01 - Regulations That Actually Affect Your Clinic

FDMSEC INSIGHTS - JANUARY -2026

From

FOGSI, Food Drugs & Medicosurgical Equipment Committee

Dr.Bhaskar Pal
President
FOGSI

Dr.Suvarna Khadilkar
Secretary General
FOGSI

Dr. Vidya Thobbi
Vice President Incharge
FOGSI

Dr. Asha Jain
Chairperson
FOGSI FDMSEC

Dr. Asha Jain

Editor & Chairperson, FOGSI FDMSE Committee

Message From Dr.Bhaskar Pal

Dr. Bhaskar Pal

President FOGSI

Dear Colleagues,

Warm greetings from FOGSI.

It gives me immense pleasure to introduce the January issue of FDMSEC “INSIGHTS”, an e-magazine that addresses a domain we often overlook in our busy clinical lives—regulatory compliance in everyday practice.

As obstetricians and gynaecologists, we devote ourselves to patient care, clinical excellence, and compassionate service. Yet, in today’s healthcare environment, quality care is inseparable from quality governance. Regulations are no longer distant policy documents; they are practical realities that directly affect how we store drugs, document procedures, manage biomedical waste, obtain consent, and maintain our clinics.Many of us become aware of these rules only when faced with an inspection, a notice, or a medico-legal challenge. This issue of INSIGHTS has been thoughtfully curated to bridge that gap—translating regulations into clear, actionable guidance for the practicing ObGyn. From CDSCO norms and drug storage laws to device documentation, consent validity, biomedical waste rules, and audit-proofing your clinic, this edition focuses on what truly matters on the ground. These are not theoretical regulations, but practical safeguards that protect our patients, our clinics, and our professional integrity.

I congratulate the FDMSEC team for bringing forth topics of such relevance under the larger vision of WHO’s emphasis on health systems, quality, and governance. By understanding and implementing these standards, we do not merely comply—we elevate the standard of care we provide. Let this issue serve as a ready reckoner, a preventive guide, and a professional ally for every ObGyn.

Wishing you an insightful read and safer, stronger practice.

With warm regards,

Dr. Bhaskar Pal
President, FOGSI

Message From Dr.Vidya Thobbi

Dr.Vidya Thobbi
VP South Zone FOGSI
Incharge FDMSEC

This January issue of FDMSEC Insights focuses on regulations that genuinely affect everyday functioning of ObGyn clinics. The articles address common gaps that most clinics face—often unknowingly—and provide practical guidance that can be implemented without disrupting routine work.

The emphasis on common regulatory mistakes, audit-proofing clinics, simple compliance checklists, and staying compliant without legal assistance reflects the committee's intent to support doctors rather than intimidate them. These are areas where small corrections can prevent major medico-legal and administrative problems.

The FOGSI theme and logo for the year, highlighting safety, rights, and awareness, is particularly relevant to this issue. Regulatory compliance is not merely about inspections—it directly safeguards patient rights, staff safety, and the doctor's professional integrity. When systems are in place, awareness improves and errors reduce naturally.

I commend the Chairperson and the editorial team for integrating this philosophy into a practical issue. The appendix provided at the end further strengthens this effort by offering tools that clinics can immediately adopt.

I am confident this issue will help members move from reactive compliance to proactive preparedness.

Dr. Vidya Thobbi
Chairperson FOGSI

Message from Dr Suvarna Khadilkar

Dr. Suvarna Khadilkar
Secretary General FOGSI

Regulations are often perceived as complex, changing, and difficult to interpret. As a result, many clinics unknowingly function with small gaps that can later become major problems. This issue of FDMSEC Insights makes an important attempt to simplify that reality.

The articles on device documentation, what inspectors actually ask for, legal validity of consent forms, and biomedical waste management rules are especially valuable. These are areas where most doctors believe they are compliant—until they are asked specific questions during audits or inspections.

What stands out in this issue is its emphasis on "what is practical and acceptable," rather than theoretical rules. Clear explanations, real-life scenarios, and common errors make this reading extremely useful for busy clinicians.

I strongly recommend every member to read this issue carefully and use it as a reference. Staying compliant is not about perfection—it is about awareness and timely correction.

Dr. Suvarna Khadilkar
Secretary General FOGSI

Message From Dr.Asha Jain

Dr.Asha Jain

Chairperson

FOGSI FDMSE Committee

FOREWORD

Most of us became doctors to care for patients, not to worry about files, temperature charts, or consent formats. Yet, in today's practice, it is often these very basics that decide whether a clinic is considered safe, compliant, and defensible.

In reality, regulatory problems rarely arise from intentional wrongdoing. They come from routine, from being overworked, and from the belief that what has worked for years will continue to be acceptable. Many clinics function well every day, until one inspection or one complaint brings attention to small gaps we never thought were important.

This issue of FDMSEC Insights has been planned keeping that reality in mind. The focus is not on abstract rules, but on regulations that actually affect an ObGyn clinic on a daily basis. Drug storage, expired medicines, device documentation, consent validity, biomedical waste segregation, and basic records are the areas most frequently questioned during inspections, and also the areas most commonly overlooked.

The theme aligns closely with the WHO focus on strengthening health systems through quality and governance. A strong system is built not by fear of regulation, but by simple, consistent practices that become part of everyday work for doctors and staff alike.

I sincerely thank FOGSI President **Dr Bhaskar Pal**, Honorary Secretary General **Dr Suvarna Khadilkar**, and Vice President In-charge, FDMSEC **Dr Vidya Thobbi**, for their guidance and continued support in keeping the committee's work practical and relevant.
I also acknowledge and thank all the contributors to this issue, **the authors as listed in the January index**, who have taken time out of busy clinical schedules to share their experience and understanding in a way that speaks to real-world practice.

Many colleagues often say, "We know the rules, but tell us what to actually do." With that in mind, this issue includes a **Clinic Compliance Toolkit, a Red Flags page, Committee Recommendations, and a fillable self-audit checklist**, placed as an appendix and also made available as a downloadable Compliance Pack. These are meant to be printed, kept in the clinic, discussed with staff, and used repeatedly.

If this issue helps you identify and correct even one small gap in your clinic before it becomes a problem, it has achieved its purpose.

Warm regards,
Dr Asha Jain
Chairperson, FOGSI Committee on Food, Drugs & Medicosurgical Equipment (FDMSEC)

FOGSI FOOD DRUGS & MEDICOSURGICAL EQUIPMENT COMMITTEE

Advisors

Dr. Narendra Malhotra
Past President Fogsi

Dr P C Mahapatra
Past President Fogsi

Dr Rishma Pai
Past President Fogsi

Dr Ashok Khurana
Patron Society of SFM

Dr Ragini Agrawal
Past VP Fogsi

Dr, Rajendra Singh Pardeshi
Past VP Fogsi

Dr Ritu Khanna
Past CP FDMSEC

Dr. Ameya Purandare
Joint Treasurer

COMMITTEE - MEMBERS

Dr Anantha Lakshmi P Hyderabad	Dr Archana Singh Hyderabad	Dr Chitra Pandey Prayagraj
Dr. Divys Mangla Haryana	Dr. Dolly Mehra Ratlam	Dr Ginni Gupta Ludhiana
Dr Himleena Gautam Assam	Dr Jyothi GS Bangalore	Dr Kiran Chhabra Delhi
Dr Kumudini Jha Darbhanga	Dr M Chandra Ponnusami Namakkal	Dr Neetha George Thrissur
Dr Nidhi Bajaj Katni	Dr Okram Sarda Devi Imphal	Dr Padmaja Veeramachaneni Vijaywada
Dr Poushali Sanyal Bengal	Dr Prabhdeep Kaur Bhilai	Dr Pratibha Baldava Solapur
Dr Prerna Saigal Pathankot	Dr Priyanka Rai Deoghar	Dr Ragweshwar Jyoti Mahajan Shimla
Dr Renu Jain Gwalior	Dr Rimpi Singla Chandigarh	Dr Ruche Bhargava Jalandhar
Dr Sandhyarani Panigrahi Berhampur	Dr Shalini Jain Raipur	Dr Shikha Sachan Varanasi
Dr Soma Datta Kolkata	Dr Sonal Gupta Faridabad	Dr Sreedevi Vellanki Vijayawada
Dr Sugandha Goel Jodhpur	Dr Sujaysri Sangita Bhimavaram	Dr Urvashi Barman Singh Vijayawada
Dr Vandana Gupta Delhi	Dr Veronica Yuel Raipur	Dr Vishnu Priya KMN Bangaluru

INDEX

01

CDSCO Rules Every ObGyn Ignores—Until Inspection Day

Author - Dr. Sugandha Goel
M.S, PGDHHM, PGDMLS FICOG
Fellowship in infertility and endoscopy (IKDRC) Certified Training - Gynaec Oncosurgery and Robotic Gynaecology (TATA Hospital, Mumbai)

Co- author: Dr Maitri Modh
MBBS, DGO, DNB (Resident, 3rd Year)
Department of Obstetrics and Gynecology, Kamla Nagar Hospital, Jodhpur

Introduction

The Central Drugs Standard Control Organisation (CDSCO) is the apex national regulatory authority in India responsible for regulating drugs, medical devices, cosmetics, and clinical trials under the Drugs and Cosmetics Act, 1940, and its associated rules. The CDSCO operates under the Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare, Government of India, with its headquarters in New Delhi and multiple zonal and port offices across the country. [1]

The overarching objective of CDSCO's regulatory framework is to safeguard public health by ensuring the safety, efficacy, quality, and performance of medical products marketed in India, including those relevant to obstetrics and gynecology. [2]

Legal Framework Governing CDSCO Regulation

1. Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940, is the primary legislation regulating the import, manufacture, distribution, and sale of drugs and cosmetics in India. It empowers CDSCO to enforce standards that protect patients using pharmaceutical products and related devices.

2. Drugs and Cosmetics Rules, 1945

The implementation of the Act is detailed in the Drugs and Cosmetics Rules, 1945, which classify drugs under various schedules and specify regulatory requirements such as licensing, labeling, storage, and sale provisions. [3]

3. Medical Devices Rules, 2017

In 2017, the Medical Devices Rules were introduced as a specific sub-regime under the Drugs and Cosmetics Rules to regulate medical devices (including those used in obstetrics and gynecology) using a risk-based classification system. [4][5]

CDSCO and Obstetrics & Gynecology

Although CDSCO does not issue practice-specific clinical guidelines for obstetricians and gynecologists (such as those issued by medical associations), its regulatory framework directly affects every drug and medical device used in obstetric and gynecological practice.

Regulation of Drugs Used in Obstetrics and Gynecology

Drugs marketed for indications related to obstetric and gynecologic conditions—for example, uterotonics, antibiotics in pregnancy, hormonal therapies, antifibrinolytics, tocolytics, or contraceptives—are regulated under the Drugs and Cosmetics Act and CDSCO requirements.

Manufacturers must obtain market authorization, and products must meet established standards for quality, safety, and efficacy before being sold in India. This includes the submission of required clinical data, pharmacovigilance commitments, and compliance with Good Manufacturing Practices (GMP). [2]

Clinical Trials for Obstetrics & Gynecology Drugs

Under the New Drugs and Clinical Trials Rules, 2019—also governed by CDSCO—clinical trials of new medications, including those relevant to obstetric and gynecological health, must be approved by CDSCO and ethics committees. These rules mandate strict adherence to Good Clinical Practice (GCP) standards, maintenance of data integrity, ethical protection of participants, and timely reporting of adverse events. Detailed guidance documents for clinical trials are available on the CDSCO website.

Medical Devices in Obstetrics and Gynecology

Medical devices play a significant role in obstetrics and gynecology, ranging from diagnostic tools (e.g., fetal monitors) to therapeutic and surgical devices (e.g., suction systems, birthing beds).

CDSCO Classification of Medical Devices

Under the Medical Devices Rules, 2017, medical devices are classified into four risk categories:

- Class A – Low risk: Devices with minimal direct patient contact or minimal associated risk
- Class B – Low to moderate risk: Devices with minimal invasiveness or limited duration of patient contact
- Class C – Moderate to high risk: Devices with direct invasive contact or significant associated risks
- Class D – High risk: Devices with direct invasive contact, long-term implantation, or life-sustaining functions

This classification determines the level of regulatory control, with higher-risk devices requiring more stringent licensing and conformity assessment before market authorization. [4]

Classification of Obstetrical and Gynecological Devices

CDSCO has issued specific classification lists for devices used in obstetrics and gynecology, detailing their intended use and associated risk class. [2] These lists are dynamic and updated periodically.

The current CDSCO classification includes 116 medical devices pertaining to obstetrical and gynecological use. [5]

Class A Devices (Low Risk)

Examples include:

- Birthing beds or tables
- Gynecological operating table tops
- Heel stirrups
- Manual amniotic membrane perforators

Different application forms apply depending on the activity (e.g., MD-15 for import licenses, MD-9 for manufacturing licenses). Higher-risk devices typically require approval from the Central Licensing Authority (CLA). [2][6]

Import Requirements

Imported obstetrical and gynecological devices must obtain a CDSCO import license (e.g., MD-15) prior to entry into the Indian market. The importer or authorized Indian agent plays a critical role in this process.

Post-Market Surveillance

Once a device is placed on the market, manufacturers or importers must conduct post-market surveillance, report adverse events, and comply with regulatory updates or safety notices issued by CDSCO.

Impact on Clinical Practice

Patient Safety and Quality Assurance

CDSCO regulations ensure that drugs and devices used in obstetric and gynecological care meet safety and quality standards. For example, devices such as fetal monitors or birthing beds must comply with classification-based regulatory requirements prior to clinical use.

Compliance by Healthcare Facilities

Hospitals, clinics, and healthcare professionals must ensure that all drugs and devices used in obstetrics and gynecology departments are appropriately registered and licensed. Use of unauthorized products may lead to legal consequences and compromise patient safety.

Conclusion

The regulatory landscape overseen by the Central Drugs Standard Control Organisation (CDSCO) in India forms a critical foundation for safe and effective obstetrical and gynecological practice. From stringent drug approvals and clinical trial oversight to risk-based classification and licensing of medical devices, CDSCO regulations ensure that products used in women's reproductive health meet scientifically validated standards.
Healthcare providers, manufacturers, and importers must remain updated on changes to the Drugs and Cosmetics Act, Drugs and Cosmetics Rules, 1945, Medical Devices Rules, 2017, and associated notifications to maintain compliance and support high-quality obstetric and gynecologic care in India.

References

[1] Central Drugs Standard Control Organisation (CDSCO). (n.d.). Acts & Rules. Ministry of Health and Family Welfare, Government of India. Drugs-and-Cosmetics-Act

[2] Central Drugs Standard Control Organisation (CDSCO). (2018, 2021, 2024). Classi cation of Medical Devices pertaining to Obstetrical and Gynecological devices. Medical Devices Rules, 2017. Ministry of Health and Family Welfare, Government of India. OB&GY1.pdf

[3] Ministry of Health and Family Welfare, Government of India. (1940). The Drugs and Cosmetics Act, 1940 and Rules, 1945. Drugs-and-Cosmetics-Act https://cdsco.gov.in/opencms/opencms/ en/Acts-and-rules/

[4] Central Drugs Standard Control Organisation (CDSCO). (2017). Medical Devices Rules, 2017. Ministry of Health and Family Welfare, Government of India. https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical Devices Rules%2C 2017.pdf Medical Devices Rules, 2017.pdf

[5] Morulaa. (2025). India Risk Classi cation for Obstetrical and Gynecological Medical Devices.India Risk Classification for Obstetrical and Gynecological as Medical Device - Morulaa HealthTech

[6] Corporate Seed. (2023). Classi cation of Medical Devices by CDSCO in India. Retrieved from https://www.corpseed.com/knowledge-centre/classi cation-of-medical-devices-by-cds co-in-india Classification of Medical Devices by CDSCO in India - Corpseed

[7] SCC Online. (2021). CDSCO issues classi cation of Medical Devices pertaining to Obstetrical and Gynecological under Medical Devices Rules, 2017.**SCC Online® | The Surest Way To Legal Research**

[8] Corpbiz. (n.d.). CDSCO Registration for Obstetrical and Gynaecological Medical Devices.CDSCO Registration for Obstetrical and Gynaecological Medical Devices

----------XXXXX----------

02

Drug Storage Laws: Temperature Logs That Can Save You

Author:- Dr. Sreedevi Vellanki
Vijaywada AP

Proper storage of drugs and maintenance of temperature records are not merely administrative tasks but legal safeguards that can protect doctors, clinics, and hospitals from regulatory action, medico-legal liability, and patient harm. Proper storage is a fundamental,legal,ethical and professional responsibility of all health care facilities.This document outlines the key legal requirements, best practices, and practical steps related to drug storage and temperature logging, with special reference to clinical practice in India.

INTRODUCTION

Drugs are sensitive products whose safety, efficacy, and potency depend heavily on proper storage conditions. Exposure to inappropriate temperature, humidity, or light can render medicines ineffective or even harmful. Regulatory authorities therefore mandate strict storage norms and documentation. In recent years,regulatory authorities have increased inspections .In the event of inspections, audits, or legal scrutiny, proper drug storage and temperature logs often serve as crucial evidence demonstrating due diligence by the treating doctor.

LEGAL FRAMEWORK GOVERNING DRUG STORAGE

Drugs and Cosmetics Act, 1940 and Rules, 1945

The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 form the backbone of drug regulation in India. These laws mandate that drugs must be stored under conditions that maintain their quality and prevent deterioration. These laws apply to manufacturers, distributors, pharmacies, hospitals, and medical practitioners who stock and dispense drugs.

Key provisions relevant to doctors include:

- Schedule N: Specifies minimum requirements for pharmacies and drug storage areas.
- Schedule P: Specifies the life period and storage conditions of drugs.It clearly mentions temperature limits.Lists life-saving drugs and their storage requirements are also mentioned.
- Schedule C and C(1): Covers biologicals, vaccines, sera, and injectables requiring cold-chain maintenance.
- Schedule M :Emphasizes good manufacturing and storage practices,which indirectly apply to institutional storage standards.Failure to comply may result in penalties, suspension of license, seizure of drugs, or prosecution.

National Medical Commission (NMC) and Professional Conduct

Under the NMC Ethics Regulations, registered medical practitioners are required to ensure patient safety and maintain standards of care. Improper storage of drugs leading to loss of efficacy or adverse outcomes can be construed as professional negligence.

Biomedical Waste and Hospital Regulations

Hospital and clinical establishment rules also mandate appropriate segregation, storage, and handling of pharmaceuticals, especially injectables, narcotics, and emergency drugs.

DRUG STORAGE REQUIREMENTS

Most medicines are required to be stored in: A cool, dry place, Away from direct sunlight, Protected from moisture and contamination and In original containers with intact labels

The commonly accepted room temperature range is 20–25°C, unless otherwise specified.
Cold Chain Drugs (2–8°C)

Certain drugs are temperature-sensitive and must be stored strictly between 2–8°C. These include: Vaccines, Insulin, Oxytocin , Ergometrine, Certain biologicals and hormonal preparations .Breaks in the cold chain can result in irreversible loss of potency.

Controlled and High-Risk Drugs

Narcotic drugs, psychotropics, and high-alert medications must be: Stored separately, Kept under lock and key ,Issued only against proper documentation

TEMPERATURE LOGS: LEGAL AND CLINICAL IMPORTANCE

What Is a Temperature Log?
A temperature log is a written or electronic record of temperatures maintained in drug storage areas, including:

• Drug store rooms• Refrigerator• Vaccine carriers,Emergency drug trays
Why Temperature Logs “Save” Doctors In inspections by:Drug Control Department NABH/NABL auditors ,Court proceedings in negligence cases

Temperature logs act as documentary proof that:
• Drugs were stored as per legal requirements
• Cold chain was maintained
• The doctor exercised reasonable care

Absence or poor maintenance of logs is often viewed as negligence, even if no patient harm is proven.From a legal perspective, NOT DOCUMENTED is often interpreted as NOT DONE.Even if drugs were stored correctly, absence of temperature logs can be viewed as negligence or non-compliance.

HOW TO MAINTAIN TEMPERATURE LOGS

Frequency of Recording
Best practice recommendations:
• Refrigerators: Twice daily (morning and evening)
• Drug stores: Once daily
• During power failure or transport: At defined intervals

Format of Temperature Logs

A standard temperature log should include:Date, Time, Recorded temperature,Acceptable temperature range ,Name and signature of responsible staff and Corrective action (if temperature deviates)

Corrective Actions

Whenever temperature excursions occur:

- Document the deviation
- Quarantine affected drugs
- Inform pharmacy or supplier
- Record corrective steps taken

This documentation is critical in defending medico-legal claims.

COMMON MISTAKES AND LEGAL PITFALLS

- Not maintaining logs on holidays or Sundays
- Back-filling entries retrospectively
- Using domestic refrigerators without thermometers
- Mixing food items with drugs in refrigerators
- Ignoring minor temperature deviations

DIGITAL TEMPERATURE MONITORING

Increasingly, clinics and hospitals are adopting Digital data loggers with Alarm-based temperature monitors and Cloud-based records

While not legally mandatory everywhere, digital systems provide strong medico-legal protection.

8. PRACTICAL CHECKLIST FOR DOCTORS

- Maintain calibrated thermometers in all storage areas
- Assign responsibility to trained staff
- Review temperature logs regularly
- Keep records for at least 2–5 years
- Conduct periodic internal audits
- Display storage SOPs near drug areas

AUDIT EXPECTATIONS: DRUG STORAGE & TEMPERATURE LOGS

1. DRUG STORAGE AREA

Physical setup : Clean, dry, well-ventilated storage area,Adequate lighting,No overcrowding of shelves,Drugs stored off the floor and away from walls,No food, water bottles, or personal items near drugs

Segregation :Oral, injectable, topical drugs stored separately (preferred), Emergency drugs clearly labelled, Expired / near-expiry drugs segregated and marked, Look-alike / sound-alike drugs stored cautiously.

Labeling: Original manufacturer labels intact ,Opened multi-dose vials labeled with **date & time of opening.**

2. REFRIGERATOR / COLD CHAIN – MAJOR FOCUS AREA

Auditors are very strict here.They expect:Dedicated drug refrigerator (not domestic use with food), Functional thermometer inside the fridge,Temperature maintained strictly 2–8°C, Refrigerator not overfilled, No storage in refrigerator door shelves, Power backup (inverter/generator) availability documented.

TEMPERATURE LOGBOOK – THEY CHECK LINE BY LINE

Frequency :Refrigerator temperature: Twice daily (morning & evening), Drug store room: Once daily, No blank days (including Sundays & holidays)

Format

Each entry should include: Date, Time, Recorded temperature, Acceptable range mentioned (2–8°C or 20–25°C), Name/signature of staff.

Consistency

No overwriting or whitener ,No identical handwriting for weeks (red flag), No back-dated entries

4. TEMPERATURE EXCURSIONS – THIS IS WHERE DOCTORS GET "SAVED"

Auditors expect proof that you know what to do when things go wrong.

When temperature goes out of range, they look for:Deviation clearly recorded, Immediate corrective action noted, Drugs quarantined (if required), Supervisor/doctor informed, Final resolution documented

✔ Even if excursion occurred, proper documentation protects you

❌ No documentation = negligence (in audit terms)

5. SOPs & DOCUMENTATION EXPECTED

Auditors usually ask for:

- Written SOP on Drug Storage,Temperature Monitoring, Power failure management, Handling temperature excursions.

These SOPs should be:Dated, Approved/signed by authority, Displayed or accessible near drug storage area.

6. STAFF RESPONSIBILITY & TRAINING

Auditors expect:Named person responsible for temperature recording, Evidence of staff training (attendance sheet or orientation note), Staff able to verbally explain:Acceptable temperature range and What to do if temperature goes out of range.

7. RECORD RETENTION

Expected retention:Temperature logs: **Minimum 2–5 years**.Older records neatly filed and retrievable

8.DIGITAL SYSTEMS (IF USED): Calibration records available, Alarm settings documented and Manual backup must be available.

9.COMMON AUDIT NON-CONFORMITIES :

Missing entries on holidays, No corrective action recorded, Fridge temperature outside range with no comment ,Opened injectables without date/time, Expired drugs found in active stock.

10. MEDICO-LEGAL PERSPECTIVE

In negligence claims, courts examine whether the doctor followed “standard of care.” Proper drug storage and documented temperature monitoring demonstrate compliance with accepted standards and significantly reduce legal vulnerability.

11. CONCLUSION

Drug storage laws and temperature logs are essential patient-safety and medico-legal tools. Consistent adherence to storage norms and meticulous maintenance of temperature records can decisively protect doctors during inspections, audits, and litigation.

REFERENCES:

1.CDSCO GDP guidelines

2.IPHS Guidelines MoHW

3.WHO TRS Storage and Distribution

4.Drugs and cosmetics Act 1940 and Rules 1945

----------**XXXXX**----------

03 Expired Drugs in Clinics: Legal Reality vs Common Practice

Author:- Dr Sonal Gupta
Faridabad Consultant – Obstetrics & Gynaecology

1. Why this matters in daily practice

In most obstetrics and gynaecology clinics, medicines are used every day—injectables, IV fluids, antibiotics, emergency drugs. With high patient load and busy shifts, expiry dates may be missed. Expired medicines are sometimes kept aside "just in case" or forgotten in cupboards, emergency trays, or refrigerators.

This usually happens without bad intention. However, expired drugs affect **patient safety, professional responsibility**, and **clinic compliance**. Knowing the correct way to handle expired medicines helps protect patients and also protects clinic staff during audits or inspections.

Points to remember

- Expired drugs are common in busy clinics
- Keeping them "just in case" is risky
- Proper handling protects patients and staff

2. What the regulation actually says

As per guidance from the **Central Drugs Standard Control Organisation (CDSCO)**, expired or unused medicines are **not fit for patient use**. Once a medicine crosses its expiry date, it should be removed from active stock and clearly marked as "Expired / Not for Use." These medicines are expected to be disposed of through authorised methods, such as approved waste handlers or return systems with proper records.

The Bio-Medical Waste Management Rules, 2016, issued by the Ministry of Environment, Forest and Climate Change, classify expired medicines as biomedical waste. This means they should be separated from general waste and handed over only to authorised biomedical waste treatment facilities.

Even if a drug looks normal or was expensive, clinical judgement does not override these rules. Expired medicines are treated as regulated waste, not usable stock.

Points to remember

- Expired = **not safe for use, legally**
- Must be **separated and labelled**
- Disposal only **through authorised channels**

3. Common mistakes seen in clinics

Many clinics unknowingly follow unsafe practices. Expired medicines are often kept mixed with usable stock, especially in emergency trays or refrigerators. Sometimes they are retained for rare emergencies, assuming one-time use is acceptable.

Another common mistake is returning expired drugs to stockists without documentation. Some clinics dispose of expired medicines along with general waste or sharps, not realising that pharmaceutical waste has separate rules. Smaller clinics may not have written instructions, so staff handle expired drugs differently depending on who is on duty.

These mistakes usually happen due to lack of awareness, unclear responsibility, or fear of extra cost—not because of negligence.

Points to remember

- Mixing expired and active stock is unsafe
- “Emergency use” of expired drugs is not acceptable
- Disposal without records creates problems during inspection

4. What inspectors usually check

During inspections, authorities usually focus on systems, not individual errors. Inspectors commonly check whether expired medicines are clearly separated from usable drugs and properly labelled. They may ask to see an expired drug register or logbook.

Inspectors also look for records showing handover of expired medicines to authorised biomedical waste handlers and proof of regular waste collection. A simple written SOP explaining how expired drugs are handled is usually expected. The focus is on consistency and documentation, not on punishment.

Points to remember

- Inspectors check records and process
- Separation and labelling are important
- Simple documentation is usually sufficient

5. Practical compliance tips

Following the rules does not need expensive systems. Clinics can keep a clearly marked box or tray labelled “Expired / Not for Use.” Nurses or pharmacy staff can check expiry dates monthly or quarterly during routine stock review.

A simple register noting the drug name, quantity, date, and disposal method is enough. Expired medicines can be disposed of along with other biomedical waste through the clinic’s authorised waste handler. Displaying a short SOP near medicine storage areas helps staff follow the same steps every time.

Points to remember

- One labelled box can solve many problems
- Monthly or quarterly checks are enough
- Simple registers protect the clinic

6. Take-home message

Expired medicines are a normal part of clinical work, not a personal failure. Regulations are meant to support safe practices, not create fear. With basic segregation, simple records, and regular disposal, clinics can meet expectations while continuing to focus on patient care.

References (Vancouver style)

1. Central Drugs Standard Control Organisation. Guidance document on disposal of expired and unused drugs. New Delhi: Ministry of Health and Family Welfare; 2018.

2. Ministry of Environment, Forest and Climate Change. Bio-Medical Waste Management Rules. New Delhi: MoEFCC; 2016.

3. Mondal S, et al. Safe disposal of pharmaceuticals: Regulatory obligations in India. Journal of Pharmaceutical Policy and Practice. 2019;12:27.

4. TeamLease RegTech. CDSCO compliance advisory on expired drug disposal. Bengaluru; 2020.

----------XXXXX----------

04

Are You Allowed to Stock This Drug? Know the Rules

Author:- Dr. Sangita Sujayasri
Sec Bhimavaram Obs & Gyn Society

Co-Author:- Dr. Asha Jain
Chairperson – FOGSI Committee on Food, Drugs & Medicosurgical Equipment (FDMSEC)

Why this question refuses to go away

In obstetric and gynecological practice, keeping medicines in the clinic is not a matter of convenience. It is a matter of safety. Oxytocin in the labour room, magnesium sulphate for eclampsia, injectable antibiotics for emergencies, IV fluids, vaccines, hormones, and analgesics are part of everyday clinical work. No responsible clinician expects a patient to step out and search for a pharmacy in the middle of an emergency.

Yet, across India, an increasing number of doctors are being questioned during inspections about drugs stocked in their clinics. The discomfort does not arise because doctors are selling medicines indiscriminately, but because regulatory interpretation does not always align with clinical assumptions. What is viewed clinically as clinic use can, in the absence of proper documentation, be interpreted legally as unauthorised stocking or sale.

This gap between clinical intent and regulatory interpretation has become one of the most frequent regulatory stress points for clinics and nursing homes. The aim of this article is not to create anxiety, but to offer clarity based on Indian law and real inspection experience.

What the law actually allows and where it draws the line

Drug regulation in India is governed by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, enforced by the Central Drugs Standard Control Organization and State Drug Control Authorities. For clinicians, the most relevant provision is Schedule K.

Schedule K permits a Registered Medical Practitioner to stock and dispense medicines to their own patients as part of treatment without holding a retail drug licence. This permission is conditional. The clinic must not function as a pharmacy, medicines must not be sold to the general public, and dispensing must be directly linked to patient care.

The law does not object to doctors keeping medicines. It objects to medicines being stocked and dispensed without accountability.

Drugs listed under Schedule H, such as oxytocin, magnesium sulphate, ceftriaxone injection, amoxicillin–clavulanate, progesterone, and estrogen preparations, may be stocked in clinics and used for patients under treatment, provided valid prescriptions are maintained.

Schedule H1 drugs include commonly used antibiotics such as azithromycin, doxycycline, cefixime, and levofloxacin. These drugs are not prohibited in clinics, but their dispensing must be recorded in a register that documents patient details, prescriber information, and quantity dispensed.

Schedule X drugs, including sedatives such as alprazolam and certain benzodiazepines, are subject to strict controls. In routine practice, most clinics are not permitted to stock these drugs unless they meet specific licensing requirements. Narcotic and psychotropic drugs such as morphine and fentanyl fall under the NDPS Act and cannot be stocked in clinics without separate authorisation, irrespective of medical intent.

Where clinics unknowingly invite trouble

Most regulatory lapses observed during inspections are not deliberate. They arise from habits that have become part of routine practice over time.

Antibiotics are a frequent problem area. Clinics often keep injectable ceftriaxone or oral azithromycin for emergency use but fail to maintain Schedule H1 dispensing records. Another common issue is expired drugs. These are often kept aside in cupboards or drawers, clearly marked as expired, but still present within patient care areas. From a regulatory perspective, expired drugs should not be present in clinical spaces at all.

Cold chain documentation is another recurring concern. Vaccines and oxytocin may be stored correctly in refrigerators, but temperature logs are missing or irregular. During inspections, the absence of records is interpreted as absence of compliance.

IV fluids such as normal saline and Ringer's lactate are not scheduled drugs and may be stocked freely. However, issues arise when clinics begin dispensing them in a manner that resembles retail sale rather than clinical use.

In most cases, the concern is not the drug itself, but the lack of traceability.

What inspectors actually look for

There is a common perception that drug inspections are arbitrary or punitive. In reality, inspections follow a fairly predictable pattern.

Inspectors verify purchase invoices to ensure medicines are procured from authorised sources. They assess whether drugs stocked are appropriate to the scope of the clinic. Prescription linkage is central to this assessment, especially for Schedule H and H1 drugs. Storage conditions, expiry dates, segregation of expired stock, and refrigerator temperature records are examined carefully.

Compliance with the Biomedical Waste Management Rules, particularly for disposal of expired or unused medicines, is also reviewed. In most inspections, adverse observations arise not because a clinic stocked an inappropriate drug, but because it could not demonstrate how that drug was used.

Inspectors often state that their primary concern is traceability. They want to see where the drug came from, who it was given to, and whether records support that use. Treatment decisions are rarely questioned when documentation is clear.

Staying compliant without complicating practice

Regulatory compliance does not require clinics to function like pharmacies. Clinics that restrict their stock to essential medicines, maintain purchase invoices, keep a simple Schedule H1 register, document refrigerator temperatures, and remove expired drugs promptly rarely face serious regulatory difficulty.

The key is consistency. When documentation becomes part of routine practice rather than a response triggered by inspection, compliance stops feeling burdensome. Stock only what is genuinely needed for patient care, and record how it is used.

Can an ObGyn clinic stock this drug in India?

Drug	Common use	Schedule	Can a clinic stock it	Conditions
Oxytocin injection	Labour, postpartum haemorrhage	Schedule H	Yes	Prescription linked use, cold chain
Magnesium sulphate	Eclampsia	Schedule H	Yes	Emergency use for own patients
Ceftriaxone injection	Infection	Schedule H / H1	Yes	Schedule H1 register required
Amoxicillin–clavulanate	Infection	Schedule H	Yes	Prescription mandatory
Azithromycin	Infection	Schedule H1	Yes	H1 register mandatory
Doxycycline	Infection	Schedule H1	Yes	H1 register mandatory
Progesterone	Luteal support	Schedule H	Yes	Prescription linked use
Estrogen preparations	Gynecologic use	Schedule H	Yes	Prescription linked use
Normal saline, Ringer’s lactate	IV therapy	Not scheduled	Yes	Not for retail sale
Vaccines such as Tdap, HPV	Immunisation	Prescription	Yes	Cold chain and temperature log
Diazepam	Sedation	Schedule X	Generally no	Licence and locked storage required

Alprazolam	Anxiety	Schedule X	No	Retail licence required
Morphine, fentanyl	Analgesia	NDPS Act	No	NDPS authorisation mandatory

The message clinicians should take home

Indian law does not prohibit doctors from stocking medicines. It expects responsibility, restraint, and documentation. Most clinics that encounter regulatory difficulty do so not because they stock prohibited drugs, but because they cannot demonstrate appropriate use.

Understanding drug schedules, maintaining basic records, and avoiding casual stocking of restricted medicines allows clinicians to practise confidently and lawfully. In the current regulatory environment, clarity remains the strongest safeguard.

References

1. Government of India. Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. Ministry of Health and Family Welfare; CDSCO.
2. Central Drugs Standard Control Organization. Schedule K, H, H1 and X provisions under Drugs and Cosmetics Rules.
3. Ministry of Health and Family Welfare. Guidance on prescription drugs and enforcement in clinical establishments, India.
4. World Health Organization. Health Systems Governance for Universal Health Coverage.
5. CDSCO. Good storage and distribution practices for pharmaceuticals.
   Central Pollution Control Board. Biomedical Waste Management Rules, 2016.

----------XXXXX----------

05

Device Documentation: What Inspectors Actually Ask for

Author- Dr Ginny Gupta
MBBS, MD, FICOG
(Ex-PGI Chandigarh)

During an inspection in a hospital clinic or OPD setting, inspectors focus heavily on patient safety, infection control, and the accuracy of medical devices. The inspection covers not just the presence of equipment, but its maintenance, calibration, and the training of staff. Presence of and date-wise entries in log registers as to date of service, quality check, time till next assessment of every device/equipment is compulsory.

Government/local authority licenses (hard copies), imperative to be present on site in case of ultrasound equipment, MTP equipment, fire safety equipment, biomedical waste disposal equipment, example: needle cutters etc.

Following is a list of devices present in all OPD, indoor areas and operation theatres.

1) Diagnostic and Examination Devices (OPD/Consultation Rooms)

Blood Pressure Apparatus: Sphygmomanometers (digital and manual) must be calibrated.
Weighing Scales: Weighing machines for adults and infants must be calibrated.
Thermometers: Clinical thermometers.
Otoscope/Ophthalmoscope/Slit Lamp: Headlights or examination lights.
ECG Machine: Needs to be calibrated and checked for paper availability.
Pulse Oximeter: Must be checked for accuracy.
Glucometer: Used for point-of-care testing.
Snellen Chart/Eye Chart: (If applicable for Ophthalmology).

2) Labour Room Equipment

Fetal Doppler, Fetal Cardiotocography, (With Paper), Sonic Jelly, Delivery Table, Oxygen source cylinder/pipeline

Suction Apparatus: Must be functional, with proper mucus suckers, catheters, neo-natal resuscitation kit, infant radiant warmers, infant infusion pumps, infant weighing scale, infantometer

3)Treatment and Procedural Equipment (OT/Procedure Room/Injection Room)

OT Table, anaesthesia machine, multi para monitor, suction machine, electro cautery and OT lights, oxygen source with regulator. Ambu bag adult and neonatal in radiant warmer
Defibrillator/AED: Needs to be in working condition, with daily checklists and battery checks.

Nebulizer Machine: Cleanliness and functionality.
Operation theatre fumigator
Emergency Trolley/Crash Cart: Needs to be fully stocked, sealed, and inspected daily for medication expiry.
Oxygen Cylinders/Concentrators: Must be securely fastened with adequate pressure gauge checks.
Electrosurgical Unit (Diathermy): If used in minor procedures.

4) Safety and Infection Control Equipment along with sterlisation machines

Hand Hygiene Stations: Soap dispensers and alcohol-based hand rubs at all points of care.
Biomedical Waste Bins: Color-coded bins with proper labelling and foot-operated lids.
Needle Destroyer/Sharp Container: Specifically checked for proper disposal.
Autoclave /ETO sterilizer
Instrument trays
UV/fumigation equipment if used
Autoclave daily logs and color tapes
Fire Extinguishers: Must not be expired and easily accessible.
Radiation Safety Devices (If X-Ray/USG is in Clinic): Lead aprons (checked for cracks via X-ray), TLD badges.
Emergency Exit Signage: Properly displayed.

5) Imaging & Diagnostics

Ultrasound machine if present : Probe condition and connectivity.
Printer / image output unit
Registration with authorities with proper certification and time period of validity.
Antenatal ultrasound records and appropriate forms in numerical order

6) Drug storage & cold chain maintanence

Medical refrigerator with thermometer inside
Key Documentation for Devices (The "Paper Trail")
Inspectors will check that every piece of electrical/medical equipment has the following:
Equipment History Card: Logbook for each device.
Calibration Certificate: Standardised accredited calibration report for all measurement devices.
Preventive Maintenance (PM) Schedule: Records of regular servicing.
User Manuals: Available in the local language or English.

Common Pitfalls to Avoid
Expired sterilizer tapes or lack of autoclaving logs.
Uncalibrated BP apparatus or weighing machines.
Emergency cart containing expired medicine.
Missing TLD badges for radiology staff.
Lack of AMC/CMC (Annual Maintenance Contract) documents.

Nebulizer Machine: Cleanliness and functionality.
Operation theatre fumigator
Emergency Trolley/Crash Cart: Needs to be fully stocked, sealed, and inspected daily for medication expiry.

Oxygen Cylinders/Concentrators: Must be securely fastened with adequate pressure gauge checks.
Electrosurgical Unit (Diathermy): If used in minor procedures.

7) Safety and Infection Control Equipment along with sterlisation machines

Hand Hygiene Stations: Soap dispensers and alcohol-based hand rubs at all points of care.
Biomedical Waste Bins: Color-coded bins with proper labelling and foot-operated lids.
Needle Destroyer/Sharp Container: Specifically checked for proper disposal.
Autoclave /ETO sterilizer
Instrument trays
UV/fumigation equipment if used
Autoclave daily logs and color tapes
Fire Extinguishers: Must not be expired and easily accessible.
Radiation Safety Devices (If X-Ray/USG is in Clinic): Lead aprons (checked for cracks via X-ray), TLD badges.
Emergency Exit Signage: Properly displayed.

8) Imaging & Diagnostics

Ultrasound machine if present : Probe condition and connectivity.
Printer / image output unit
Registration with authorities with proper certification and time period of validity.
Antenatal ultrasound records and appropriate forms in numerical order

9) Drug storage & cold chain maintanence

Medical refrigerator with thermometer inside
Key Documentation for Devices (The "Paper Trail")
Inspectors will check that every piece of electrical/medical equipment has the following:
Equipment History Card: Logbook for each device.
Calibration Certificate: Standardised accredited calibration report for all measurement devices.
Preventive Maintenance (PM) Schedule: Records of regular servicing.
User Manuals: Available in the local language or English.

Common Pitfalls to Avoid
Expired sterilizer tapes or lack of autoclaving logs.
Uncalibrated BP apparatus or weighing machines.
Emergency cart containing expired medicine.
Missing TLD badges for radiology staff.
Lack of AMC/CMC (Annual Maintenance Contract) documents.

To Summarise What The Inspectors Commonly Do With These Essential Devices,
Check Presence
Check Working Condition
Check Expiry /Validity
Check Basic Cleanliness And Placement.

06

Consent forms: When they are legally invalid

Author- Dr Himleena Gautam
from Guwahati Consultant Obstetrician and Gynecologist, Apollo Hospitals

INTRODUCTION-

Consent is a very important aspect of law to give legality to every transaction. Consent in medical practice is different as its between two unequal parties- patient and doctor. Thus, here is the requirement of informed consent. Informed consent is a vital document of communication process between the clinician and the patient.

Implied & Expressed Consent- visiting a doctor for consultation itself implies consent for examination and investigations, which is implied consent. Invasive procedures require expressed consent, which can be oral or written. For doing a per vaginal examination, an oral explicit consent is enough. Informed consent differs by the fact that for that, providing all information and documentation is necessary.[1]

WHY IS CONSENT IMPORTANT?[2-5]

Consent ensures that the patient is fully informed about the nature of the procedure or intervention, the risks and benefits, risks of not undergoing treatment and the alternative treatments available.
Ethical Importance - there is an ethical principle of basic human rights and patients' autonomy. No one can coerce a person for any intervention and he has the right to receive all information before deciding about it.

Legal Importance - any intervention done against proper permission is considered 'battery/ physical assault'.

For publications- consent is a must for participation in trials and researches and for taking photographs for either scientific, educational or research purpose, as per the ICMR guidelines; otherwise, it shall be construed as misconduct(clause 7.22). Specific consent is needed if identity or any specifics of the patient is published.

WHEN ARE CONSENT FORMS LEGALLY VALID/ WHAT RULES TO BE FOLLOWED- The following criteria are to be strictly fulfilled- [1-3,6]

Patient has capacity to give consent- the patient should be competent enough to understand everything explained and with a sound mind. In patients <18years, parental consent is needed. Those not in capacity to consent, or children with no parents, immediate family members or legal guardians can provide consent. In India, legal age for giving consent is 18 years. A child >12 years can give a valid consent for physical/medical examination(Indian Penal Code, section 89).

Well informed and adequately understood- the patient should be informed about the procedures or interventions, its necessity, benefits, associated risks and alternative management options using simple, clear and non-technical language. However, the list of risks and side effects cannot be exhaustive. The common risks needs to be explained. If the possibility of a risk, including death, due to a procedure or its refusal is remote or theoretical, it need not be explained. Some may demand detailed information and some may not. If a patient knowingly prefers not to get full information, or refuses treatment, that also needs to be respected.[2,7]

Well documented- the consent should be well documented, signed by patient/guardian, doctor and an independent witness. A duplicate copy should be handed over to the patient.

Voluntary consent- patient should give consent for the treatment out of his own free will. The individual must have the freedom to refuse or withdraw consent as well; but needs documentation.

Specific consent- "I authorise Dr _____ to conduct the _____ test/procedure for my treatment" – such consents are totally invalid. Procedure specific consents mentioning everything explained are valid. Also, if consent is taken under Dr X, the intervention cannot be done by Dr Y. If the timing of the procedure is postponed by >48hours, it is advisable to take fresh consents

COMMON MISTAKES IN TAKING CONSENTS- just signing consent does not guarantee validity. Consents are not valid if [1-3,6,8]

Patient is not legally fit to consent- these include intoxicated or mentally ill or <18years patients or who do not have the capacity to understand the facts.

Not obtained voluntarily- Once all information has been disclosed, patients should be given the chance to ask questions and clarify all doubts. Patients can give or revoke consent without any fear, injury, intimidation, fraud, misconception or misinterpretation of the facts.
Extra procedures should not be done during surgery, as the unconscious patient cannot give consent during course of surgery. Such procedures are only acceptable if done to save the life of the patient.

Not well informed or documented- if vital and necessary information have not been provided or have not been explained and written in the language of the patient's understanding, the consent can be considered invalid. Using the vernacular language is preferred. Signature of the patient, proper witness and doctor must be present before the procedure.

Pre-printed/ Blanket consent- this is considered an "unfair trade practice" by the NCDRC(The National Consumer Disputes Redressal Commission). Separate consents should be taken for different procedures or if any fresh procedure needed. If alterations or additions are made in the consent form without patient's signed authorisation, it is again invalid. If changes are made, it should be signed again and the copy given to patient.

Surrogate/ proxy consent- if patient is mentally sound, consent from parents, spouse or children without the patient's consent is not considered valid.

EXCEPTIONS-

[i] Emergency procedures- if intervention or test is done in order to prevent life threatening complications or to save the life of the patient, consent may not be taken. In fact, not doing a lifesaving procedure on a patient may be considered negligence, unless the patient or the legal guardian refuses to get the treatment; which again should be properly documented, signed and informed to hospital authority.[3]

[ii] Therapeutic privilege- if the doctor analyses that certain information can harm the patient's physical, mental or emotional health or the patient cannot rationally process the information, the doctor can withhold the information. But those should be shared with the close relatives[6].

[iii] Using placebos- in certain self-limiting conditions where patient insists on taking medications, despite of not needing treatment, prescribing placebos can be justified which will not harm the patient.[8]

WHAT INSPECTORS CHECK-

All records of consents should be well preserved for 5years or indefinitely in a medicolegal case. All the points mentioned above for a legally valid consent must be followed in order to defend in the court of law.

PRACTICAL COMPLIANCE TIP-

- All hospitals/clinics can have a printed consent form with adequate spaces left for- patient's details, name of surgery, complications, benefits, alternative management and the name of doctor authorised for the procedure.
- One form in English and one form in local language should be kept.
- All the signatures should be taken at same time and some time prior to procedure.
- Anaesthesia consent and additional procedure consents should be separate

TAKE HOME MESSAGE- a properly explained and well documented consent, following all the above-mentioned criteria, is the only document that can help us in court of law in case of any litigations.

REFERENCES-

[1] Satyanarayana Rao KH. Informed consent: an ethical obligation or legal compulsion? J Cutan Aesthet Surg. 2008 Jan;1(1):33-5.

[2] Kumar A, Mullick P, Prakash S, Bharadwaj A. Consent and the Indian medical practitioner. Indian J Anaesth 2015;59:695-700

[3] Arora V. Role of consent in medical practice. J Evol Med Dent Sci 2013;2:1225-9.

[4] Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Published in Part-III, Section 4 of the Gazette of India, dated 6th April, 2002, Amended up to December; 2010.

[5] General Ethical Issues. In: Ethical Guidelines for Biomedical Research on Human Participants. New Delhi: Published by: Director General Indian Council of Medical Research; 2006. p. 21-33. Available from: http://www.icmr.nic.in/ethical_ guidelines.pdf

[6] Medical Ethics Manual, World Medical Association, Inc; 2005. p. 42-50. Available from: https://www.wma.net/wp-content/uploads/2022/10/International-Code-of-Medical-Ethics-2006.pdf

[7] Indian Contract Act, Sec 12-22; 1872. Available from:
http://www.indianlawcases.com/Act-Indian.Contract. Act.,1872.

[8] Francis CM. Autonomy and Informed Consent, Medical Ethics. 2nd ed. New Delhi: Jaypee Brothers; 2004. p. 54-65.

07

Biomedical Waste Rules Doctors Still Get Wrong

Author- Dr. M. Chandra Ponnusamy
MBBS,DGO,FICOG,DRM Consultant &
clinical director ,Chandra nursing Home &
Infertility Centre, Namakkal,Tamilnadu

Broadly ,**Biomedical waste** refers to any waste which is generated during the diagnosis,treatment or immunization of human beings or animals or in research activities pertaining to or in production or testing of biological products.

Hospital waste refers to all waste ,biological or non-biological that is discarded and not intended for further use.

Infectious waste :- the wastes which contain pathogens in sufficient concentration or quantity that could cause diseases.it is hazardous. E.g : culture and stocks of infectious agents from laboratories, waste from surgery, waste originating from infectious patients.

To avoid the spread of the diseases and to keep the environment clean and healthy,The Bio-Medical Waste (Management and Handling) Rules, 1998 was published on 20th July, 1998, by the Government of India in the erstwhile Ministry of Environment and Forests.

It provides a regulatory frame work for the management of bio-medical waste generated in the country. These rules are implemented more effectively to improve the collection, segregation, processing, treatment and disposal of these bio-medical wastes in an environmentally sound management thereby, reducing the bio-medical waste generation and its impact on the environment.

Biomedical Waste Management Rules,was amended in 2016. It mandate strict segregation, collection, treatment (autoclaving, incineration, chemical disinfection), and disposal of healthcare waste, requiring color-coded bags, pre-treatment of lab waste, phasing out chlorinated plastics, and extending coverage to new waste types, with penalties for non-compliance to protect health and the environment.

Whom should these apply ?

These rules shall apply to all persons ,so called occupiers who generate, collect, receive, store, transport, treat, dispose, or handle bio medical waste in any form including hospitals, nursing homes, clinics, dispensaries, veterinary institutions, animal houses, pathological laboratories, blood banks, ayush hospitals, clinical establishments, research or educational institutions, health camps, medical or surgical camps, vaccination camps, blood donation camps, first aid rooms of schools, forensic laboratories and research labs.

Key Provisions of the 2016 Rules (as amended)

- **Occupier Responsibility:** Healthcare facilities (HCFs) must ensure safe handling, secure storage in color-coded bins, and timely transfer to authorized Common Biomedical Waste Treatment Facilities (CBWTFs).

- **Segregation & Color-Coding:** Waste is segregated into categories like yellow (anatomical, soiled), red (plastics, recyclable), blue (glassware), and white (sharps), using specific bags/containers.

- **Pre-treatment:** Laboratory waste, blood samples, and blood bags require on-site disinfection (autoclaving/chemical treatment) before disposal.

- **Time Limits:** Untreated BMW cannot be stored for more than 48 hours, except in specific conditions with State Pollution Control Board (SPCB) approval.

- **Phase-Out of Chlorinated Plastics:** Mandates phasing out chlorinated plastic bags, gloves, and blood bags, promoting non-chlorinated alternatives.

- **Technology & Treatment:** Promotes technologies like autoclaving, microwaving, incineration (with pollution controls), and chemical treatment.

- **COVID-19 Waste:** Mandates dedicated, labeled bins for COVID-19 waste for priority treatment.

- **Sharps:** Needles and sharps go into puncture-proof, leak-proof white containers, treated (autoclaving/shredding/encapsulation) and sent for disposal, often to foundries or landfills.
  These rules aim to create a robust framework for managing hazardous health-care waste, ensuring compliance through authorization, record-keeping, and penalties.
  reducing toxins by managing waste correctly, especially phasing out harmful plastics and Protect the environment.

Common mistakes done in the clinics /hospitals

1.Mixing Medical Waste with Other Types of Waste

Medical waste should never be combined with household waste. Instead, it should alwaysbe placed in specialized and clearly marked containers. Also, do not put medical waste

2. Multi tasking-

Because medical waste contains very hazardous substances, handlers are specifically instructed not to engage in other activities in order to prevent exposure.

3.Allowing Liquids to Leak

Medical waste must be contained in sealed and sturdy containers to keep these liquids from spraying or leaking during handling, disposal, transport and hauling.

4. Treating Sharps the Same as all Other Medical Waste

sharps need to be disposed of differently. Also, never bend or break sharps.

5. Opening Medical Waste Containers

Opening closed medical waste containers can cause contamination and exposure.
Inspection is not applicable on medical waste containers that are already sealed.

6. Using Your Bare Hands

Wearing proper personal protective equipment (PPE) is mandatory for anyone who handles and collects medical waste. This includes wearing nitrile gloves, facemasks, goggles and full-length gowns.

7. Storing Containers in Unrefrigerated Rooms

Medical waste destined for storage must be stored in refrigerated rooms specifically designated as a staging area for biohazardous waste. Refrigeration units for food or other chemicals must never be used to refrigerate medical waste.

8. Using Unmodified Vehicles for Transport

Transport vehicles must have an enclosed and sealed compartment for waste, as well as an impermeable lining to prevent unintentional leaks.

9. Allowing Untrained Individuals to Handle Medical Waste

Only persons trained in medical waste management should handle and dispose of biohazardous waste.

10. Neglecting Documentation During Storage and Disposal

Collected medical waste must have tracking documents with it at all times stating the quantity of waste transported, the date transported and the name of the registered hazardous waste hauler or trained individual transporting the waste. This ensures that it is accounted for throughout processing — from collection to disposal.
All these mistakes should be rectified and the rules be followed stingently.
These rules aim to create a robust framework for managing hazardous health-care waste, ensuring compliance through authorization, record-keeping, and penalties. reducing toxins by managing waste correctly, especially phasing out harmful plastics and Protect the environment.

Take Home Message

- Effective management of biomedical waste is essential to prevent the spread of diseases.
- Strict adherence to waste management protocols reduces the risk of health hazards for those who handle biomedical waste.
- Improper dumping of biomedical waste contaminates soil and water resources. Proper waste management prevents environmental pollution.
- Collection and disposal of waste as per protocols help maintain hygiene in hospitals. This is critical for patient care.
- Scientific management of biomedical waste can reduce operating costs for healthcare facilities

RESPECT THE RULES, BE A ROLE MODEL TO THE SOCIETY and LET THE FUTURE GENERATION LIVE IN A CLEAN WORLD.

References :

https://www.google.com/searchsca_esv=d6b133a3ec0f132f&rlz=1C1JJTC_enIN1014IN1014&sxsrf=ANbL-

n5CS8Pc2EPe2cd6BR8cj89BRa1bdQ:1769850953196&q=Biomedical+Waste+Management+latest+guidelines+2023&sa=X&ved=2ahUKEhttps://www.google.com/searchsca_esv=d6b133a3ec0f132f&rlz=1C1JJTC_enIN1014IN1014&sxsrf=ANbL-n5CS8Pc2EPe2cd6BR8cj89BRa1bdQ:1769850953196&q=Bio-

Medical+Waste+Management+Rules&sa=X&ved=2ahUKEwiAnfvKuLWSAxV-WHADHcNSIDAQ1QJ6BAhKEAEwiAnfvKuLWSAxV-WHADHcNSIDAQ1QJ6BAhLEAE
https://www.researchgate.net/publication/370224432_Latest_Biomedical_Waste_Management_Guidelines

08

Audit -Proofing Your Clinic: A Simple Checklist

Author- Dr Archana Singh
FICOG Fellowship in reproductive medicine(Germany), Fellowship in Day Care Endoscopy Hyderabad

1. Introduction

Obstetric clinics are among the most frequently audited healthcare establishments in India due to the medico-legal sensitivity of:

- Maternal morbidity and mortality
- Caesarean deliveries
- Termination of pregnancy services
- Ultrasound regulation under PCPNDT
- Biomedical waste generation
- Neonatal outcomes

Audit-proofing ensures that clinical practice is supported by legally compliant infrastructure, documentation, and ethical standards, thereby reducing litigation risk and improving patient safety.

2. Legal Framework Governing Obstetric Practice in India

Obstetric consultants must ensure compliance with the following major laws and rules:

Domain	Relevant Act/Rule
Clinic Registration	Clinical Establishments Act, 2010 / State Nursing Home Acts
Medical Practice Regulation	National Medical Commission Act, 2019
Termination of Pregnancy	MTP Act, 1971 (Amended 2021)
Ultrasound & Sex Selection	PCPNDT Act, 1994
Biomedical Waste Disposal	BMW Management Rules, 2016

Patient Rights & Litigation	Consumer Protection Act, 2019
Data Confidentiality	Digital Personal Data Protection Act, 2023
Blood Storage	Drugs and Cosmetics Act, 1940
Fire & Building Safety	National Building Code of India

3. Audit-Proof Checklist for Obstetric Clinics

A. Registration and Licensing

An obstetric clinic must have:

- Valid registration under the Clinical Establishments Act or relevant State Act
- Trade license from local authority
- Display of registration certificate prominently

Inspection readiness requires:

- Consultant qualifications displayed
- OPD timings displayed
- Emergency referral contacts available

B. Consultant and Staff Credential Compliance

Under the National Medical Commission Act:

- Consultant must have valid State Medical Council registration
- Renewal and registration proof available

Staff documentation must include:

- Nursing council registration certificates
- Employment records
- Vaccination records (Hepatitis B, TT)

C. Core Obstetric Documentation (High Audit Priority)

Mandatory registers:

- Antenatal register
- Delivery register
- High-risk pregnancy register
- Maternal near-miss and death review file

Essential case documentation:

- Admission notes with risk stratification
- Partograph for labour monitoring
- Discharge summaries for every patient

4. Caesarean Section (LSCS) Audit-Proofing

Caesarean section is one of the most legally scrutinized obstetric interventions due to rising CS rates and consent-related disputes.

A. Indication Documentation

Each LSCS must clearly record:

- Primary indication
- Secondary contributing factors
- Emergency or elective nature
- Decision-to-incision interval (in emergencies)

Vague terms such as “maternal request” must be supported with documented counselling.

B. Mandatory Pre-operative Records

Audit file must include:

- Admission notes and examination findings
- Anaesthesia fitness note
- Baseline investigations (Hb, blood group)
- Fetal monitoring record (CTG if applicable)
- Blood arrangement note

C. Consent Requirements for LSCS

Written informed consent must include:

- Indication explained
- Risks (haemorrhage, infection, hysterectomy possibility)
- Anaesthesia-related risks
- Neonatal risks
- Patient signature with witness
- Date and time

Separate consent required for:

- Tubectomy
- Blood transfusion
- Anticipated hysterectomy

D. Intra-operative OT Notes

Operative record must document:

- Surgeon and assistant names
- Anaesthetist name
- Type of anaesthesia
- Time of incision and delivery
- Estimated blood loss
- Findings (adhesions, placenta abnormalities)
- Sponge and instrument count confirmation

E. Post-operative Monitoring

Mandatory records:

- Post-op vitals chart
- Antibiotic and analgesia chart
- Urine output monitoring
- Wound inspection notes
- Neonatal outcome (APGAR, NICU admission)

F. Caesarean Section Rate Audit

Clinics should maintain monthly data:

- Total deliveries
- Total LSCS
- Primary vs repeat LSCS
- Indication-wise breakup

Robson Classification is recommended for standardized audit.

5. Record Maintenance and Retention Periods

Proper record retention is essential for medico-legal safety.

A. General Medical Records

Record Type	Minimum Retention
OPD records	3 years
Indoor/IPD case sheets	3–5 years
Consent forms	5 years
Discharge summaries	5 years

B. Obstetric-Specific Records

Record	Retention
Antenatal register	5 years
Delivery register	5 years
Partograph	5 years
LSCS operative notes	10 years (recommended)
High-risk pregnancy files	10 years

C. Medico-Legal and Mortality Records

Case Type	Retention
Maternal death case files	Permanent/until enquiry completion

Neonatal death files	10 years
Court-related medico-legal cases	Permanent till disposal

D. PCPNDT Records

Record	Retention
Form F	Minimum 2 years (longer if case pending)
Monthly reports	2 years

E. MTP Records

Record	Retention
MTP Register	5 years
Forms I–III	5 years
Confidentiality	Strictly protected

6. Medical Termination of Pregnancy (MTP) Forms Explained
Under the MTP Act and Rules, documentation is mandatory.

Form I – Opinion of Registered Medical Practitioner
- Certifies termination is justified under the Act
- Required opinions:
  - Up to 20 weeks → 1 RMP
  - 20–24 weeks → 2 RMPs

Form II – Monthly Report
- Monthly case numbers reported to CMO
- No patient identifiers included

Form III – Admission Register (Confidential)
Contains:
- Serial number
- Age
- Gestation
- Indication
- Procedure performed

Must be stored securely under lock and key.

Form IV – Consent Form
- Only woman's consent required if ≥18 years
- Guardian consent required for minors or mentally ill patients
- Husband/family consent not legally required

Form V – Certificate of Approval of Place

Termination can only be performed in:

- Government hospitals
- Approved MTP centres with Form V certificate displayed

Confidentiality Clause

Under Section 5A of the MTP Act:

- Disclosure of woman's identity is punishable
- Records can only be accessed by lawful authority

7. Quick Audit-Safe Summary Checklist

✅ Clinic registration displayed
✅ LSCS indication and consent complete
✅ OT notes and post-op monitoring documented
✅ Partograph used in labour cases
✅ MTP Forms I–V properly maintained
✅ BMW segregation and vendor tie-up available
✅ PCPNDT compliance ensured
✅ Records retained as per rules
✅ Patient Rights Charter displayed

8. Conclusion

Audit-proofing an obstetric clinic is a continuous process integrating:

- Evidence-based obstetric care
- Strong documentation
- Legal compliance
- Ethical confidentiality

A consultant who maintains systematic records and adheres to statutory requirements ensures patient safety and protects the clinic from medico-legal risk.

References

1. Government of India. The Clinical Establishments (Registration and Regulation) Act, 2010. Gazette of India; 2010.
2. Government of India. National Medical Commission Act, 2019. Ministry of Law and Justice; 2019.
3. Government of India. The Medical Termination of Pregnancy Act, 1971. Gazette of India; 1971.
4. Government of India. The Medical Termination of Pregnancy (Amendment) Act, 2021. Gazette of India; 2021.
5. Government of India. Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994. Ministry of Health and Family Welfare; 1994.
6. Ministry of Environment, Forest and Climate Change. Biomedical Waste Management Rules, 2016. Gazette of India; 2016.
7. Government of India. Consumer Protection Act, 2019. Ministry of Law and Justice; 2019.
8. Government of India. Digital Personal Data Protection Act, 2023. Ministry of Electronics and IT; 2023.
9. Government of India. Drugs and Cosmetics Act, 1940. Ministry of Health; 1940.
10. Bureau of Indian Standards. National Building Code of India. New Delhi: BIS; 2016.

09

Common Regulatory Mistakes Seen in ObGyn Clinics

Author- Dr. Jyothi G. S.
MBBS, MD OBG, PGDMLE, FICOG, FICMCH Professor and Head,Department of Obstetrics & Gynaecology,Ramaiah Medical College & Hospitals, Bengaluru 560054

Co- Author - Dr. Varsha G.
MBBS, MS OBG Senior Resident
Department of Obstetrics and Gynaecology, Ramaiah Medical College and Hospitals, Bengaluru 560054

Why well-functioning clinics still fail inspections—and how to prevent it

When inspections surprise otherwise well-run clinics

Many ObGyn clinics provide consistent, ethical, and safe care. Patients are satisfied, outcomes are good, and the team functions smoothly. Yet, when an inspection occurs, the experience can feel unexpectedly unsettling. Notices are issued not because patient care is unsafe, but because certain processes are not visible on record.

This gap between day-to-day functioning and inspection expectations is common. Regulations are designed to assess whether safety-related activities can be demonstrated consistently. Inspections therefore test systems, not intentions. Clinics that understand this difference are better positioned to avoid repeat observations.

Regulations examine systems, not clinical judgement

Healthcare regulations in India are often misunderstood as tools that evaluate treatment decisions. In practice, most inspections focus on whether minimum safety systems are in place and functioning as expected.

Authorities reviewing clinics under drug regulations, biomedical waste rules, or medical device guidelines usually examine whether:

- Required approvals and authorisations are current
- Drugs are stored, monitored, and documented safely
- Medical equipment is traceable and maintained
- Biomedical waste handling is recorded correctly
- Consent reflects informed participation by patients

Clinical outcomes or treatment choices are usually outside the scope of such inspections. What matters is whether the clinic can show that safe practices are embedded into routine work.

Compliance gaps often hide in plain sight

Most regulatory lapses do not stem from lack of knowledge. They arise because certain tasks are considered secondary to clinical work. Over time, these tasks become invisible until an inspection brings them into focus.

Typical examples include records maintained by different people without a single point of oversight, temperature logs that are filled irregularly, consent forms that are standardised but not individualised, or authorisations that lapse because renewal dates are not tracked. These gaps develop gradually and often go unnoticed in busy clinical settings.

Drug handling: assumptions that invite observations

Drug storage and expiry management are frequently reviewed during inspections. Clinics often assume that small-scale use or emergency stocking exempts them from detailed requirements. In reality, even limited drug storage is expected to follow basic safety norms.

Observations commonly relate to missing temperature monitoring records, expired drugs kept aside within clinical areas, or lack of documented review of emergency medications. Inspectors usually rely on what is immediately visible. Clear labelling, regular checks, and simple documentation go a long way in preventing avoidable remarks.

Biomedical waste compliance extends beyond segregation

In many clinics, waste segregation at the point of generation is done correctly. However, inspections also focus on authorisation validity, handover records, and staff awareness. Expired permissions, missing monthly logs, or uncertainty among staff regarding colour coding are common reasons for repeat observations.

Since biomedical waste management has public health implications, authorities tend to view even minor administrative lapses seriously. Periodic review of documents and brief refresher discussions with staff help maintain consistency.

Consent: a process that needs visibility

Consent is another area where clinics may feel confident but still face scrutiny. The issue is rarely absence of consent; rather, it is how consent is recorded. Use of generic forms, lack of procedure-specific details, missing signatures, or mismatch with case notes are frequently noted.

Medico-legal standards in India emphasise that consent is a communication process. Documentation should reflect that patients were informed and involved. Inspectors often examine recent consent forms because they offer insight into both ethical practice and record quality.

Medical devices: responsibility does not end with purchase

With expanding regulatory oversight of medical devices, clinics are expected to maintain basic documentation for commonly used equipment. This includes proof of purchase, installation details, and service or maintenance records.

Clinics sometimes assume that responsibility lies entirely with suppliers. During inspections, inability to produce even basic device-related records may result in observations, despite equipment functioning well clinically. Keeping essential documents accessible helps address this easily.

Why the same mistakes keep repeating

Repeated observations usually reflect system-level issues rather than individual oversight. Compliance tasks often depend on memory, informal delegation, or inspection-driven urgency. Without assigned responsibility or periodic review, gaps reappear.

Inspections act as stress tests for clinic systems. They reveal areas where processes are not integrated into daily workflow. Clinics that move from reactive correction to routine review tend to see a marked reduction in notices over time.

Making compliance part of everyday clinic work

Effective compliance does not require elaborate systems. Simple steps—such as maintaining a single compliance file, assigning a staff member to track renewals, conducting brief monthly reviews, and updating consent formats periodically—are often sufficient.

When compliance activities are treated as routine operational tasks rather than external impositions, clinics find inspections far less disruptive and more predictable.

The reassuring bottom line

Regulatory observations in ObGyn clinics usually highlight system gaps, not unsafe care. Inspections focus on visibility, consistency, and documentation. By understanding what regulations seek and integrating basic compliance into daily practice, clinics can remain inspection-ready without anxiety. Compliance, when approached thoughtfully, supports safe and sustainable clinical practice.

References

- Samanta A, Samanta J. Consent, documentation and medico-legal pitfalls. Indian J Med Ethics. 2015;12(3):146-152.
- Central Drugs Standard Control Organisation. GDP non-compliance observations during inspections. New Delhi: Ministry of Health & Family Welfare.
- Central Pollution Control Board. Common biomedical waste segregation errors in clinics. Delhi: CPCB; 2019.
- Indian Medical Association. Legal advisory on common compliance lapses in private clinics. New Delhi: IMA; 2021.

----------XXXXX----------

10

How To Stay Compliant Without Hiring A Lawyer

Author- Dr. Sarda Okram Devi
Associate Professor
Churachandpur
Medical College Manipur, India.

Obstetrics and Gynecology (OBGYN) has long been regarded as one of the most medico-legally vulnerable medical specialties. Obstetric practice involves responsibility for two lives—the mother and the unborn child which naturally places it under greater scrutiny. Although pregnancy is essentially a physiological process, any deviation from the expected course is often perceived as abnormal by patients and their families. The increasing awareness, easy access to information, and rising expectations from healthcare providers, has contributed to a noticeable increase in medico-legal litigation in modern OBGYN practice.

Obstetricians and gynecologists often face legal challenges, not necessarily because of clinical negligence, but due to gaps in communication, documentation, or systems of care. However, many medico-legal issues can be prevented through simple, consistent, and well-structured clinical practices

There are methods and ways that can prevent an OBGYN practicer from litigation and from needing to hire a lawyer. There are some key factors leading to Malpractice litigation.

Obstetrics	Failure to meet care standards (e.g., During Labour)
	Mismanagement of complications (e.g., shoulder dystocia, fetal distress)
	Deficient patient counseling
	Inadequate documentation
	Failure to diagnose major congenital anomalies
Gynecology	Failed sterilization procedures
	Uterine perforation
	Urinary tract injuries
	Endoscopic surgery complications

	Lack of informed consent or incomplete inform consent
	Inadequate documentation
	Improper postoperative monitoring
	Failure to diagnose injuries during the intraoperative period
	Treating a patient in a place without proper facilities
	Leaving behind foreign objects inside abdomen

It is important to recognize that most medico-legal vulnerabilities do not stem solely from a lack of clinical knowledge or skill. More often, they arise from system-related failures such as equipment and device issues, process breakdowns, and weaknesses in organizational culture.

Preventing litigation therefore requires a multidisciplinary approach. Responsibility for patient safety does not rest solely with the doctor. Nurses, paramedical staff, technicians, and administrative personnel all contribute to the quality and safety of care. A coordinated effort among healthcare providers and risk management teams is essential to minimize errors and ensure compliance.

Importance of Infrastructure and Facility Support

Healthcare facilities form the backbone of safe medical practice. Adequate infrastructure, well-maintained equipment, and a supportive organizational framework are critical components of patient safety. Regular maintenance of equipment, adherence to safety protocols, and periodic training of staff significantly reduce the risk of adverse events as well as litigation.

Addressing Process Failures Through Governance

Process failures such as delayed responses to emergencies, inadequate staffing, and ineffective triaging are some of the common contributors to litigation. These issues can be addressed through a strong clinical governance framework within healthcare institutions. Real-time performance monitoring, clear escalation protocols, and structured communication tools help ensure timely decision-making and accountability.

Role of Clinical Risk Management and Safety Culture

Clinical risk management strategies play a vital role in reducing malpractice risk. The use of standardized protocols, regular training programs, and periodic audits of adverse events helps identify gaps in care before they result in harm.

Fostering a culture of patient safety system that encourages open communication, early reporting of errors, and continuous quality improvement is also one important step in preventing litigation.

It is essential for the healthcare providers to have a basic understanding of key medico-legal laws such as the Consumer Protection Act, National Medical Commission regulations, the MTP Act, and the PCPNDT Act. Awareness of these statutory requirements allows clinicians to give good care to the patients while minimizing unintended legal risks.

Conclusion

Legal compliance in OBGYN practice does not depend solely on legal knowledge but on sound clinical practice supported by strong systems. Meticulous documentation, meaningful informed consent, adherence to clinical guidelines, awareness of statutory requirements, and honest communication with patients and families form the foundation of medico-legal safety. By integrating these principles into everyday practice, obstetricians and gynecologists can provide safe, compassionate, and high-quality care to women without litigation.

References

1) Gowda SL, Bhandiwad A, Anupama NK. Litigations in Obstetric and Gynecological Practice: Can it be prevented? A Probability to Possibility. J Obstet Gynaecol India. 2016 Oct;66(Suppl 1):541-7. doi: 10.1007/s13224-016-0881-3. Epub 2016 Apr 16. PMID: 27651659; PMCID: PMC5016466.

2) Toma-Tumbar L, Nagy RD, Marinaș MC, Iliescu DG, Cara ML. Navigating the Complex Terrain of Obstetrics and Gynecology Malpractice: Stakeholders, Expectations, and Legal Implications. J Clin Med. 2025 Mar 26;14(7):2266. doi: 10.3390/jcm14072266. PMID: 40217716; PMCID: PMC11989799.

3) Brunello S, Gay-Berthomieu M, Smiles B, Bardho E, Schantz C, Rozee V; et al. Obstetric and gynaecological violence in the EU - Prevalence, legal frameworks and educational guidelines for prevention and elimination [Internet]. Policy Department for Citizens' Rights and Constitutional Affairs, Directorate-General for Internal Policies, European Parliament; April 2024. PE 761.478. Available from: https://www.europarl.europa.eu/RegData/etudes/STUD/2024/761478/IPOL_STU(2024)761478_EN.pdf

----------XXXXX----------

APPENDIX

PAGE 1 – THE TOOLKIT

Clinic Regulatory Compliance Toolkit – January 2026
This page lists the minimum standards expected in every ObGyn clinic during inspections, audits, or legal scrutiny.

1. Drug Storage & Stock SOP (OPD + OT)

MUST

- Storage temperature **15–25°C** (or as per label)
- **Daily temperature log** (manual or digital)
- Separate, labelled shelves for:
  - Emergency drugs
  - High-alert drugs
  - Expired / near-expiry drugs

DO NOT

- Store drugs near sunlight, sinks, sterilizers, or electrical heat
- Keep loose strips without outer packaging
- Mix paediatric, adult, and emergency drugs

2. Expiry & Batch Tracking Checklist

□ Monthly expiry check documented
□ Batch number visible on every strip / vial
□ FIFO (First-In-First-Out) followed
□ Expired drugs removed immediately
□ Disposal as per BMW rules
□ Emergency trolley checked monthly

3. Device & Equipment Documentation SOP

□ Purchase invoice available
□ Installation report filed
□ AMC / maintenance record maintained
□ Calibration / servicing dates recorded
□ User manual accessible
□ Trained user documented

One undocumented device or expired drug is enough to question the entire clinic system.

PAGE 2 – RED FLAGS

20 Regulatory Traps Doctors Commonly Fall Into

Tick honestly. Three or more ticks = immediate correction needed.

1. No temperature log for drug storage
2. Expired emergency drugs in crash cart
3. Mixing OPD and OT drug stocks
4. Oxytocin stored at room temperature
5. Missing batch numbers on strips
6. Drugs used without outer packaging
7. No AMC records for equipment
8. Untrained staff handling devices
9. Reuse of single-use items
10. Incomplete consent forms
11. Consent without date / time
12. Illegible prescriptions
13. No adverse event documentation
14. Improper biomedical waste segregation
15. Sharps disposed in wrong container
16. No purchase invoices available
17. No SOPs displayed in clinic
18. Using expired samples
19. Mixing patient drugs with clinic stock
20. Ignoring “minor” audit observations

Most inspections fail not because of intent, but because of small ignored details

PAGE 3 – COMMITTEE RECOMMENDATIONS

FDMSEC – 10 ACTION POINTS FOR EVERY OBGYN CLINIC

(January 2026 Advisory)

1. Maintain **written SOPs** for drugs, devices, BMW
2. Record **daily temperature logs**
3. Audit expiry & emergency kits **monthly**
4. Use **procedure-specific valid consent**
5. Maintain equipment service & calibration records
6. Train staff **annually** in safety & compliance
7. Segregate BMW **at source**
8. Procure drugs/devices only from verified suppliers
9. Document and report adverse drug/device events
10. Conduct a **self-audit every 6 months**

Dr Asha Jain
Chairperson – FOGSI Committee on Food,
Drugs & Medicosurgical Equipment (FDMSEC)

ONE-PAGE LAMINATED WALL CHART

“OBGYN CLINIC COMPLIANCE – DAILY & MONTHLY CHECK”

(Designed for OT / Drug Store / Nursing Station)

□DAILY

□ Drug storage temperature recorded
□ Emergency drugs checked
□ BMW segregation followed
□ Sharps disposed correctly

□ MONTHLY

□ Expiry check documented
□ Crash cart audited
□ Equipment log updated
□ Consent formats reviewed

□ ALWAYS AVAILABLE

□ Drug invoices
□ Device installation & AMC records
□ SOPs displayed
□ Valid consent templates

This clinic follows FDMSEC safety and regulatory recommendations.

Dr Asha Jain,
Chairperson FDMSEC

STAFF-TRAINING VERSION

“What Every Staff Member Must Know”

1. Medicines

- Check expiry dates
- Store medicines properly
- Never use loose strips
- Inform doctor if temperature log is missed

2. Machines

- Use only if trained
- Do not ignore alarms
- Report faults immediately
- Do not shift equipment without permission

3. Consent & Records

- Consent must be signed, dated, timed
- Never take blank or pre-signed consent
- Write clearly and completely

4. Waste Disposal

- Separate waste at source
- Never mix sharps
- Follow colour coding strictly

Designing content approved by

Dr Asha Jain
Chairperson FDMSEC

01 - Regulations That Actually Affect Your Clinic

FDMSEC INSIGHTS - JANUARY -2026

From

FOGSI, Food Drugs & Medicosurgical Equipment Committee

Dr.Bhaskar Pal
President
FOGSI

Dr.Suvarna Khadilkar
Secretary General
FOGSI

Dr. Vidya Thobbi
Vice President Incharge
FOGSI

Dr. Asha Jain
Chairperson
FOGSI FDMSEC

Dr. Asha Jain

Editor & Chairperson, FOGSI FDMSE Committee