website
2. CDAC Team

NEWS

CDSCO Seizes Large Quantities of Drugs without Proper Docs from Kolkata-Based Company

Central Drugs Standard Control Organisation (CDSCO) and Drugs Control Directorate of West Bengal recently seized large quantities of anti-cancer, anti-diabetic, and other drugs from a Kolkata-based company.

The seized drugs, labelled as being manufactured in various countries including Ireland, Turkey, the USA and Bangladesh, were found without any supporting documents to prove their legitimate import into India.

The investigating team also discovered several empty packing materials, further raising concerns over authenticity of the seized products.

According to health ministry, a woman identified as proprietor of the wholesale firm has been arrested and to ensure proper investigation, samples of the drugs have been sent for quality testing. "The remaining seized quantity is being kept in safe custody by CDSCO," the health ministry said.

A court granted judicial custody of the arrested proprietor for 14 days and permitted further interrogation. Further investigation into the matter is ongoing, the ministry said.

The statement added that CDSCO and state authorities will continue to work in close coordination to combat the threat posed by spurious drugs and to safeguard the interests of consumers.

Recently, CDSCO introduced new guidelines for inspections. It stated that all drug inspectors in the country should collect at least 10 samples in a month; nine samples of drugs and one sample of cosmetics/medical device. It also said the drug inspectors must plan the sampling in such a way that samples are forwarded to the laboratory on the same day of sampling. In case of rural location or distant location to office, sample shall be forwarded to laboratory by next day and not later than that.

The new guidelines also provide for centralised information on sale outlets where sub-standard or spurious products are reported to keep them under regular vigilance.

Source: *The Times of India,* 1st January 2025

Licences of 36 TN Drug Stores Revoked

The Tamil Nadu drug control administration has revoked the licences of 36 retailers and wholesalers across the state for selling habit-forming drugs, opioid-based formulations used for anxiety or pain relief, and antibiotics without bills and valid prescriptions in bulk quantities in 2024.

Additionally, more than 385 licences were suspended for various violations, including selling prescription drugs over the counter, not issuing bills, and selling drugs without the presence of chemists.

Such sales pose serious risks, including the development of antibiotic resistance, drug addiction, adverse drug reactions, and masking underlying health conditions, stated the state drug controller, M N Sridhar.

"Yet, such sales are not uncommon. Most bulk sales happen online, making them difficult to track," he said. However, during routine inspections, drug inspectors found shops were repeatedly selling these drugs to known customers without bills or proper prescriptions.

"Shops keep a count of prescriptions they buy in their log. Drug inspectors question them when they see a mismatch in sales. In some cases, chemists did not have bills for 100 out of 500 such drugs they sold," he said.

Among those whose licences were suspended, at least 322 were retailers and 63 were wholesalers. In some cases, inspectors have forwarded complaints to the joint director of health to frame charges of quackery.

"Sometimes, chemists give medicines based on symptoms described by customers. This can be a dangerous trend too," he said. The police, through their intelligence network, have also caught shops selling drugs without bills. Chemists argue that in most situations, they sell prescription drugs over the counter only to known customers.

"We know a person is buying a diabetic or hypertensive drug regularly. In that case, we may not ask for a prescription. Or they may move to another shop or buy medicines online. However, billing must be done to prevent abuse," said a senior chemist who runs a shop in West Mambalam.

"There may be a few exceptions, but most chemists don't intend to harm. If they know there is a possibility of abuse they exercise restraint," he said.

The TN druggists and chemists association have asked their members to ensure they do not violate the Drug and Cosmetics Act, he said.

Chennai: The TN drug control administration filed 226 cases against manufacturers, dealers, wholesalers, and retailers in 2024 for various violations, including the sale of spurious and substandard drugs, selling drugs above the maximum price, and other lapses.

The cases filed against drug manufacturers are serious and are in various stages of legal action, Sridhar said. Additionally, the state has filed 125 cases against pharmacists for not maintaining prescription registers and 28 cases for the sale of drugs under Schedule H and H1 without a prescription. Another 156 cases have been filed for other lapses, including sales without chemists and improper storage of drugs.

Source: *The Times of India,* 4th January 2025

Now Quality is King

The Parliamentary Standing Committee on the Union Ministry of Chemicals and Fertilisers has recently asked the Pharmaceuticals & Medical Devices Bureau of India (PMBI), which is the implementing agency of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), to take stringent measures to prevent any malpractices of the Jan Aushadhi Kendra (JAK) owners to the quality and safety of the medicines sold through the Kendras.

The panel, headed by Member of Parliament Kirti Azad Jha, in its fifth report on the Demands for Grants of the Department of Pharmaceuticals (DoP) for the fiscal year 2024-25 submitted in the Lok Sabha during the recently concluded session, expressed its dismay on the issue noting that the DoP has not furnished any specific reply as regards to the mechanism to inspect the JAK retail outlets and malpractices in JAKs.

The DoP launched the Jan Aushadhi project with much fanfare on November 25, 2008 when it opened the first Jan Aushadhi store at Amritsar in Punjab. No doubt, it was a bold initiative by the then UPA government to provide generic drugs at affordable prices to the masses. Prices of medicines sold through these Jan Aushadhi stores are cheaper at least by 50 per cent and in some cases medicines are cheaper by 80-90 per cent of the market price of branded medicines.

Unfortunately, the scheme never really took-off in the initial years as there were vested interests even within the government who did not really want the scheme to go ahead due to intense pressure from the industry. As a result, the project dragged on for several years, and the target of opening at least 100 stores every year in various parts of the country was never achieved as the government could open only a couple of hundred stores in the first 7 years.

The scheme got a new lease of life when the new government led by Prime Minister Narendra Modi not only saw it as a vehicle to provide affordable generic medicines but also an employment avenue for thousands of small entrepreneurs. The scheme was then revamped and rechristened as PMBJP in 2016. Since then, the project has been gaining momentum and the number of stores has steadily been increasing across the country.

Presently, there are more than 14,000 JAKs located in 773 districts and the government has now set an ambitious target of opening 25,000 Kendras across the country by March 31, 2026. Over the last 10 years, there has been 200 times increase in sales turnover from Rs. 7.29 crore in 2014 to Rs. 1,470 crore till June 30, 2024. The product basket currently comprises 2047 medicines and 300 surgical and medical consumables, growing from 900 medicines and 154 surgical and medical consumables in 2019-20. No doubt, the PMBJP is cruising towards new heights as more and more people are resorting to generic

drugs instead of the branded medicines which are costlier by several times. But, there is still the quality issue which is holding back a large number of people from buying cheaper medicines from JAKs.

Even a large section of doctors is also not prescribing generic drugs because of lack of assurance on quality. Since the JAKs are owned and run by private entrepreneurs, it becomes imperative on the part of PMBI to check the quality of medicines sold at JAKs. The PMBI should take stringent measures to prevent any malpractices of the JAK and should ensure the quality and safety of medicines sold through these Kendras. As the customer base for the JAKs is swelling day by day, now quality will be the king.

Source: *Pharmabiz,* 29th January 2025

NPPA Asks Online Pharmacies to Comply with DPCO Provisions of Price List Display

The National Pharmaceutical Pricing Authority (NPPA) has asked the online pharmacies to ensure compliance with the provisions under the Drugs Prices Control Order (DPCO), 2013, for displaying the current price list on the virtual or online premises, in line with the price list displayed in the physical premises of retailers.

The Authority's directive comes at a time when the wholesale and retail medical stores are contesting the lack of legal standing for the operation of online pharmacies and the Centre yet to make any regulations in place for sales of drugs online.

The Authority, in an office memorandum issued earlier this month, clarified that the provisions under the DPCO, 2013, for display of the current price list at the conspicuous part of the premises not only covers the physical premises, but also the virtual premises.

The Para 24 (4) states that every retailer and dealer shall display the price list and supplementary price list, if any, as furnished by the manufacturer, "on a conspicuous part of the premises where he carried on business in a manner so as to be easily accessible to any person wishing to consult the same". Similar provisions are incorporated in the Para 25 for non-scheduled drugs.

The Authority said that use of the terminology "on a conspicuous part of the premises where he carries on business" covers not only the physical premises where the retailer or dealer carries on business, but also covers the virtual or online or electronic premises where the retailer or dealer carries on business.

"Therefore, all the retailers and dealers including online pharmacies carrying on business of purchase or sale of drugs through physical mode as well as online mode i.e through website/online portal/mobile

app/e-commerce platforms or any other online mode are required to display the current price list as per the provisions of DPCO, 2013," said the Office Memorandum.

It also warns that it would initiate appropriate action against those who fail to comply with the direction, as per the provisions of the DPCO, 2013 read with Essential Commodities Act, 1955.

Source: *Pharmabiz,* 12th February 2025

TN Drugs Control Department Stresses Need for Regulations to Curtail Online Sale of Habit-Forming Drugs

Easy access to habit-forming drugs online and the lack of regulations to curb such illegal sale continue to pose a challenge for the Tamil Nadu Drugs Control Department.

Since January 1, 2025 (in a span of 48 days), the department has cancelled 17 retail and wholesale licences over the sale of habit-forming drugs. However, online pharmacy platforms remain beyond the bounds due to the lack of regulations.

Director of Drugs Control Administration, Tamil Nadu, M.N. Sridhar said that checks on the sale of habit-forming drugs were stepped up in the State.

Keeping a tab

Tamil Nadu's Drug Control Administration has been monitoring various drug-related violations. A closer look at the violations and action taken against retail and wholesale dealers.

Details of sanction given	April 1, 2024 to December 31, 2024	January 1, 2025 to February 17, 2025
For the manufacture of spurious drugs	Tamil Nadu - 1 Other - 3 Total - 4	Tamil Nadu - 0 Other - 1 Total - 1
For the manufacture of Not of Standard Quality drugs	Tamil Nadu - 5 Other - 43 Total - 48	Tamil Nadu - 0 Other - 17 Total - 17
For the sale of drugs without supervision of pharmacist	39	6
For not maintaining prescription register property	96	8
For not maintaining prescription register, and for sale of Schedule H and H1 drugs without prescription of registered medical practitioner or not in accordance with prescription of registered medical practitioner	18	1
For stocking/sale of date expired drugs	Nil	Nil
Contravention under Drugs and Cosmetic Act, 1940 and Rules 1945	120	18
Contraventions under Drugs and Magical Remedies (Objectionable Advertisements) Act, 1945	1	0
Contraventions under Drugs Price Control Order, 2013	1	1
Total number of sanction orders issued	**174**	**36**
ADMINISTRATIVE ACTIONS TAKEN		
Number of retail licences suspended	273	54
Number of wholesale licences suspended	49	5
Total number of licences suspended	322	59
Total number of retail and whole licences cancelled	28	17

Source : Tamil Nadu Drug Control Administration

"Whenever the police department seizes such drugs, we are informed about it, and if the medicines were purchased from a wholesale or retail dealer, we initiate immediate action; show-cause notices are issued, licences are cancelled, and the premises are sealed. However, most of the habit-forming drugs are procured from online pharmacies, which pose a challenge," he said.

Among the drugs that are commonly misused are Tapentadol tablets (painkillers used mostly during the post-operative period) and Tramadol tablets (used in the treatment of arthritis). Painkillers prescribed for patients in the post-surgery period and antidepressants are also purchased online and misused, he said.

Most of the supplies are from Gujarat, Bihar, and Maharashtra. We wrote letters to the Drugs Controllers of the respective States, but we have not received a reply so far. We also wrote to the Drugs Controller General of India (DCGI), but there has been no reply. A special legislation is the need of the hour. Online sale of medicines should be through prescriptions that are monitored," Mr. Sridhar said.

In November, the State's Health Secretary wrote to the DCGI, raising concerns about the availability of certain habit-forming drugs on e-commerce platforms.

S.A. Ramesh, president of Tamil Nadu Chemists' and Druggists' Association, said the several representations they made to the Union Health Ministry to curb the sale of medicines online were to no avail.

"Medicines are not a commodity. Sale of medicines on e-commerce platforms is basically a violation of the Drugs and Cosmetics Act, 1940, which outlines the role of a qualified pharmacist. A prescription from a doctor should be honoured by a qualified pharmacist, who should dispense the medicine after explaining its usage, efficacy, and side effects. Where is the role of a pharmacist on an e-commerce platform?" he questioned.

People have been purchasing painkillers and sleeping pills from e-commerce platforms, he said, adding: "What if something goes wrong when such drugs are purchased online and delivered from other States? How can the dealers be traced and penalised? Lack of regulations is a setback, and we have been reiterating the need to curb the sale of medicines online, but the Central government is not taking any action."

Source: *The Hindu,* 18th February 2025

Key Diabetes Drug to Cost up to 90% Less in A Few Days

Several domestic drug companies are set to transform diabetes therapy by launching the blockbuster drug Empagliflozin at a fraction of the innovator's price.

Affordable generics will hit the market within days, following the expiry of Boehringer Ingelheim's patent on Empagliflozin on March 11, industry sources told TOI.

The launch of generic Empagliflozin, used to treat diabetes, related comorbidities, including heart failure, promises to slash therapy costs, making it more accessible to millions of diabetics and easing the financial strain of this debilitating disease. Those looking to launch the drug include Mankind Pharma, Torrent, Alkem, Dr Reddy's and Lupin.

GOING OFF-PATENT

- German firm Boehringer Ingelheim **markets Empagliflozin as Jardiance**
- Jardiance family **sales pegged at $8 bn** in 2023
- Diabetes mgmt drug to go off-patent on Tuesday
- With multiple generic versions expected to enter mkt, **significant price cut expected,** improving access for millions of patients

Mankind Pharma, India's fourth-largest firm by market share, plans to offer Empagliflozin at one-tenth the innovator's Rs 60 per tablet, sources said.

Most generic versions will cost Rs 9-14 per tablet, disrupting the high-growth diabetes therapy market valued at nearly Rs 20,000 crore, up 43% from Rs 14,000 crore in 2021.

10.1cr Indians live with diabetes, most end up paying out of pocket

The market was further bolstered by Torrent Pharmaceuticals' acquisition of three Empagliflozin brands from Boehringer Ingelheim last year. With India facing a staggering public health burden—10.1 crore people live with diabetes, according to International Diabetes Federation— this shift is critical.

The market size of Empagliflozin and its combinations is estimated at Rs 640 crore. Experts highlight its ability to significantly reduce heart failure hospitalisations, slow chronic kidney disease progression and improve survival in both diabetic and non-diabetic patients, though high pricing has long limited access.

Metformin remains the first-line treatment for type-2 diabetes, but as the disease progresses, additional medications — such as Sulfonylureas (glimepiride, glyburide, glipizide, chlorpropamide), DPP-4 Inhibitors (sitagliptin, vildagliptin), and SGLT2 Inhibitors (empagliflozin, dapagliflozin, canagliflozin)—are added. Now, newer therapies like semaglutide and tirzepatide enhance management, offering improved glycemic control and cardiovascular benefits.
The economic burden of diabetes weighs heavily in India, where most patients pay out-of-pocket due to limited medical reimbursement. Treatment costs escalate with complications, magnifying the challenge.

Source: *The Times of India,* 10th March 2025

Par Panel Recommends Single Independent Drug Controller for AYUSH

A parliamentary committee has recommended the consolidation of all AYUSH drug-related standard-setting processes under a single independent drug controller in alignment with the Drugs and Cosmetics Act, 1940, and its associated rules.

To achieve this, the ministry should establish a streamlined and inclusive mechanism that actively involves stakeholders in the development of pharmacopoeial standards, ensuring greater efficiency and uniformity, said the Parliamentary Standing Committee on Health and Family Welfare in a report presented in the Rajya Sabha this week.

Additionally, the Pharmacopoeia Commission for Indian Medicine & Homoeopathy and Central Council for Research in Ayurvedic Sciences may come

together to coordinate and collaborate in this initiative, the committee emphasised in its 165th report on "Demands for Grants 2025-26 of Ministry of Ayush".

This will enhance the scientific testing and evaluation of a larger number of ASU&H drug samples to ensure safety, efficacy, and quality, strengthening the foundation of research and standardisation in the sector.

The committee flagged that the state-wise reach of Arogya Fair/Ayurveda Parv is less compared to the size of India with its 28 states and eight Union Territories.

It recommended that the reach should cover 50 per cent of Indian states in the coming year and eventually all of the country in the near future to propagate the Ayush System for the prevention and treatment of common ailments.

It recommended that the ministry leave no stone unturned in efficiently and effectively implementing the IEC Scheme, thus generating awareness amongst the common masses, especially in rural, urban slum, hilly and tribal areas.

The committee also took note of the financial and physical performance made under the international cooperation scheme with respect to budgetary allocation and set objectives.

It recommended that going forward communication should be made with first-world countries like the UK and the US for promoting AYUSH among the Indian diaspora as well as their native citizens.

Underlining the potential in promoting AYUSH-related healthcare travel to India, the panel said that the Ministry has to chalk out strategies to vigorously promote the AYUSH system of medicine in international markets, and support investment and exchange of exports to boost Ayush products in the global market.

"The Ayush Ministry should keep the consideration that Ayush Vision@2047 has a target to enhance the contribution of the Ayush Sector up to 7.7 per cent of GDP," it said.

It suggested that the strategic course of action viz. road shows abroad, CMEs for the foreign audience, familiarisation trips, strategic marketing communication through a professional agency, collateral audio-video content and social media marketing can further be taken up by the Ministry for the achievement of the Mission Objective of the scheme.

The committee also recommended that the ministry give equitable impetus to all sub-components of the capacity building and continuing medical education in Ayush under the Ayurgyan Scheme.

Underlining the vital role of research and innovation in Ayush Drugs for prioritised diseases, the committee recommended collecting data on safety, standardisation and

and quality control for Ayush products and practices in order to develop evidence-based support on the efficacy of Ayush drugs and therapies.

In order to inculcate scientific aptitude and expertise relating to Ayush systems, the ministry should chalk out a strategy for the development of potential human resources and their management in the Ayush system, the report said.

The committee reiterated its recommendation that the outcome of the research scheme should successfully demonstrate the effectiveness of Ayush systems and the novel technology successfully developed out of such research and development must harness the potential of Ayush in the interest of public health delivery.

Further, noting that the scheme is one of the most significant schemes under AYUSH, the panel recommended extending it in financial years beyond 2025-26 with adequate budgetary allocation.

The committee expressed happiness and welcomed the laying of the foundation of a WHO Global Traditional Medicine Centre at Jamnagar, Gujarat and said that increasing collaboration with WHO in the Ayush Sector is significant in the global acceptance of traditional medicine and Ayush healthcare.

Such events will certainly help with the rapid growth of traditional medicine and healthcare.

It recommended that steps be taken on priority to complete the project early and make the GTMC functional.

Source: *Hindustan Times,* 16th March 2025

Weight-Loss Medicine Goes on Sale in India

American drugmaker Eli Lilly and Company launched its weight-loss injectable drug Mounjaro in India on Thursday, becoming the first multinational pharma firm to bring a treatment already widely used in Western markets to India, where obesity and associated type-2 diabetes poses a major health burden.

Launched as a once-weekly injection, the drug is priced at ₹4,375 rupees for a 5 mg vial and ₹3,500 rupees for a 2.5 mg vial, its lowest dose, the company said separately.

The drug, which earlier received authorisation from India's Central Drugs Standard Control Organisation (CDSCO) on June 16, 2024 for import and sales, has demonstrated significant weight-reduction effects in clinical trials. Adults participating in controlled studies lost an average of 21.8 kilogrammes at the highest dose and 15.4 kilogrammes at the lowest dose over 72 weeks when combined with diet and exercise, according to company data.

Mounjaro, known chemically as tirzepatide, has already gained popularity in the US, UK and European markets. Since the CDSCO authorisation, Indian patients had been importing the drug for personal use prior to the India launch, which helps bring the cost. A monthly course of four 2.5mg shots in India, based on the above pricing, comes to about ₹14,000, while in a country such as the UK, it costs ₹23,000 to ₹25,000 when converted to Indian currency.

India faces significant public health challenges related to metabolic disorders. According to various estimates cited by the company, India has approximately 101 million people living with diabetes, with nearly half of adult patients receiving inadequate treatment resulting in suboptimal glycaemic control. Additionally, adult obesity prevalence in India stood at around 6.5% as of 2023, affecting nearly 100 million people.

Obesity is linked to over 200 health complications, including hypertension, dyslipidaemia, coronary heart disease, and obstructive sleep apnoea, and is a major risk factor for diabetes.

"The dual burden of obesity and type 2 diabetes is rapidly emerging as a major public health challenge in India. Lilly is committed to collaborating with the government and industry to promote awareness and improve the prevention and management of these diseases," said Winselow Tucker, president and general manager of Lilly India.

However, experts emphasise caution regarding the use of such medications. Dr Nikhil Tandon, head of endocrinology at All India Institute of Medical Sciences (AIIMS) in Delhi, warned against unsupervised use of emerging anti-obesity drugs.

"At the moment they are our best bet but these must be taken under strict medical supervision," Dr Tandon said. "There are clear recommendations for who they work and for who they don't, especially when talking about weight-loss in non-diabetics. The percentage of people who can tolerate maximum dose is not 100%."

The drug represents a significant advance in obesity pharmacology by simultaneously targeting two critical hormone pathways in the body.

It activates what is known as glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptors. These receptors are expressed in key brain regions that regulate appetite. When activated, they create a dual effect that suppresses hunger, reduces food intake, decreases fat mass through appetite regulation, and alters how the body utilises lipids.

According to Eli Lilly's statement, Mounjaro is indicated as a supplement to reduced-calorie diets and increased physical activity for chronic weight management in adults with specific body mass index (BMI) thresholds.

These include individuals with a BMI of 30 kg/m² or greater (classified as obesity) or 27 kg/m² or greater (classified as overweight) who have at least one weight-related health condition. The drug is also approved for glycaemic control in adults with type 2 diabetes mellitus alongside diet and exercise.

The efficacy of Mounjaro was established through two global clinical programmes: the SURMOUNT-1 trials for chronic weight management and the SURPASS trials for type 2 diabetes.

In the SURMOUNT-1 study, which involved 2,539 adults with obesity or excess weight and weight-related medical problems (excluding diabetes), participants taking Mounjaro alongside diet and exercise experienced substantial weight loss compared to those on placebo at 72 weeks.

At the highest dose of 15 mg, participants lost an average of 21.8 kilogrammes, while at the lowest dose of 5 mg, the average loss was 15.4 kilogrammes. The placebo group lost an average of 3.2 kilogrammes.

"Additionally, one in three patients taking Mounjaro at the highest dose lost over 26.3 kilogrammes (25% of body weight), compared to 1.5% on placebo, according to data not controlled for type 1 error," the company stated.

For diabetes management, the phase 3 SURPASS programme evaluated Mounjaro's efficacy at various doses, both alone and in combination with commonly prescribed diabetes medications over 40 weeks. Participants achieved average A1C reductions (an indicator of long-term blood sugar levels) between 1.8% and 2.1% for the 5 mg dose and between 1.7% and 2.4% for both the 10 mg and 15 mg doses.

Source: *Hindustan Times,* 21st March 2025

Goal is to Offer More Innovative Medicines

Eli Lilly, the $45 bn US pharma giant known globally for its weightloss treatment, Mounjaro (tirzepatide), aims to transform India from an underperforming market into a growth engine by addressing the country's rising diabetes and obesity challenges. Just days after the India launch of its blockbuster therapy, which targets type 2 diabetes and obesity, beating rival Novo Nordisk to this key market—at a fraction of its US price of over $1,000 per month, the company's chair and CEO, David Ricks, highlighted India as one of the most "exciting economic stories globally." Eli Lilly, with a 30-year presence in India mainly through partnerships for its key therapies, plans to accelerate access through local tech collaborations for obesity and diabetes. A 150-year insulin pioneer, it operates two global capability centers, with India as its second-largest employment hub after the US.

It must be an exciting time to be here just days after the launch of Mounjaro in India. How do you see the Indian market evolving?

The therapy is really transformative, and many people were already seeking it in India. It highlights the power of innovation and what Mounjaro is doing for millions worldwide. Tirzepatide is a first-in-class treatment that activates two hormone receptors—glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1)—which play key roles in regulating blood sugar and appetite.

We're optimistic about India's growth and expect to expand significantly with more access to life-saving treatments.

India is the 14th largest market, but most of it is dominated by generics rather than innovative medicines. We believe both can coexist, and generics play a key role in public health. Our goal is to introduce more innovative medicines to the market, while maintaining the importance of generics.

This is your third visit to India as CEO. How do you assess the Indian market over the years?

India is one of the most exciting economic stories globally. It's a vast country, and achieving scale can be challenging, but the pace of progress here is remarkable. Lilly has expanded operations here, and India is now our second-largest market for employment (after the US). We've opened a new service center at Hyderabad, and are leveraging Indian talent for global performance.

We have a good history here and are expanding (Hyderabad GCC) --part of my visit is to check progress on a number of initiatives put in place last year, discuss partnerships that we're forming here to reach more patients in India. The consumer nature of obesity treatments makes partnerships with large tech players in health pathways even more crucial.

How do Trump's policies impact the supply chain for companies like yours?

It's a modest effect for us. We tend to make our own active pharmaceutical ingredients (APIs) and drug products. We have a flexible supply chain, and multiple manufacturing hubs around the world, including in the US, Europe, and Asia.

As regards diabetes, how do you see the future evolving with new treatments?

We've been serving people with diabetes for over 100 years.. and insulin still is a backbone of glucose management for type 1 and type 2 diabetes. The rise in diabetes, driven by obesity, is a major concern. We have a number of oral medications in development, including an oral GLP-1 one with results anticipated in the second quarter.

We also have data from Mounjaro showing a dramatic reduction in the risk of developing diabetes. If we can scale these treatments, we could slow the rise of diabetes significantly

You were the pioneer in commercialising insulin, and now you offer newer therapies like Mounjaro. How do you see the shift in the treatment landscape over the next few years?

Yes, we're hopeful that oral treatments like Mounjaro can play a major role in prevention and help people live healthier, longer lives. We're also developing a triple-active treatment, retatrutide, a next-gen weight-loss therapy that will give patients even more control over weight and diabetes

The core treatment (for diabetes) insulin would continue. But our goal (is), if we can show that we can slow the disease or even stop it before it gets going, before you need insulin.

Besides tirzepatide, we have 11 medicines in clinical trials today that can potentially treat a wide variety of cardiometabolic diseases, as well as R&D efforts for type 1 and type 2 diabetes to obesity and cardiovascular disease.

How is artificial intelligence being utilized in the industry, and what specific benefits is it providing to your company?

We use AI to improve efficiency in clinical trials, manufacturing, and drug development. AI helps us scale and speed up processes. We're also using AI in our research and development, collaborating with external partners.

Interestingly, one of the success stories is the repurposing of an existing drug, baricitinib, during COVID, where AI helped us identify it as a potential treatment. After trials, we found it significantly reduced mortality rates for patients on ventilators, and we donated thousands of doses in India during the Delta wave.

Source: *The Times of India,* 26th March 2025

Indian Generic Drugs Linked to Deaths in US? Trade Group Slams Study Blaming Desi Pharma

A study linking Indian-made generic drugs to a higher risk of serious side effects in the US has drawn backlash from the industry's most influential lobby group, as India moves to defend its dominant market share amid trade tensions under President Donald Trump.

The study, which analyzed more than 2,400 drugs sold in the US between 2009 and 2018, found that Indian generics were associated with a 54% greater risk of serious adverse events — including hospitalization, disability, and death — compared with equivalent domestically made medicines. The research links operations and supply chain issues in the manufacturing process as “most likely” explaining the findings.

Published last month in the journal Production and Operations Management, the findings

prompted a three-page statement from the Indian Pharmaceutical Alliance, which represents two dozen of the country's largest drugmakers.

"We strongly disagree with the study's premise that differences in operations and supply chain factors — suppliers, manufacturing and/or distribution practices by different manufacturers — impact the quality and efficacy of Indian generic drugs," the industry body said in its response.

Still, last month's study — led by researchers with experience working with the US Food and Drug Administration — adds to mounting concerns over the quality of Indian-made medicines. India, the world's largest supplier of generic medicines, produces about a fifth of the global supply and its 752 FDA-compliant factories meet roughly 40% of US demand for non-patented medications.

Between 2018 and 2024, US pharmaceutical imports from India nearly doubled to $13 billion, underscoring the growing influence of the country's drugmakers. Meanwhile, Trump has warned companies to move production to the US or face tariffs of up to 25%, a move that could further strain pharmaceutical firms with rising costs.

Regulatory lapses at Indian factories — including unsanitary conditions, poorly trained staff, and shredded paperwork — have raised concerns worldwide, as many countries rely on India for essential medicines. In 2022, tainted cough syrup was linked to the deaths of dozens of children in Gambia and Uzbekistan, while more recently, contaminated eye drops caused blindness in US patients.

'Quality Corner-Cutting'

The authors of last month's study suggested that "quality corner-cutting" due to cost pressures likely explains their findings. Drugs that had been on the market longer were more frequently linked to adverse events, possibly because manufacturers faced growing pressure to reduce operational and supply-chain costs.

The office of the Drugs Controller General of India and the US FDA didn't respond to requests for comment on the research

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The study is the first to link a large sample of drugs to their manufacturing plants, using the Structured Product Labeling dataset, which contains detailed information on each drug approved for sale in the US, including its application number and production facility. However, the analysis didn't associate specific adverse events with particular classes of medications.

"Our logic and results together imply that manufacturers in India are, on average, operating in a way that results in more quality risk than those in the US, particularly when the drug has been on the market for a relatively long amount of time," the authors wrote.

There is a widespread assumption that generic drugs are the same when they have the same dosage form and route of administration, said study co-author John Gray, a dean's distinguished professor of operations and business analytics at Ohio State University, in an interview.

The Indian pharma body said it believes that the use of data of adverse events to conclude product quality has limitations such as reporting biases and inability to establish causality.

"There has been a significantly greater engagement that the Indian industry and the regulator have had with the FDA in addressing manufacturing and quality operations in the Indian subcontinent," the Indian pharma alliance said, adding that the FDA's enforcement of quality through measures including routine inspections is adequate.

The authors urged the FDA to strengthen oversight, particularly through unannounced inspections. The agency has already increased inspections of Indian factories by 46% between 2014 and 2024, with instances of objectionable conditions rising 38% in the same period, according to its database.

"The FDA mandates things, but firms can voluntarily do quite a bit on their own," the authors noted. Drugmakers should compete on quality and transparency, making it easier for buyers to assess standards. They suggested companies include quality data on labels, benchmark themselves against peers using public records, and leverage superior quality to attract buyers.

The study also called for greater transparency in drug quality, arguing that rewarding better manufacturers with stronger demand and higher prices could help push inferior players out of the market.

Source: *The Economic Times,* 13th March 2025

Prolonged Use of Steroids Linked to Risk of Glaucoma, AIIMS Docs Warn

Prolonged use of steroid-based inhalers for respiratory conditions like asthma and bronchitis, continuous application of nasal sprays for allergies, and steroid-containing skin creams for allergic reactions and cosmetic purposes may lead to glaucoma, doctors at AIIMS have observed.

They have highlighted the issue and advised regular eye checkups, indicating that early identification significantly improves the chances of vision preservation. Glaucoma is a persistent eye condition that can damage the optic nerve, potentially causing vision loss or blindness.

Dr Tanuj Dada, professor-in-charge of the glaucoma unit, emphasised the significance of timely detection. "Glaucoma is is known as the thief of vision because it has no

symptoms until significant damage occurs. After 40, regular check-ups every 1-2 years are essential, even if your vision seems fine."

Dr Dada also cautioned against steroid misuse for children who are often prescribed steroid eye drops by unqualified persons, resulting in glaucoma. He explained that they frequently encountered young children with eye allergies, particularly those from Rajasthan affected by sand-related allergic reactions. These children, when experiencing eye irritation and redness, often get medicines from chemists or seek assistance from unqualified practitioners. Although the immediate allergy symptoms and redness may subside, some children later develop glaucoma.

Students sustaining eye injuries from sports equipment such as balls or shuttlecocks during playground activities should also undergo regular eye examinations as these injuries could progress to glaucoma after 10-20 years.

The doctor also warned against the use of skin whitening creams that mostly contain steroids.

Early-stage detection significantly increases the chances of preserving vision. This service is accessible at every govt-run hospital, said doctors.

Emphasising the need for lifelong care, Dr Dada pointed out, "Once diagnosed, you must use eye drops for life — stopping treatment can lead to further vision loss. New laser treatments and surgeries can help, but unlike cataract surgery, glaucoma surgery only preserves remaining vision; it cannot restore what is lost."

According to doctors, the AIIMS research also linked stress to glaucoma, with meditation and breathing exercises showing potential benefits.

Dr Praveen Vashist, professor and officer-in-charge of community ophthalmology, highlighted the need for nationwide screening. "Most people with glaucoma don't know they have it. We need more awareness and screening programs at the primary care level."

AIIMS operates 21 vision centres offering AI-based glaucoma detection tests, he noted, underlining the need to expand such facilities across India. He also emphasised the importance of adherence to medication, "Putting more than one drop at a time is wasteful — regularity is the key."

Source: *The Times of India,* 16th March 2025

India's Generic Medicines Steal the Spotlight as US Exempts Pharma From Tariffs

India's pharma sector has emerged as a big winner amid Trump's tariff woes, as the US has exempted pharmaceuticals from reciprocal tariffs, recognizing the vital role of India's generic medicines in global healthcare. This decision comes amid US President Donald Trump's announcement of 27 percent tariffs on imports from about 60 countries, including India, in retaliation to high import duties on American goods. Industry leaders are calling this exemption a significant win for India, reinforcing its status as a global pharmaceutical powerhouse.

The US administration's decision to exempt pharmaceuticals from reciprocal tariffs emphasizes the essential role of generic medicines in global healthcare, Sudarshan Jain, Secretary General of the Indian Pharmaceutical Alliance (IPA) told news agency PTI.

Jain highlighted that the exemption underscores the importance of affordable, life-saving generic medicines for public health, economic stability, and national security. "India and the US share a strong, growing bilateral trade relationship, and pharmaceuticals remain a cornerstone of this partnership," he said. Jain also emphasized India's pivotal role in global and US healthcare by ensuring a steady supply of cost-effective medicines. India's pharmaceutical industry, he added, remains committed to furthering the shared priorities of both nations —strengthening the resilience of the medicine supply chain and reinforcing national security by ensuring access to affordable medications for all.

IPA, a network of top 23 Indian pharmaceutical companies including Sun Pharma, Dr Reddy's Laboratories, Lupin, Torrent, and Glenmark, represents the sector's growing influence. Bhavin Mukund Mehta, Vice-Chairman of Pharmexcil and Whole-Time Director of Kilitch Drugs, noted that the pharmaceutical sector is emerging as a clear beneficiary of this decision.

“India exports USD 8.7 billion worth of pharmaceuticals to the US while importing just USD 800 million. This strong trade relationship creates a win-win scenario, driving significant cost savings on life-saving medicines,” Mehta stated.

He also highlighted that Indian exporters stand to gain a competitive advantage over their Asian counterparts, strengthening India's global leadership in pharmaceuticals.

Sheetal Arora, Promoter and CEO of Mankind Pharma, described the exemption as a strategic recognition of the critical healthcare dependencies between the US and India. Arora pointed out that the US healthcare system heavily depends on India's robust generic manufacturing and China's active pharmaceutical ingredient (API) production. Any disruption in these supply chains would

have immediate, severe consequences for patient care, he added

Arora also emphasized that the exemption provides India with an opportunity to reshape its pharmaceutical sector. By focusing on next-generation generics, accelerating biosimilar development, and boosting domestic API production, India could reduce geopolitical vulnerabilities and further strengthen its position as the global pharmacy. He mentioned that initiatives like the Production Linked Incentive (PLI) scheme, along with targeted R&D incentives and regulatory harmonization, offer a framework to drive this transformation.

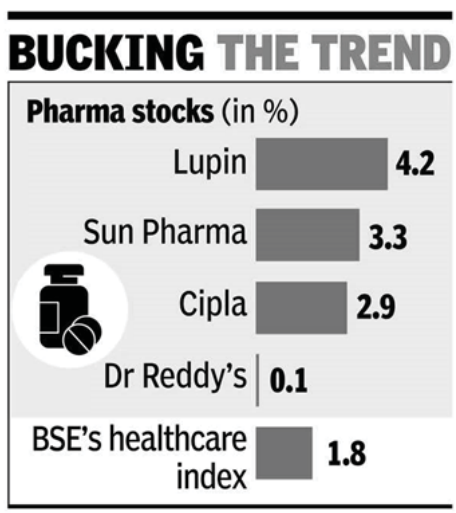
The pharmaceutical sector is India's largest industrial export, valued at USD 12.72 billion in 2024. Indian pharmaceutical companies supply a significant portion of drugs to the US, with four out of ten prescriptions filled in the US in 2022 coming from Indian companies. In fact, medicines from Indian companies saved the US healthcare system USD 219 billion in 2022 and a total of USD 1.3 trillion from 2013 to 2022. Over the next five years, generics from Indian companies are expected to generate an additional USD 1.3 trillion in savings.

Experts had previously warned that higher tariffs on pharmaceutical imports to the US could increase production costs for Indian drug manufacturers, making their products less competitive. Smaller drug firms, operating on thin margins, could face financial pressure, potentially leading to consolidation or closure.

Source: *The Times of India,* 3rd April 2025

Pharma Companies Escape Bitter Pill, for Now

The Trump administration's decision to exempt tariffs on pharma imports from India calmed industry nerves, delivering relief to a sector tied to India's $9 billion-plus US export market. This move underscores the critical role of India's domestic pharma industry in supplying cost-effective, life-saving generic medicines, with the US relying on India for nearly 30% of its prescription medications. The sector was jittery with the expectation of a 10% tariff on Indian pharma exports to the US. However, some analysts caution that this relief may be short-lived, saying tariffs are not completely ruled out for the future.



Sudarshan Jain, secretary general, Indian Pharmaceutical Alliance, says, "India and the US share a strong and growing bilateral trade relationship, with a shared vision to double trade to $500 billion under the Mission 500 initiative. Pharmaceuticals remain a cornerstone of this partnership, as India plays a vital role in global and US healthcare by ensuring a steady supply of affordable medicines."

Meanwhile, the medical device sector wasn't as fortunate, facing the brunt of new tariff challenges and cost pressures. "The imposition of a 26% reciprocal tariff on Indian medical device exports to the US may pose a significant challenge to the sector's growth. Historically, India has been a key supplier of cost-effective, high quality medical devices to the US, primarily in low-value, high-volume consumables categories. However, this new tariff may possibly impact domestic medical devices exports, and we have to explore windows of opportunities where the US has been seeking to diversify its supply chain dependence on any one nation," Rajiv Nath, forum coordinator, AiMeD, said.

In 2023-24, India's medical device exports to the US stood at around $714 million, while US exports to India were double, around $1,500 million, as per data shared by the Exports Promotion Council of Medical Devices. India levies a duty of 0 to 7.5% on imports of medical devices, with most devices charged at 7.5%. Medical devices include consumables and disposables (gloves, syringes, PPP kits), electronic equipment, instruments, implants, and IVD reagents.

Source: *The Times of India,* 4th April 2025

FDA Uncovers 'Significant' Data Falsification by Indian Company, Rejects All Studies

The U.S. Food and Drug Administration (FDA) has notified an unspecified number of drug companies that data from all in vitro bioequivalence studies conducted by the Navi Mumbai-based contract research organisation (CRO) Raptim Research Ltd "must be rejected" due to data falsification. The letter mentions that the FDA had identified data falsification for "multiple subjects/samples across multiple studies".

The FDA had inspected the company between April 24 and April 28, 2023, and also carried out post-inspection data analyses. The letter further says that because Raptim Research has been "responsible for the creation of false in vitro study data", it has "no reason to believe that any in vitro data that Raptim [Research] has produced are reliable". Hence, the FDA has "determined that all study data from all in vitro studies conducted at Raptim [Research] must be rejected". The drug regulator has told the companies that the data generated by Raptim Research will not be sufficient to support a bioequivalence finding. The companies have been asked to reconduct the in vitro studies at an alternate study site besides Raptim Research.

In an email dated March 27, 2025, the FDA told Rajen Shah, Owner and Director of Raptim Research, that "significant objectionable conditions" were observed during the inspection and data analyses. As per the email, the FDA had sent a General Correspondence Letter (GSL) on August 6, 2024, asking the company to provide specific responses to the concerns raised by it about the falsified data that were submitted. The FDA had observed "nearly identical concentration profiles between different donors in different studies for different sponsors".

Regarding FDA's concerns about data falsification, it said "in vitro study conduct resulted in the submission of false information to FDA regarding the measurement of the bioavailability of a drug product or the demonstration that a drug product is bioequivalent to a reference listed drug".

The September 4, 2024, and October 17, 2024 responses by the company had failed to "adequately address FDA's concerns or substantively explain what caused the significant data anomalies" in the studies, leading to the FDA sending the letter on March 27, 2025. The FDA's email to Raptim Research also mentions that the company failed to "provide a legitimate, scientifically valid reason why the evidence of falsification of data discussed in FDA's GCL should not call into question all in vitro study data generated by your firm". The company also failed to provide "specific corrective action plans that fully address the identified pattern of in vitro and in vivo issues".

Source: *The Hindu,* 5th April 2025

Trump's Tariffs: Exporters Seek Restoration of Benefits, Bilateral Deal Push

Staring at a steep dent, exporters have asked govt to restore several benefits that have been stopped, such as the interest equalisation scheme and Remission of Duties and Taxes on Exported Products (RODTEP) for SEZ and export oriented units, while prioritising sectors that will be more adversely hit by Trump's tariffs during the first tranche of the trade agreement with the US.

While life is looking challenging for all sectors, given the steep 26% levy imposed on all Indian exports to the US, marine products, dairy, medical equipment, machinery and carpets are among sectors that are seen to be the hardest hit. Given that these are also labour intensive sectors, govt may be inclined to push them more aggressively

Sources, however, indicated that there is no clarity on how the Trump administration will lower tariffs even if govt were to offer immediate concessions, which would be permanent in nature.

KEY GAINERS & LOSERS

	India's exports to US (In 2023 $bn)	US Existing Tariff (%)	Tariff effective April 9 (On India)	Tariff effective April 9 (On top competitor)	Impact
Textiles/Apparels	3.7	0-12	26%	China (54%)	Gain
Electrical machinery & equipment	7.4	0	26	China (54)	Gain
Machinery & mechanical appliances	2.2	0-3.8	26	China (54)	Gain
Precious or semi-precious stones	9.9	0-13.5	26	Switzerland (31)	Gain
Marine Products	2.2	10	26	Chile (10)	Loss
Chemical products	0.7	0-6.5	26	Germany (10)	Loss
Vehicles & parts and accessories	1.5	0-27.5	25*		Status Quo
Articles of iron or steel	1.1	0	25*		Status Quo
Pharma	7.1	0	Exempted		Status Quo
Petroleum products	6.3	0	Exempted		Status Quo

*25% tariff under separate order, has already come into force, but for auto component (additional tariff to be implemented no later than May 3, 2025)

Source: PwC

A day after the tariff hike was announced, govt departments actually got down to gauge the impact. Several exporters, who were drawing from India's tariffs being lower than some of its rivals were also more measured in their response, having assessed the possible extent of damage. A section of businesses has petitioned that govt should seek a deferment of reciprocal tariffs with the US authorities, given that India is already negotiating a bilateral trade deal. Officials, however, see little chance of Trump agreeing to accept the demand.

Sources in govt, however, appeared more amenable to accepting some of the demands of exporters, particularly enabling them to beat some of the handicap by allowing for interest subsidy, especially for labour intensive sectors, such as textiles, leather and handicrafts.

The scheme was discontinued in Jan and despite repeated suggestions from the commerce department, the finance ministry has refused to restart it. Similarly, RODTEP stopped in Feb for a section of exporters while the entire scheme is due to end in Sept with no guarantee of extension. "It will provide much-needed certainty," said an industry executive
The commerce department is working on some other steps, which are expected to be expedited now.

Some exporters have suggested that govt provide some assistance in helping them diversify their markets at a time when every country is seeking to reduce their exposure to the US and derisk their exports. Besides, the proposal is meant to ensure some of the edge that will accrue to countries like Turkiye in, say, textiles can be blunted with the support.

Source: *The Times of India,* 5th April 2025

Central Labs Find 47 Drug Samples to be 'Not of Standard Quality': Government

Central drug testing laboratories have identified 47 drug samples to be 'not of standard quality (NSQ)' in the latest survey. These include some batches of commonly used vitamin supplements, antibiotics and antacids.

Identification of drug samples as NSQ is done based on failure of a drug sample in one or the other specified quality parameters, according to the health ministry. The failure, it said, is specific to drug products of a batch tested by a govt laboratory - a routine process carried out every month. "It does not warrant any concern on the other drug products available in the market," the ministry said.

State drug testing laboratories have also identified 56 drugs. In Feb, govt had said that one sample from Bengal had been identified as a spurious drug, which was made by an unauthorized manufacturer using a brand name owned by another company. The matter is under investigation.

Officials stated that NSQ, misbranded and spurious medicines are regularly identified and removed from the market through coordinated efforts with state regulators.

Source: *The Times of India,* 31st March 2025

3 Lotion Companies Fail to Prove 'Skin Whitening' Claims, Fined

Advertisements on e-commerce platforms that claim certain body lotions can whiten your skin in just minutes always sounded fictitious. What you doubted has turned out to be true. In three recent cases, companies have admitted to the Central Consumer Protection Authority (CCPA) that these were exaggerations and they resorted to such claims of "unique selling point (USP)" to just come up on e-commerce platforms.

In orders passed by the CCPA in Feb against four companies selling whitening creams and body lotion, including the three which cited USP, the consumer watchdog has recorded how the companies failed to substantiate their claims. They withdrew their advertisements from e-commerce platforms after the authority issued notices to them

In all these cases, investigations by the Bureau of Indian Standards confirmed that the companies failed to provide any scientific validation to their claims or any proof to support their claims. It has imposed fines on these entities and instructed them not to make such unverified and unsubstantiated claims. It cautioned them of a Rs 50 lakh fine for repeat of offence.

Interestingly, in all the four cases, the companies claimed they were unaware of the law against misleading advertisements of the CCPA

Source: *The Times of India,* 1st April 2025

World's Smallest Pacemaker, Tinier than the Size of A Rice Grain, is Here: How it Works

In a breakthrough development, scientists from Northwestern University, have unveiled the world's smallest pacemaker, tinier than one could ever imagine- even smaller than the size of a rice grain. The revolutionary device, in the early stages of development, offers a temporary solution for regulating heartbeats and could dramatically change the future of heart care. The findings have been detailed in a study published in Nature.

Powered by light and capable of dissolving into the body once no longer needed, this pacemaker marks a significant leap forward in medical technology.

While it would take years before it can be tested in humans, the wireless pacemaker is considered a "transformative breakthrough" which could also pave the way for other advancements in other areas of medicine.

“We have developed what is, to our knowledge, the world's smallest pacemaker,” said Northwestern bioelectronics pioneer John A. Rogers, who led the device development. “There's a crucial need for temporary pacemakers in the context of pediatric heart surgeries, and that's a use case where size miniaturization is incredibly important. In terms of the device load on the body — the smaller, the better.”

“Our major motivation was children,” said North western experimental cardiologist Igor Efimov, who co-led the study. “About 1% of children are born with congenital heart defects — regardless of whether they live in a low-resource or high-resource country. The good news is that these children only need temporary pacing after a surgery. In about seven days or so, most patients' hearts will self-repair. But those seven days are absolutely critical. Now, we can place this tiny pacemaker on a child's heart and stimulate it with a soft, gentle, wearable device. And no additional surgery is necessary to remove it.”

A permanent or classic pacemaker is a device that can be placed in your body, usually by surgery, to support the electrical system in your heart. This helps in stabilizing abnormal heart rhythms and preventing problems that can disrupt or endanger your life.

What is the difference between a permanent pacemaker and a temporary pacemaker?

In some cases, a pacemaker is needed for a short time to assist heart function. This is especially done when heart rate changes owing to open-heart surgery, heart attack, infection, medication or other issues. This kind of pacemaker stays in place until your heart rate is stabilized, typically for just a few days. Permanent pacemaker is implanted only when things don't improve on their own. Another distinctive trait that sets the new pacemaker apart is its ability of being wireless. It's just one millimeter thick and 3.5 millimeters long, and can fit into the tip of a syringe.

Besides it doesn't have to be taken out from the body as it is designed to dissolve into the body when no longer needed.

Temporary pacemakers currently need surgical procedure to sew electrodes onto heart muscles, with wires connecting to a powered device on the patient's chest. When the pacemaker serves its purpose, doctors or nurses pull out the wires, which can at times cause damage.

The pacemaker is connected to a soft patch worn on the patient's chest, as described in a study published in the journal Nature.

When the patch detects irregular heartbeats, it emits a light signal that instructs the pacemaker on the appropriate heartbeat to stimulate.

The pacemaker is powered by a galvanic cell, which harnesses the body's fluids to convert chemical energy into electrical pulses that regulate the heart.

According to the study, the pacemaker has shown effective results in tests on mice, rats, pigs, dogs, and human heart tissue in the lab.

When are human trials expected to be launched?

Senior study author John Rogers of Northwestern University in the United States told AFP that the pacemaker could be tested in humans in approx. two to three years and his lab has launched a start-up for the same.

Source: *The Times of India,* 4th April 2025

Pharma Companies Need to Look Beyond US Market

With the Trump administration's flip-flops on tariffs giving the Indian pharma industry a headache, experts feel it's time the sector looked at an 'America plus' strategy to reduce heavy dependence on US consumers and explore other markets to derisk business.

The US market dominates India's pharma exports, accounting for over 30% ($9 billion) of the total $28 billion in FY24, while the European Union stands as the second-largest market at around $4 billion. "The industry was relieved when Trump did not announce any tariff earlier and put a 90-day pause on tariffs after earlier stating his intention to impose tariffs on pharma, but the situation is still very dicey," said an industry source.

Many major Indian pharmaceutical companies, including Dr Reddy's, Sun Pharma, and Aurobindo, derive 40-45% of their revenues from the US market, making them particularly vulnerable to any adverse policy changes. Prescribing an 'America Plus' strategy for the Indian pharma sector, former Pharmaceuticals Export Promotion Council of India (Pharmexcil) Director General Ravi Uday Bhaskar said there are significant

opportunities in the global generic drug market, which is projected to grow from $430 billion currently to $790 billion by 2030. He advocated market diversification for the Indian pharma sector while maintaining their US presence.

"We can't leave the US as 31% of our products go there, but we also need to look at expanding to other geographies. There is a huge opportunity we can tap in Latin America, Africa, and Asean," said Bhaskar. However, industry sources pointed to some challenges in finding alternative markets that could match the US market's scale.

Source: *The Times of India,* 11th April 2025

Indigenous TB Test Can Enhance Accuracy, Speed up Testing

Researchers at the Thiruvananthapuram - based Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) have developed and tested a novel, cost-effective, real-time LAMP (rt-LAMP) assay for early diagnosis of TB. Much like GeneXpert and Truenat, the rt-LAMP assay too is a molecular test with high sensitivity and specificity. The rt-LAMP assay was able to detect TB DNA even when only 10 copy numbers were present per microlitre in a sample.

The main handicap that prevented the use of LAMP for TB diagnosis so far was the inability of using any dye, as dyes generally inhibit reaction leading to false negatives. Researchers at SCTIMST have overcome this challenge by turning to a fluorescent dye Syto 16, which is routinely used in labs for studying cells and other biological samples. And unlike RT-PCRs that require three different temperature settings to complete a test, the rt-LAMP test works at a single temperature. Since a fluorescent dye is used, the amplification can be measured not at the end of the run but every minute.

"With six primers used for amplification compared with two in the case RT-PCRs, the rate of amplification is high, and hence results of positive samples can be obtained in 10-20 minutes," says Dr. Anoopkumar Thekkuveettil from SCTIMST and the corresponding author of a paper published in Scientific Reports. "Since all six primers need to bind to the DNA for amplification to begin, the rt-LAMP assay has very high specificity." Since no probe is used unlike in the case of RT-PCR tests, and as the dye and primers are inexpensive, the rt-LAMP test becomes highly affordable.

The assay was tested on 350 presumptive pulmonary TB sputum samples. The rt-LAMP kit was evaluated against a microbiological reference standard (MRS), GeneXpert, and smear test. The study was conducted from October 2019 to March 2020 and from January 2023 to March 2024. The rt-LAMP assay demonstrated slightly higher

sensitivity and specificity than the GeneXpert assay. Compared with MRS, rt-LAMP showed 89.36% sensitivity and 94.06% specificity.

"The rt-LAMP assay kit has been developed as an open platform system which allows existing RT-PCR machines to be repurposed for TB diagnosis. This can be done by programming an existing RT-PCR machine to run at one temperature setting instead of three," Dr. Anoopkumar says. "It is possible to process up to 96 or 384 tests in a single run. Thus the assay facilitates high throughput testing, allowing for a large number of patient samples to be processed in a single run."

"The technology has been licensed to industry, has received approval from CDSCO, and is currently being validated by ICMR. The WHO Health Technology Access Pool program is currently evaluating the technology and is waiting for ICMR validation," he says.

With nearly 79% of presumptive TB cases in India diagnosed using sputum smear microscopy and only 21% tested using molecular assay as recently as 2023, India continues to over-rely on smear microscopy for TB diagnosis. Despite an increase in molecular testing facilities from 5,090 in 2022 to 6,496 in 2023, it is nowhere close to meeting the National Strategic Plan 2017-2025 of reducing the reliance on smear microscopy.

Source: *The HIndu,* 12th April 2025

Experts Warn Against Overuse of Last-Line Antibiotics

Infectious diseases experts have flagged the overuse of a potent antibiotic leading to it losing its efficacy, and drug resistance. The Drugs Controller General of India has been urged to lay down strict pathways for these newer antibiotics, so that they are not misused by practitioners.

Abdul Ghafur, infectious diseases specialist, and founder of the AMR Declaration Trust, has written to Rajeev Singh Raghuvanshi, DCGI, about ceftazidime-avibactam. "One of the most potent antibiotics currently available in our armamentarium is rapidly losing its efficacy due to extensive, irrational, and uncontrolled use."

The drug which was initially registered with the U.S. FDA in 2015 and approved in India three years later is a last-line antibiotic. It is to be used as targeted therapy for certain carbapenem-resistant gram-negative infections and not prescribed as a broad spectrum antibiotic.

Dr. Ghafur however claims it is already being misused in the community. "To overcome this resistance, aztreonam is often added to ceftazidime-avibactam, unfortunately, resistance has now emerged even to this combination, due to irrational use."

The problem, he explains, is that while the DCGI has licenced the drug, it has only provided indications for use. There are no clear-cut pathways laid out, and nothing to deter mis-prescriptions.

This trend could erode the huge gains secured in India primarily with the ban on use of colistin as a growth promotion drug amongst poultry, in recent times. This 'bold and meaningful action' from the government resulted in a significant drop in prevalence of colistin-resistant bacteria in hospitals in India, he adds.

Rational use

There are two new very powerful antibiotics that are about to enter the Indian market, Cefierocol and Cefepime-zidebactam. Dr. Ghafur urges the DCGI to kick in with antibiotics stewardship: “We need these drugs in India. However, their use must be restricted strictly to infections where no other effective alternatives exist. Education alone is not enough; we need a clear regulatory pathway to ensure the rational use of these molecules from the moment they are licensed.

“If we do not act now, we risk losing the few therapeutic options left. Antimicrobial resistance (AMR)is already a serious crisis in our country. Without urgent and strong action, it may escalate to an unmanageable level. We cannot change the past — but we still have time to act for the immediate future,” he says.

Source: *The HIndu,*24th April 2025

Patients With Rare Spinal Disorder Closer to Life-Saving Med for 1st Time

Rustom Irani (45), an Andheri screenwriter, has been racing against time all his life. Diagnosed with type 2 spinal muscular atrophy (SMA) at 13, whose symptoms appeared earlier, he has spent decades watching his body weaken, knowing that his condition would only deteriorate.

"Every couple of months, our patient support groups get a message about a child's death because the disease had advanced," he says.

For Irani and over 1,000 SMA patients in India, about 200 of whom are in Mumbai, life-saving treatments remain out of reach, with medicines priced in crores. But last month, the community finally saw hope—Delhi HC allowed Natco Pharma to market a generic version of risdiplam, a drug developed by US-based Roche. While Roche's version costs Rs 6.2 lakh per bottle, Natco promised to slash the price to Rs 15,900. One bottle lasts about a month. But the breakthrough hangs in legal limbo. Roche has appealed the verdict, and the case awaits a review by a division bench.

SMA is a rare genetic disorder that destroys motor neurons and progressively robs patients of muscle strength. Type 1, the most severe, strikes infants; types 2 and 3 manifest in childhood or adolescence; and type 4, the mildest, often appears after 30.

“It's a lifelong treatment, and even at the proposed generic manufacturer's price, many still can't afford it," says Karan Shah (31), a Dadar resident and dog trainer who was

diagnosed with SMA at 17. He says it now feels like another endless wait. "The case will take time to be resolved, and for SMA patients, time is a matter of life and death," says Shah, who lost his older brother to SMA a few years ago.
Neither Shah nor Irani has ever had access to any of the medicines. Irani says fundraising efforts often fail for adults compared to children. Both have relied on interventions like physiotherapy.

"In the absence of medication, adherence to supportive care becomes essential," says a doctor from BMC-run KEM Hospital who works with rare disease patients. The hospital's Centre of Excellence for Rare Diseases treats patients and helps families secure the Centre's one-time Rs 50-lakh aid for rare diseases.

Badlapur's Kirti Singh has been trying to get this aid since 2023, when her two-year-old daughter was diagnosed with SMA. "We've been told the hospital is still waiting for funds from govt," she says. Singh says even if the aid is offered, it would only cover the cost of medicine for about one year. "We were lucky to be included in Roche's sampling programme, which provided a six-month dose, soon after diagnosis. Since then, we've managed to buy medicines through fundraising, but that can last just a little longer."

Dr Neelu Desai, a paediatric neurologist at PD Hinduja Hospital, says the drug's generic version will be a win for patients. "The condition can't be reversed, but the drug can prevent it from worsening." Dr Desai had facilitated gene therapy, a one-time dose costing Rs 8-14 crore, in 13 infants in 2021. She says 10 of them survived and are doing well. "The disease in the other three had advanced by the time they received the medication."

K M Gopakumar, senior researcher at Third World Network whose work focuses on global intellectual property rules, says if Delhi HC's division bench upholds the single bench's order, the generic manufacturer will be able to market it even if the global company goes to Supreme Court. "But if the generic manufacturer loses, the case will be prolonged."

Source: *The Times of India,* 26th April 2025

When A Spoonful Becomes Lethal: Hidden Risks with Child Medication

A child suffering from acute gastroenteritis was prescribed an Oral Rehydration Solution (ORS) by a doctor. While the prescription detailed the child's age, weight, diagnosis, and instructions on dissolving the sachet in 200ml of water, the doctor inadvertently missed specifying a 'paediatric' ORS sachet. The pharmacist, unaware of this crucial detail, dispensed an adult ORS sachet, which is meant to be dissolved in one litre of water. Following the instructions on the prescription, the parents

gave their child a highly concentrated dose of ORS. The child subsequently developed seizures and kidney failure and succumbed to these complications.

Such scary mess-ups are more common than you think. Though there is no Indian study on this, a US study published in the journal Clinical Pediatrics in 2023 found that every eight minutes, a child in the US gets a wrong dose of medicine at home.

Weight decides dose

"For children's medicines, all calculations are weight-based ones. Giving too much or too little medication can have serious consequences. But there's scant awareness about this," says senior paediatrician Dr Bala Ramachandran, who heads the intensive care unit at the Kanchi Kamakoti Childs Trust in Chennai. Paediatric medication errors can occur at various stages — while prescribing, dispensing, and administering — he points out, adding, "There must be constant effort from healthcare providers, caregivers, and other stakeholders to ensure that such errors don't happen."

The Indian Paediatrics Association has been urging the govt to standardise dosages of common liquid medicines such as paracetamol, one of the most used drugs in children to avoid such confusions. There are different concentrations of liquid paracetamol (120mg/5ml, 125mg/5ml and 250mg/5ml) available. "It's hard to believe paracetamol is harmful but nearly 85% of patients, aged from a few months to 17 years, admitted to our hospital with paracetamol poisoning had liver injury," says Dr Ramachandran

In one instance, a nurse had mistakenly overdosed her three-year-old with paracetamol. Her six-month-old had been prescribed Crocin drops (100mg per drop) for fever. A day later, when her three-year-old fell ill, the doctor prescribed a teaspoon of Crocin syrup (120mg). The three-year-old was given a spoonful of the drops instead of the syrup, resulting in an overdose that required over two weeks of hospitalisation. In March, the same drop-syrup confusion led to an eight-month-old boy in Kerala needing critical care.

Be candid about medication

Most medication errors in kids are preventable. And often, it's because the medicines are within the child's reach. There have been several instances where toddlers drank up from syrup bottles because they were strawberry or cherry flavoured. "Most parents tell kids that they are giving them sweet treats for fever while feeding the medicines. Though there are child protection locks on most medicine bottles, we must admit kids are smart and learn to open them," says senior nurse Stella Thomas from a private hospital in Chennai, who regularly advises parents to keep all medications, including over-the-counter products, vitamins, and supplements, out of children's reach and sight. "It's more important to tell kids they are being fed medicines and the reason for it. They must understand that medicines cannot be taken without their permission," she adds.

Parents must spend time discussing the prescription with the doctor before they leave the consultation room. If they can't, they must talk to the chemists at the drug store for clarity. “And for this, it is always better to visit a shop physically instead of buying drugs online,” says Tamil Nadu Chemists and Druggists Association president S A Ramesh

Qualified chemists tell customers what medicines must be taken with water, what can be taken with milk or juice, and what must be taken before or after food. “It's important to follow these instructions for drugs to work well. Most chemists, like family physicians, know the families. So, even if a customer is buying an over-the-counter product as simple as a sachet of fruit salt, which is high on sodium and not recommended for those with hypertension, they may ask them why,” he adds.

In 2021, the American Academy of Paediatrics (AAP) had recommended that doctors educate parents on how to administer correct medicine dosages as well as store them safely. “Make medication regimens as simple as possible. Encourage the use of a standardised dosing tool with all liquid medications. Provide dose amount using millilitre units only, and avoid spoon-based or nonmetric units,” AAP had said.

Tamil Nadu director of public health Dr TS Selvavinayagam recently warned against picking up ready-to-drink rehydration beverages marketed in tetra packs or bottles as substitutes for ORS packets, after complaints from doctors. “Dehydration cases rise in summer, particularly among the elderly and children. We often see even hospital pharmacies offering customers tetra pack liquids that are not ORS,” he pointed out, adding that the ready-to-drink versions may not provide adequate electrolyte replenishment, and may even worsen dehydration and diarrhoea.

Preventing common medication errors in kids demands collective vigilance from healthcare providers, pharmacists as well as parents, with clear communication and safe home handling. “We need to increase awareness among all healthcare providers, common people, as well as policymakers,” says Dr Ramachandran.

Source: *The Times of India,* 6th May 2025

Pharmacy Council Introduces New Rating System for Colleges

Currently, Gujarat and neighbouring regions lack a uniform rating system for pharmacy colleges, which poses difficulties for students and parents in evaluating institutional standards, infrastructure, and educational parameters.

The Pharmacy Council of India has collaborated with the Quality Council of India (QCI) to develop a comprehensive rating structure for pharmacy colleges. The evaluation process will begin soon, with institutions being assessed across 11 specific

parameters set by the council. These assessment criteria include infrastructure quality, faculty qualifications, research output, academic performance, placement records, and other relevant aspects. This system intends to assist students and parents in selecting suitable educational institutions.

Pharmacy institutions interested in participating for the 2025-26 academic year must complete their applications and registration procedures. All participating colleges are required to attend QCI orientation programmes before joining the assessment scheme. Additionally, institutions need to provide necessary details via an online portal as per QCI guidelines.

The assessment fee for participating institutions is Rs 1 lakh. The QCI registration and fee submission period is scheduled from May 15 to 30. Following this, institutions must submit their inspection and assessment applications between June 1 and July 7. The final institutional ratings will be announced after the completion of the evaluation process.

Source: *The Times of India,*7th May 2025

Phase III Clinical Trials of Bharat Biotech's Oral Cholera Vaccine Over

Vaccine maker Bharat Biotech on Wednesday said its oral cholera vaccine Hillchol has successfully completed phase III clinical trials.

The double-blind, randomised phase III clinical trial was to evaluate safety, immunogenicity, non-inferiority and lot-to-lot consistency of single component of the OCV in comparison to a comparator vaccine (Shanchol) in a participant group of 1,800 individuals, from infants to adults, across 10 clinical sites in India.

The primary endpoint focused on the proportion of participants achieving >4-fold increase in vibriocidal antibody titres against Ogawa and Inaba serotypes 14 days after two doses. Secondary endpoints included Geometric Mean Titre (GMT) measurements and safety.

"Hillchol demonstrated a greater than 4-fold rise in vibriocidal antibodies against both Ogawa (68.3%) and Inaba (69.5%) serotypes, proving non-inferiority to licensed vaccines... supporting its potential as an effective OCV," Bharat Biotech said in a release on the study findings published in the Vaccine journal Science Direct.

Paves way for distribution

Adverse events were mild and comparable between the two vaccines. The vaccine was well-tolerated and immunogenic across all age groups — including infants, children, and adults. The trials pave the way for distribution of Hillchol within the next few months, it said.

"The publication [of the study] reaffirms our commitment to advancing vaccines built on rigorous research, thorough clinical trials and

reliable clinical data. It highlights our continued commitment to providing affordable, effective and accessible vaccines for the populations who need them the most," Executive Chairman Krishna Ella said.

Cholera is a vaccine-preventable disease that faced a surge in outbreaks along with a huge shortage of vaccines. Hillchol features a simplified single stable O1 Hikojima strain. It aims to enhance production efficiency and affordability, particularly in lower- and middle-income countries where waterborne diseases continue to pose serious health threats, he said.

Global demand for OCVs is close to 100 million doses a year. Given that only one manufacturer supplies them, there is a global shortage. Bharat Biotech's facilities in Hyderabad and Bhubaneswar have a capacity to produce up to 200 million doses of Hillchol, the company said.

BBV131 - trade name Hillchol – has received market authorisation in India.

Source: *The Hindu,* 21st May 2025

Silk and Collagen Based Gel to Speed up Wound Healing

Silk has long been worn on the skin. Now, city scientists have found a way to make it help the skin heal too.

A research team at CSIR-Central Leather Research Institute (CLRI) developed a new gel by combining silk fibroin and a lab-made collagen-like protein. The gel, called PASCH (Photo-activated Silk fibroin and Collagen-like protein Hydrogel), is designed to speed up wound healing and support the body's natural repair process.

Silk fibroin, extracted from silkworm cocoons, is safe for the body but does not support cell growth well. To solve this, scientists added a lab-made collagenlike protein, CLP-BS. While natural collagen aids skin repair, it comes with risks like allergies and instability. The synthetic version avoids these problems.

The two proteins are bonded using visible blue light and riboflavin (vitamin B2), which safely trigger strong chemical bonds known as dityrosine crosslinks. This process helps form a stable gel without the need for UV rays or harmful chemicals.

Researchers say the hydrogel can be used for diabetic wounds and burn injuries. It can be applied directly, carried easily, and stored in a regular refrigerator or even at room temperature (around 27C) without losing effectiveness. The gel keeps wounds cool and moist, which supports healing and reduces discomfort. It is also biologically compatible and unlikely to trigger allergic reactions.

"The hydrogel would benefit elderly patients the most. Their skin is fragile, and frequent dressing is difficult. A self-managing gel that maintains hydration and supports healing

without extra help is ideal," said Scientist Niraikulam Ayyadurai of the Department of Biochemistry and Biotechnology, CLRI.

The team tested different silk-to-collagen ratios and found the 7:3 blend worked best. Researchers said it formed a porous gel that allowed skin cells to grow, spread, and move. It absorbed wound fluids and broke down slowly, which is helpful for deep or long-lasting wounds. The material also showed strength, flexibility, and thermal stability

The team found lab tests with human skin and blood vessel cells showed faster cell movement and growth. The gel supported quicker wound closure and boosted proteins that aid tissue repair. It also reduced inflammation and did not damage red blood cells, suggesting it may be safe for use inside the body.

The team is now planning clinical studies with this and other hybrid materials developed for wound healing.

Source: *The Times of India,* 28th May 2025

How Blood Sugar Might be Quietly Stealing Your Memory, Brain Power

When Meena — a 62-year-old retired schoolteacher in Pune — began forgetting appointments and repeating herself, her family initially brushed it aside as part of normal aging. But then she started struggling with basic tasks, even leaving the gas burner on for hours in one instance. Alarmed, the family took her to a neurologist who gave an unexpected diagnosis: Alzheimer's disease, with diabetes likely playing a central role. “We had been managing her diabetes for 20 years,” says daughter Anjali. “We knew about the risks to her kidneys and eyes, but no one warned us about memory loss.”

For decades, public messaging around Type 2 diabetes has focused on complications like blindness, heart problems, kidney failure and amputations. But recent studies confirm a quieter, equally devastating consequence — the erosion of memory, cognition, and identity. “Insulin is not just a hormone for sugar control, it's vital for brain health. When the brain becomes resistant to insulin, memory begins to falter. People often don't realise that diabetes can quietly damage the brain over time,” says endocrinologist Dr Uday Phadke.

Forty and forgetful

It's particularly worrying for India, home to over 100mn diabetics, according to a Lancet study, with many being diagnosed in their 40s and even 30s. A 2021 study by European researchers published in JAMA Network Open observed more than 10,000 people aged between 35 and 55 years for more than three decades. For every 1,000 people with Type 2 diabetes examined annually, the dementia rate was 10 for those with onset around five years ago, 13 for onset six to 10 years earlier, and more than 18 for those with onset a decade ago.

So, the longer the exposure to elevated blood sugar, the higher the lifetime risk of significant cognitive decline. “We are seeing diabetics in their 40s already experiencing symptoms like brain fog and forgetfulness,” says Dr Phadke. India's diabetes epidemic, coupled with a rapidly aging population, means its dementia rates are also set to explode. A Lancet study predicts a 197% rise in dementia cases in India by 2050 — among the sharpest increases globally.

“Diabetes affects the brain through multiple pathways,” says senior neurologist Dr Sudhir Kothari, adding, “It causes inflammation, damages the tiny blood vessels that feed the brain, and interferes with the brain's ability to clear out toxic proteins like amyloid-beta, a hallmark of Alzheimer's. Over time, this buildup accelerates nerve cell death and memory loss.”

'Type 3 diabetes'

The link is so strong that researchers have begun referring to Alzheimer's as 'Type 3 diabetes'. It's not that everyone with diabetes will get Alzheimer's, but having diabetes doubles the risk. Obesity can triple it, say experts.

Contrary to earlier beliefs, this is not because the brain needs insulin. In Alzheimer's, the brain shows both insulin resistance (like Type 2 diabetes) and insulin deficiency (like Type 1). This double blow prevents brain cells from using glucose properly, causing them to starve, which sets off a chain reaction — inflammation, toxic buildup, and nerve cell death.

Though Alzheimer's is the most common form of dementia among diabetics, vascular dementia caused by damage to the brain's blood vessels is also common. “Among long-standing diabetics in India, what we see more often is mixed dementia — where patients have features of both Alzheimer's and vascular dementia. This reflects how diabetes affects both brain metabolism and blood vessels,” says Dr Kothari.

Even those without diabetes are not spared if their blood sugar levels are consistently high. A 2013 study published in the New England Journal of Medicine found that people with glucose levels above 115 mg/dL — still within the normal range — had an 18% higher risk of dementia. Those with diabetes and poorly controlled blood sugar faced a 40% higher risk.

The unique risk profile of Indians — high-carb diets, low physical activity, and a genetic predisposition to belly fat and insulin resistance — compounds the crisis. Cultural stigma often delays diagnosis. “In many households, memory lapses are still disregarded as stress or normal aging while patients suffer in silence,” says Dr Kothari.

Source: *The Times of India,* 10th June 2025

US Approves Gilead's Twice-Yearly Injection to Prevent HIV

The US Food and Drug Administration approved Gilead Sciences' twice-yearly injection to prevent HIV -- a move the company hailed as a major breakthrough in the fight against the sexually transmitted virus.

Drugs to prevent HIV transmission, known as pre-exposure prophylaxis or PrEP, have existed for more than a decade. But because they typically require taking a daily pill, they have yet to make a signifcant dent in global infections.

"This is a historic day in the decades-long fight against HIV," Gilead chairman and chief executive Daniel O'Day said in a statement.

Lenacapavir, marketed under the brand name Yeztugo, has been shown to reduce the risk of HIV transmission by more than 99.9 percent in adults and adolescents -- making it functionally akin to a powerful vaccine.

The company conducted two large clinical trials. The first, involving more than 2,000 women in sub-Saharan Africa, resulted in a 100 percent reduction in infections and demonstrated superiority over the daily oral pill Truvada.

In the second trial, involving over 2,000 men and gender-diverse individuals, only two infections were recorded - a 99.9 percent prevention rate, again surpassing Truvada.

Reported side effects included injection site reactions, headache, and nausea.

Results from both trials were published in The New England Journal of Medicine, and the journal Science named lenacapavir its 2024 "Breakthrough of the Year."

- Price concerns dampen hope –

Despite the impressive results, optimism may be tempered by the drug's cost -- a list price of $28,218 per year in the United States, Gilead spokeswoman Blair Baumwell told AFP in an email.

An earlier long-acting HIV prevention shot -- cabotegravir, which is injected every two months and was approved by the FDA in 2021 -- costs tens of thousands of dollars per year and has yet to make a major global impact.

Lenacapavir's current list price for its previously approved use as a treatment for HIV is $39,000 annually.

Baumwell said the $28,000-plus per year cost for Lenacapavir as a preventive drug is "in line with" those of existing PrEP products and that the company inspects insurers to cover it.

"We are working to make Yeztugo accessible for anyone who needs or wants it and expect to see broad insurance coverage," she said in the email.

Activists are urging Gilead to drastically cut the price to help end the HIV pandemic.

"Even high-income countries will not be able to afford widescale use of lenacapavir at prices above US $20,000 per year," said Andrew Hill of Liverpool University, who led a team of chemists and scientists that found it could be mass-produced and sold for as little as $25 per person per year.

"I congratulate Gilead and US partners for advancing this important innovation," added Winnie Byanyima, undersecretary-general of the United Nations. "Lenacapavir could be the tool we need to bring new infections under control -- but only if it is priced affordably and made available to everyone who could benefit."

In October, Gilead signed agreements with six pharmaceutical companies to produce and distribute generic versions of the drug, pending regulatory approval, in 120 low- and middle-income countries

Because it will take time for those countries to begin production, the company also announced a separate deal in December with the Global Fund -- an international partnership established by the United Nations, alongside the US President's Emergency Plan for AIDS Relief (PEPFAR) and others -- to purchase doses for two million people.

However, cuts to the PEPFAR program under President Donald Trump's administration have cast uncertainty over the future of that agreement.

Source: *The Economics Time,* 20th June 2025

Why More Indians are Ditching Costly Medicines — and Trusting Generics

Manikant Thakur and his wife, who have diabetes and hypertension, used to spend nearly Rs 2,000 a month on medicines until last year. But then, in December, Thakur lost his job and, to cut expenses until he could find a new job, he decided to switch to generic drugs supplied from the Jan Aushadhi store. These were 50%-80% cheaper than the branded generics he had been using earlier.

“We went against the advice of our family doctor, who said the generic medicines supplied at Jan Aushadhi stores weren't of good quality, which is why they were cheap,” Thakur says. “But we still wanted to give it a shot, as every single penny counted.”

Medicines can be sub-divided into three categories: generic drugs, branded generics and branded drugs.

A generic drug is one that is sold under its chemical name, rather than under a specific brand name. Branded generic is a medicine that contains the same active ingredients, and is intended to have the same dosage, quality, and use as their generic counterparts but are typically sold by pharmaceutical companies under a brand name.

On the other hand, branded medicines are products developed and marketed by the original manufacturers. Most medicines sold in India are branded generics, since branded drugs are prohibitively expensive.

"We have been using generic medicines bought from a Jan Aushadhi store for nearly six months now, and both blood sugar and blood pressure are under control," Thakur, an accountant, says.

Changing Perceptions

Thakur is not alone. Generic drugs were received poorly when the Jan Aushadhi scheme was launched in 2008, but people's outlook towards it is changing, slowly. This is also reflected in govt data.

Until 2014-15 — six years since the launch of the scheme to provide generic medicines at affordable prices — there were only 80 Jan Aushadhi stores in the country, and their sales value stood at around Rs 7.5 crore.

Ravi Dadhich, who served as CEO of Pharmaceutical and Medical Devices Bureau of India (PMBI), which runs the Jan Aushadhi scheme — officially called Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) — from Dec 2021 until recently, told TOI the number of Jan Aushadhi Kendras had increased 180 times, and more than 200 times in the last 11 years.

"One of the key concerns of patients seeking to use generic medicines sold at Jan Aushadhi stores is quality," Dadhich says. "One should know that all drugs sold at Jan Aushadhi stores are centrally procured from the World Health Organization (WHO) — Good Manufacturing Practices (WHOGMP) certified suppliers. And it's not just that. Each batch of drugs, after being received at the warehouses, is tested at laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL) to ensure best quality."

Even the packaging of the drugs, sold at govt-approved stores, have recently been improved to make them "more presentable", Dadhich explains, adding that many new items — sanitary pads, BP monitors, nebulizers and thermometers — are now available.

PMBI also has a mobile app — Janaushadhi Sugam, a single-window platform to assist users to locate nearby PMBJKs (Pradhan Mantri Bhartiya Janaushadhi Kendra, the dedicated sales outlets), search for medicines and telephone numbers, among other things.

Lingering Doubts

The Centre has also, from time to time, directed doctors to prescribe drugs with generic names. States have also been advised to ensure prescription of generic drugs and conduct regular prescription audits of public health facilities.

But the scepticism around generics refuses to go away, though government has repeatedly assured the public about their safety.

"I use generic medicines for my whole family, and the results are as good as earlier, when I used to buy branded generics at much higher prices," says Sumati Sinha, a Delhi resident. "But because there is so much negativity about generic medicines — among both doctors and patients — I wonder whether I am compromising on long-term health to cut costs."

Branded generics are tried and tested, which is why even doctors tend to prefer those over generic medicines, says Dr Anoop Misra, chairman, Fortis C-Doc. But things are changing slowly, he concedes. "At my practice, I still see most patients opting for branded medicines. However, in the last two years, there has been a gradual shift, with 5%-10% patients opting for generic medicines sold at Jan Aushadhi stores," he says.

What Needs To Change

Dr Vinay Aggarwal, a former president of the Indian Medical Association (IMA), clarified that doctors were not against generic medicines. "But the quality of those drugs should be certified by govt," he adds.

A study by researchers Mehak Chandhok and Sarita Gautam (from B R Ambedkar University and National Institute of Health and Family Welfare, respectively), published recently in International Journal of Pharmaceutical Sciences, also highlighted this.

The study recommends improving accessibility, affordability, availability, and customer satisfaction of generic medicines.

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