02 - Biosimilars, Generics & Brand Confusion

FDMSEC INSIGHTS - February -2026

From

FOGSI, Food Drugs & Medicosurgical Equipment Committee

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Message From Dr.Bhaskar Pal

Dr. Bhaskar Pal
President FOGSI

Dear Colleagues,

Warm greetings from FOGSI.

It gives me immense pleasure to introduce the February issue of FDMSEC “INSIGHTS”, an e-magazine that addresses a domain that sits at the intersection of ethics, economics and patient care-generic versus branded medicine.

The 2026 FOGSI theme, Sarvaih Saha Pragatih **सर्वैः सह प्रगतिः** - progress for all, together, is deeply reflected in this February issue. Access to essential medicines cannot remain uneven, confusing, or dependent on individual interpretation.
This issue takes up a very real problem faced across India - generic versus branded prescription and the confusion it creates at the patient, pharmacy, and clinic level. Articles addressing realities of cost involving generic vs branded medicine, same-salt myths, and ethical prescription in the age of discounts are especially relevant to ensure equity without compromising safety.
Standardised prescription format, clarity in documentation, and ethical decision-making are necessary if progress is to be shared by all- doctors and patients alike. I congratulate the FDMSEC for addressing this theme thereby encouraging rational, ethical and evidence-based prescribing in true spirit of Sarvaih Saha Pragatih .

Wishing you an insightful read and safer, stronger practice.

With warm regards,

Dr Bhaskar Pal
President, FOGSI

Message from Dr Suvarna Khadilkar

Dr. Suvarna Khadilkar
Secretary General FOGSI

Regulatory clarity and uniform standards are essential when therapeutic options multiply. This February issue addresses areas where lack of standardisation is most visible- **biosimilars, tender drugs, storage practices, and traceability.**

The articles on biosimilars explained for ObGyns, tender drugs versus market brands, and storage and handling errors align closely with regulatory expectations and governance requirements. The committee recommendations provide much-needed direction for consistent implementation across clinics.

I appreciate the FDMSEC for converting complex regulatory concepts into clear, **implementable guidance** that supports both quality care and professional accountability.

Dr. Suvarna Khadilkar
Secretary General FOGSI

Message From Dr.Vidya Thobbi

Dr.Vidya Thobbi
VP South Zone FOGSI
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In day-to-day ObGyn practice, some of the most frequent errors arise not from clinical judgement, but from **prescription writing and brand substitution**. This issue addresses these exact pain points.

The articles on prescription writing mistakes, mid-treatment brand switching, and the red-flag list of prescribing traps are particularly valuable for busy clinicians. These are not academic discussions; they are tools to reduce errors, patient confusion, and medicolegal exposure.

I strongly recommend that members use this issue as a clinic reference, especially for training junior doctors and staff. Small corrections in routine practice can make a large difference in patient safety.

Dr. Vidya Thobbi
Chairperson FOGSI

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FOREWORD

One of the commonest questions I hear from colleagues is: “What is safe to prescribe, what can be switched, and how do we protect ourselves and our patients?” This February issue is built around answering exactly that.

Each article in this issue addresses a specific gap- whether it is **generic versus branded cost realities, biosimilars in women’s health, prescription writing errors, storage failures, or ethical dilemmas created by discounts**. Together, they reflect the everyday challenges faced by ObGyns across practice settings.

I sincerely thank our **FOGSI President Dr. Bhaskar Pal, Vice President (In-charge) Dr. Vidya Thobbi, and Secretary General Dr. Suvarna Khadilkar** for their leadership and guidance. I also thank all the contributing authors for sharing their expertise and practical insights.

Authors- February 2026 Issue: **Dr. Kiran Chhabra, Dr. Chitra Pandey, Dr. Vandana Gupta, Dr. Neetha George, Dr. Prerna Saigal, Dr. Urvashi Barman, Dr. Sugandha Goel, Dr. Sandhya Rani Panigrahi, Dr. Rimpi Singla, Dr. Shikha Sachan.**

Aligned with the WHO theme of Access to Essential Medicines and FOGSI’s vision of **Sarve Sah Pragati**, this issue aims to convert access into **safe, ethical, and consistent practice**. I hope these pages are used actively in clinics, audits, and team discussions.

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

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01 Generic vs Branded Drugs: Are We Really Saving Money?

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In clinics across the world, a common question echoes in consultation rooms: “Doctor, can I take the generic? Is it the same?” Behind that simple question lies a complex intersection of science, economics, trust, and lived experience. Generic medicines are widely promoted as cost- saving alternatives to branded drugs. Governments encourage their use, insurance systems prefer them, and public health programs rely heavily on them. But the deeper question remains- are we truly saving money, and at what level?

The rapid rise of generic medicines has transformed how healthcare is delivered and financed globally- and nowhere more than in India is often described as the “pharmacy of the world” because of its large generic drug manufacturing capacity.

But the central question remains: are we genuinely saving money by using generics instead of branded drugs, without compromising quality or health outcomes? So, let’s examine the economic, scientific, regulatory, and real-world aspects of the generic vs branded debate, with a focus on the Indian landscape

To answer this, we must look beyond the printed price on a medicine strip and examine the broader landscape of healthcare costs, patient behaviour, regulatory oversight, and long-term outcomes.

Understanding the Basics

A branded drug is the original product developed by a pharmaceutical company after extensive research, clinical trials, and regulatory approval. The innovator company holds a patent, usually for about 20 years from filing, during which it has exclusive marketing rights. These drugs are marketed under proprietary brand names and often carry higher prices to recover research and development (R&D) investments.

Generic drugs enter the market after patent expiry, other manufacturers can produce generic versions, medicines that contain the same active pharmaceutical ingredient (API), same strength, dosage form, and route of administration. However, generics may differ from their branded counterparts in manufacturing processes, packaging, and sometimes bioavailability (must demonstrate Bioequivalence to branded drug) & these are factors that can influence clinical performance in certain situations.

Regulatory authorities such as the US FDA, EMA, and CDSCO require that generics meet strict standards of quality, safety, and efficacy.

On paper, generics are therapeutically equivalent. In pricing, however, they are significantly cheaper — often 30% to 80% lower than branded counterparts.

Direct Savings: The Immediate Financial Impact

From a purely economic perspective, generic clearly reduces direct medication costs. Studies show that generic substitution has led to billions of dollars in savings globally. In the United States alone, generic drugs saved the healthcare system an estimated $373 billion in 2021 (Association for Accessible Medicines, 2022).

In India, most market prescriptions are for branded generics, generic drugs sold under a company's brand name, rather than purely unbranded generics.

Cost: The Most Visible Advantage of Generics

The primary appeal of generics is cost savings. Generic medicines often cost significantly less than branded drugs, and that price difference directly affects patients' ability to afford treatment. A comparative study of commonly used medicines in India found that: • Branded drugs cost about ₹11.17 per tablet on average • Branded generics cost around ₹9.12 per tablet • Local trade generics cost about ₹5.74 • Jan Aushadhi (government generic) medicines cost an average ₹2.40 per tablet & in some cases up to 14 times cheaper than top-brand equivalents (e.g., pantoprazole) For chronic conditions requiring long-term treatment, these savings can be transformative.

For individual patients, especially those with chronic conditions such as hypertension, diabetes, epilepsy, or cardiovascular disease, long-term medication costs can be substantial. Lower drug prices improve affordability, which in turn improves adherence. And better adherence translates into fewer hospitalizations, fewer complications, and lower overall healthcare costs.

In low and middle-income countries, where out-of-pocket expenditure forms a major component of healthcare spending, generic medicines have been transformative. Affordable generics allow patients to continue life-saving therapies without financial distress.

At this level, the savings are real and measurable.

However, the economic story is not always straightforward.

Bioequivalence and Quality:

What the Science says Regulators typically require generics to demonstrate bioequivalence. They must deliver the active drug to the bloodstream at a similar rate and extent as the reference branded product, usually within an 80- 125% range. Evidence from India confirms that this standard is met in many widely used medicines:

- A quality audit of generic and branded drugs across 22 therapeutic categories found no meaningful difference in drug content or quality between generics and branded products.

- Most generics effectively met Indian Pharmacopoeia standards for drug content, dissolution, uniformity, and impurities. These results support the clinical interchangeability of many generics with their branded equivalents

For most drugs, this variation is clinically insignificant. But for drugs with a narrow therapeutic index- such as warfarin, levothyroxine, or certain antiepileptics- even small differences can matter. If switching between brands or generics leads to instability, additional monitoring, laboratory tests, or even hospitalization may offset initial savings.

Second, patient perception plays a powerful role. Research shows that some patients associate lower cost with lower quality. This "nocebo effect" can influence therapeutic outcomes. If a patient loses confidence in a generic medication, adherence may decline, leading to disease progression and increased healthcare costs.

Third, variability in manufacturing standards across regions can influence quality. While regulatory agencies enforce Good Manufacturing Practices (GMP), enforcement strength differs globally. Poor-quality or substandard medicines- whether branded or generic- can lead to treatment failure and additional medical expenses.

Thus, while the medicine itself may be cheaper, the broader economic picture depends on regulation, monitoring, and patient trust.

When Generics Are Generally **Safe and Effective?**

Common conditions,
As hypertension, diabetes, acid peptic disease, pain, and infections generics are as safe and effective as branded drugs.

Caution Is Warranted
Not all situations are equally suited to generic substitution:

1. **Narrow Therapeutic Index (NTI)** Drugs Medicines like warfarin, levothyroxine, and certain antiepileptics require minimal variability in blood levels, and small differences between products can alter therapeutic effectiveness
2. **Complex or Modified-Release formulations** & Extended-release or specialized formulations can behave differently depending on excipients and manufacturing methods, even if bioequivalence standards are formally met.
3. **Persisting Trust and Perception Issues**

Despite policy support: Many doctors and patients still mistrust generics due to branding effects & perceived superiority of branded products.

The Marketing Effect: What Are We Really Paying For?

It is important to acknowledge that branded drugs initially fund innovation. The high prices during patent protection help recover R&D costs, including failed drug candidates. Without that incentive, pharmaceutical innovation might slow down. Therefore, branded pricing supports future drug development, while generics enhance present affordability

Branded drugs often cost more not because they are pharmacologically superior, but because of marketing, brand positioning, and promotional expenditure. Pharmaceutical marketing includes medical representative visits, conferences, advertisements, and brand-building strategies.

Generics typically operate with lower promotional expenditure, contributing to lower prices. In this sense, choosing generics may reduce costs that are not directly linked to therapeutic value.
The healthcare system requires both.

System-Level Savings vs Individual-Level Concerns

From a public health standpoint, widespread generic substitution significantly reduces national healthcare expenditure. Insurance systems and government programs rely on these savings to allocate resources elsewhere- preventive care, vaccination programs, infrastructure, and new technologies.

Yet at the individual level, decision-making is more nuanced. A physician may prefer a specific brand due to familiarity, consistent supply, or confidence in manufacturing quality. Patients may feel reassured by a recognizable name.

The challenge lies in balancing macroeconomic efficiency with micro-level trust and continuity of care.

Are We Saving Money in the Long Run?

The strongest argument in favour of generics lies in improved adherence. Studies consistently show that lower medication costs lead to better compliance. Better compliance reduces complications of chronic diseases- fewer strokes, fewer heart attacks, fewer hospital admissions.

For example, increased generic use in cardiovascular medicines has been associated with similar clinical outcomes at lower cost compared to brand-name drugs (Kesselheim et al., 2008). From this perspective, generics not only save money upfront but also prevent costly complications later.

However, savings depend on consistent quality assurance, robust pharmacovigilance, and proper patient counselling. Without these, short-term savings may be offset by long-term consequences.

India's Policy Landscape on Generics

India has pursued several major policy initiatives to encourage generic usage and make medicines more affordable:

1. Pradhan Mantri Bhartiya Janaushadhi Pari yojana (PMBJP) Launched in 2008 and restructured in 2016, the PMBJP is the flagship government scheme to expand access to quality-assured generics through Janaushadhi Kendras (JAKs). As of 2025:

• Over 16,000 Janaushadhi Kendras are operational nationwide. • The scheme offers more than 2,000 medicines and 300 surgical items at 50–90% lower prices than branded alternatives.

• Generics under PMBJP are sourced from GMP-certified suppliers and tested in NABL-accredited laboratories to ensure quality. The government also promotes awareness through campaigns, mobile apps for price comparison, and rent-**free space in public health facilities to set up JAKs.**

2. Regulatory Actions and Prescribing Guidelines the Central Drugs Standard Control Organisation (CDSCO) regulates drug approval in India. While CDSCO enforces quality standards, occasional alerts about substandard medicines remind us that quality vigilance remains vital. Past efforts by the National Medical Commission (NMC) to mandate prescribing by generic names were temporarily held back due to concerns raised by professional bodies, showing the complex balance between policy and clinical autonomy.

3. Hospital Initiatives Some public hospitals like the Surat Municipal Institute of Medical Education and Research (SMIMER) have directed doctors to prioritize generic prescriptions to cut patient costs, which reflects growing institutional support for generics.

The Human Dimension

Behind every statistic is a human story.

An elderly pensioner choosing between blood pressure tablets and monthly groceries. A young diabetic mother stretching insulin supplies. A rural patient traveling long distances to purchase a trusted brand because cheaper options feel uncertain. Savings in healthcare are not merely economic figures- they influence dignity, peace of mind, and trust. When a doctor confidently explains that a generic medicine is equally effective and safe, the patient gains both financial relief and psychological reassurance. That combination & affordability plus trust- is where true savings lie.

The Way Forward

To ensure that generic substitution genuinely saves money, several elements are essential:

1. Strong regulatory oversight and quality control.
2. Transparent bioequivalence standards.
3. Consistent supply chains.
4. Physician education and confidence.
5. Patient counselling to address misconceptions.

When these pillars are strong, generic medicines represent one of the most effective tools for cost containment without compromising care.

Conclusion

So, are we really saving money with generic drugs?

The answer is yes- but conditionally.

Generics unquestionably reduce direct medication costs and improve access. They enhance adherence and reduce long-term healthcare expenditure when quality is assured. However, savings depend on regulation, monitoring, and patient trust. Without these safeguards, cost-cutting may become cost-shifting.

In the end, the real measure of savings is not just financial. It is about preventing disease progression, avoiding hospitalization, and ensuring that no patient has to choose between treatment and survival.

A medicine, whether generic or branded, fulfils its purpose only when it is safe, effective, affordable- and trusted.

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02 Biosimilars Explained For Busy Obgyns

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INTRODUCTION:

Biological medicines are derived from living system using biotechnology like vaccines, blood and blood components and recombinant therapeutic proteins. Biosimilars are highly similar to already approved biologic medicines and offer comparable safety, quality and effectiveness at an affordable cost. Biosimilars play a vital role in addressing the growing burden of non-communicable diseases in India while aligning with global standards of quality and patient safety. In India first similar biologic was developed in 2000 for Hepatitis B vaccine.

DEFINITIONS OF BIOSIMILARS

WHO : A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product. They are termed as similar biologic products (SBP) [1]

US-FDA : A biopharmaceutical product highly similar to the reference product without meaningful differences in safety, purity and potency. They are termed as follow on Biologics. (FOB) [2]

CDSCO : Similar biologics-A, biological product/drug produced by genetic engineering techniques and claimed to be similar in terms of safety, efficacy and quality to a reference biologic which has been granted a marketing authorization in India by DCGI.

Biosimilars include

- Blood and plasma products
- Non recombinant products
- Recombinant products
- Monoclonal antibodies
- Vaccines

USES OF BIOSIMILARS

- Blood disorders: Leukaemia, pancytopenia
- Cancers: Colon, breast, NHL
- Immune system disorder: Rheumatoid arthritis, Psoriasis, Crohn's disease
- Neurological disorders: Multiple sclerosis

DIFFERENCE FROM GENERICS

Difference Between Biosimilars and Generics

Biosimilars	Generics
Produced by living cell cultures	Produced by chemical synthesis
High molecular weight compounds	Low molecular weight compounds
Complex dimensional structure	Well defined structure
Immunogenic	Stable
Clinically identical to their reference products but not the same (Active product likely to have variations)	Mostly non immunogenic
Manufacturing is complex and variable	Therapeutically equivalent with their reference products (Active product is always same)
For approval regulators require clinical trials, manufacturing and post-approval safety monitoring programs similar to that of the original innovator companies.	For approval regulators require bioavailability and bioequivalence studies.

Comparison of Biologic, Biosimilar and Generic products

Process	Biologic	Biosimilar	Generic
Manufacturing	Produced by biological process in host cells.	Produced using existing "reference" biologic blueprint of biologics	Produced by using chemical synthesis.
	Proprietary original cell lines, Sensitive to production changes, expensive	Independently developed similar cell lines, Sensitive to production changes, expensive	Less sensitive to production changes.
	Manufacturing recipe developed by innovator, Reproducibility difficult to establish.	Reverse engineered to match innovator, Reproducibility difficult to establish.	Reproducibility easy to establish.
Clinical Development	Extensive clinical studies, including phase I-III	Extensive clinical studies, including phase I-III	Often only Phase I-III
	Pharmacovigilance and periodic safety updates needed.	Pharmacovigilance and periodic safety updates needed.	Short timeline for approval
Regulation	Needs to demonstrate, comparability regulatory pathway defined by Europe (EMEA)	Needs to demonstrate, comparability regulatory pathway defined by Europe (EMEA)	Needs to show, Bioequivalence abbreviated registration procedures in Europe
	Currently no automatic substitution intended.	Currently no automatic substitution intended.	Automatic substitution allowed.

REGULATION OF BIOSIMILARS IN INDIA
REGULATORY AUTHORITIES IN INDIA

1.The Central Drugs Standards Control Organization CDSCO (DCGI) and Review Committee on Genetic Manipulation (RCGM) under the Department of Biotechnology (DBT) govern approval.

2.Genetic Engineering Appraisal Committee (GEAC): Reviews and approves when final drug product contains genetically modified organisms.

3.Institutional Bio-safety committee (IBSC)

REGULATORY GUIDELINES ON BIOSIMILARS

Guidelines on regulatory requirements for marketing authorization in India were published by CDSCO in collaboration with DBT in 2012 and revised in the year 2016 with more focus on scientific principles and stepwise approach to demonstrate similarity between a biosimilar and its reference biologic product.

Guidelines framed in 2025 consider the current scientific evidence andupdates from the international guidelines majorly WHO TRS 1043: Guidelines for evaluation of biosimilars.

BIOSIMILAR PATHWAY IN INDIA

1: Product Development

- Approval needed from IBSC
- Approval needed from DBT

2: Animal Toxicity Studies

- Protocol to be designed approved by RCGM and DBT
- Study should be conducted in GLP accredited Laboratory

3: Clinical Trial

- Protocol should be approved by DCGI andethics committee.
- Any deviation need to be approved by DCGI.

4: Marketing and Manufacturing License

- CT report to be submitted to DCGI
- The dossier needs approval by DCGI
- Mfg. License should be issued after inspection of the facility

5: First 3 Commercial batches need to be tested at NTB

6: Post Approval Committee

- Post marketing surveillance mandatory at least for 4 years
- Every 6-month safety reporting to DCGI for 2 Years and annually for remaining years.

KEY ISSUES WITH BIOSIMILARS

1.Efficacy:

Issues arising from differences between the bio activity of biosimilars and their innovator products.

2. Safety:

Safety profile of biosimilar is not identical to that of reference product because of Variation in immunogenicity.

3.Substitution:

- Automatic substitution of chemical generics to biosimilar agent is appropriate and benefits the patient.
- Biosimilars are not interchangeable with their original biologic but a physician may choose to switch the patient from original biologic to biosimilar product if they think it will benefit the patient.
- Switching refers to a onetime change made by a physician in patient's interest and if patient agrees.[3]

4.Nomenclature:

Biosimilars require unique nomenclature which facilitate prescribing and dispensing them and also aid in their Vigilance.

5.Labelling:

Labels of original reference product and biosimilar must be different.

BIOSIMILARS IN OBSTETRICS AND GYNECOLOGY

1.Infertility and Assisted Reproductive Technology (ART) Recombinant follicle stimulating hormone (rFSH) biosimilar are widely used and demonstrates comparable outcomes in terms of oocyte retrieval, pregnancy rate and safety profile compared to original products. Cost reduction remarkably improves affordability of ART cycles.

2. Gynaecological oncology:

Biosimilars of monoclonal antibodies such as bevacizumab and trastuzumab are used in ovarian cancer, cervical cancer, HER2 positive breast cancer. Bevacizumab became first FDA approved biosimilar in 2017 for gynaecological cancer. [4]

Supportive care in oncology- Biosimilars of leukocyte growth factors such as filgrastim are used to decrease infections caused by neutropenia in patients receiving chemotherapy.

3. Endometriosis and Immune-related Conditions:

Biologics Like TNF-alpha inhibitors are used in selected cases of severe endometriosis or autoimmune disorders affecting reproductive health.

COUNSELLING FOR BIOSIMILARS

Counselling is focused on educating healthcare professionals and patients about the safety, efficacy and cost effectiveness of these treatments.

Information should be provided on potential immunogenic reaction and reassuring patients based on post marketing surveillance data.[5]

Affordability and access to biosimilars should be highlighted crucial for the treatment of infertility and chronic conditions like cancer, diabetes etc.

TAKE HOME MESSAGES

- Biosimilars are officially approved versions of original innovator product and can be manufactured when the original product patent expires.
- High degree of variability among the biosimilar products and safety issues like immunogenicity call for careful selection and substitution.
- Common biosimilars in India are rFSH, erythropoietin, human insulin, interferon, streptokinase, Filgrastim, teriparatide, monoclonal antibodies etc.
- Counselling is essential to ensure patient's confidence, adherence and safe use of biosimilar medicines.

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03 Can You Switch Brands Mid Treatment

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INTRODUCDTION

In health management three P's play very important role.

1.Physicians - are the health experts with knowledge about disease management & diagnosis of the disease. They are the actual customers of the medicines

2.Patient - are the consumer about the medicines who may not have enough knowledge about the effectiveness & adverse effects of the medicines. They completely rely on the physician's prescription.

3. Pharmacist - is drug expert, in terms of drug manufacturer & drugs selling in market.

BRAND- is one of the most important tools for disparity that a company uses to gain competitive advantage

GENERIC- have the same active ingredient as brand-name drugs, different manufacturers may use different inactive ingredients (fillers, dyes, binders), which can cause new side effects, allergic reactions, or differences in absorption.

Why Side Effects Differ

- **Inactive Ingredients (Excipients)**: Inactive ingredients make up a large portion of a pill, and variations can cause different side effects or allergic reactions.
- **Absorption Differences**: Although bioequivalent, a switch in manufacturer can cause slight, but sometimes significant, changes in how much of the drug reaches the bloodstream.
- **Narrow Therapeutic Index (NTI)**: For drugs with a small, precise window for effectiveness (e.g., Synthroid vs. generic levothyroxine, Coumadin vs. warfarin), even minor formulation changes can cause side effects or reduced efficacy.
- **Individual Sensitivity**: A patient might be sensitive to a specific filler used by one manufacturer but not another.

DISCUSSION ON SWITCHABILITY

On average, the cost of generics is 80-85 percent less than brand-name. Yet, inspite of their higher price, brand-name drugs account for nearly 75 percent of the total cost of prescriptions.

- A generic drug is a **"bioequivalent"-** a chemical copy of the original brand-name medication. It must be made with the same active ingredient(s), work the same way and provide the same benefit(s) as the brand-name drug.

Bioequivalence and switchability

- An innovator medicine can generally be substituted with an approved generic and vice versa because of the comparable bioavailability demonstrated through bioequivalence studies. However, these studies are not designed to investigate patients' suitability to change from one brand to another during their treatment ('switchability').

Generics must meet the same FDA (U.S. Food and Drug Administration) standards for safety, quality, strength, purity and efficacy as brand-name drugs

- Not all drugs have generic alternatives available on the market. Generics become available only after a brand drug's patents expire, 20 years after the date the patent was filed.

Why Are Generic Drugs Cheaper Than Brand-Name Drugs?

A pharmaceutical company invests extremely large amounts of money and time to research and develop a drug & obtain patent mark.

After this company markets the drug exclusively for years, at their own price, profiting without competition. When patents expire, other drug companies can develop and market generic equivalents using the same active ingredient(s).

Companies developing generics don't have to invest major amounts of time and research , means generics can get to market quicker and be sold for much cheaper than brand drugs. Additionally, many generic options for a brand drug may enter the market at the same time, creating market competition that drives down prices

Are Generic Drugs as Effective as Brand-Name Drugs?

Yes. They offer the same benefits. Generally, they also have the same side effects and adverse reactions as brand drugs.

Are Generic Drugs as Safe as Brand-Name Drugs?

Yes, the FDA monitors and ensures the safety and quality of both brand-name and generic drugs. While it is possible for the inactive ingredients in generic drugs to cause side effects or adverse reactions, the same is true of brand drugs. If these are reported, the FDA responds appropriately.

Is It Safe to Switch?

Bioequivalence and switchability

- An innovator medicine can generally be substituted with an approved generic and vice versa because of the comparable bioavailability demonstrated through bioequivalence studies. However, these studies are not designed to investigate patients' suitability to change from one brand to another during their treatment ('switchability').

- For most medicines, patients can switch between approved brands during treatment without issue.

- A medicine's switchability may be affected by its therapeutic index or pharmacokinetics, or the patient population

- In some patients or for certain medicines, formulation or significant manufacturing changes can affect the patient's response, despite the demonstration of bioequivalence. Just a slight variation in the body's response to a different drug can create a significant problem.

- Sometimes it's not safe to switch from a brand to a generic or vice versa. Certain medications have a narrow therapeutic index (NTI) or "safe range" between the benefits and harmful effects of a drug.

e.g. Thyroid medication Brand vs Generic- Levothyroxine
Blood thinner Brand (Coumadin) vs Generic- warfarin

Anti-epileptic medicines

Anti-epileptic medicines (AEMs) can cause difficulties when switching patients between brands. Medsafe recommends that prescribers follow the UK Medicines and Healthcare products Regulatory Agency's (MHRA) advice regarding AEMs, which places them in three categories based on switchability.[5]

- **Category 1 (Avoid Switching)**: Phenytoin, carbamazepine, phenobarbital, primidone.
- **Category 2 (Switch with Caution)**: Valproate, lamotrigine, perampanel, clonazepam.
- **Category 3 (Generally Acceptable)**: Levetiracetam, gabapentin.

Recent New Zealand experience supports this advice, with many patients experiencing difficulties when the funded lamotrigine brand (a category 2 AEM) was changed in 2019,[6] and when the formulation of the brand name phenytoin medicine Dilantin was altered.[7]

Multiple studies and case reports have described relapses and worsening clinical outcome in patients after a switch from a brand name to a generic medication

Always check with the doctor before switching between generic and brand medications.

Filling the Prescription: Generic or Brand Name?

some things patient should know.

- A doctor can require the brand by writing "dispense as written" or "do not substitute" on the order.
- You can refuse a generic if you're willing to accept the costs associated with the brand-name drug.
- Generics are often substituted simply to reduce cost.

When Is Generic a Better Choice?

When choosing between generic and brand-name drugs, it's a matter of availability, cost and preference. "Generics are a great choice when cost is a priority and you have no adverse reactions or side effects to the generic,"

When Is Brand-Name a Better Choice?

"If your health doesn't improve or you have side effects or reactions to a generic.
"Sometimes there is no choice because there is no generic alternative.
Or your doctor determines that the brand name is better for you."

FOLLOWING A SWITCH

If a bad reaction to a medicine, it might not be the drug itself, but what are called "inactive ingredients" in the pill or capsule.

A study co-author Giovanni Traverso, a gastroenterologist at Harvard-affiliated Brigham and Women's Hospital, had a patient with a severe gluten intolerance called celiac disease. The person was having trouble with a medication that apparently contained gluten as an inactive ingredient- potentially making the condition worse

Traverso, also a biomedical engineer, explored this with colleagues by weighing pills in the hospital pharmacy. They concluded that, on average, about 75 percent of a pill or capsule is made up of inactive ingredients – that is, material other than the chemical or chemicals that determine the therapeutic effect of a drug.

The scientists say drug companies have more than a thousand of these inactive constituents to choose from. "In some instances there can be up to 35 of them in a single pill,"

These inactive ingredients are essential to stabilize medications and sometimes to help the body absorb the active ingredients & are very helpful."

But they can include materials such as gluten and lactose, and dyes that can trigger allergies.

In general, the amounts in a given pill aren't concerning. But many people take multiple medicines, and if those drugs contain the same inactive ingredients, the doses can add up

If you are lactose intolerant and take a pill that uses lactose as an inactive ingredient, "it's probably not going to manifest in any significant symptoms," he says. "But as the number of pills you're taking [increases], then certainly you might cross that threshold."

Different manufacturers of the same medicine often use different inactive ingredients, so if one drug might be causing trouble, it's worth considering a switch to the same product produced by a different manufacturer

SUSTAINED RELEASE , EXTENDED RELEASE FORMULATIONS

- **Sustained Release (SR)**: Releases the drug over a prolonged period, designed to maintain therapeutic blood levels without causing sharp peaks, **often used for immediate, yet prolonged, action.**
-
- **Extended Release (ER/XL/XR):** Often used interchangeably with SR, but specifically designed to extend the duration of action, allowing for a reduction in the required daily dosage (e.g., once-daily dosing).

- **Modified Release Categories:** These are subcategories of extended release that include controlled release and prolonged release, often utilizing polymer matrices (e.g., HPMC), coating technologies, or osmotic systems to control release rates.

Switchability considerations

- **Bioequivalence:** Switching between immediate-release (IR) and modified-release formulations (SR/ER) is generally not recommended without medical advice, as their plasma concentration profiles differ significantly.

- **Drug-Specific Dynamics:** The switchability of SR and ER versions depends heavily on the specific drug, as different manufacturers may use different, non-equivalent,, time-release technologies.

- **Adherence and Efficiency:** Both SR and ER improve patient compliance by reducing dose frequency and, in many cases, decreasing gastrointestinal side effects.

Switchability

Switching between immediate-release and modified-release (SR/ER) versions- or between different brands of modified-release drugs- requires caution due to differences in bioavailability and release kinetics.

- **Dose Equivalence**: A direct 1:1 milligram switch is not always appropriate. For instance, an IR drug taken multiple times a day may be replaced by a single, higher-dose ER tablet that releases that amount over 24 hours.
- **Bioequivalence Concerns**: Because ER/SR formulations use complex technologies (like osmotic pumps or polymer matrices), different brands may not be therapeutic equivalents, leading to "dose dumping" or variable absorption if switched.
- **Clinical Guidance**: The FDA's Orange Book is used to determine if two modified-release products are "switchable" (AB-rated), ensuring they provide the same clinical effect and safety profile.

CONCLUSION

Latest pharmacological guidelines and evidence suggest that while generic medicines are bioequivalent to brand-name products, **switching brands in the middle of a treatment cycle (specifically for certain medications) can lead to reduced treatment effectiveness, poor adherence, and increased adverse events.**

Regulatory bodies, such as the Indian Pharmacopoeia Commission (IPC) and international agencies (FDA, EMA), emphasize that while bioequivalence (80%-125% range) is acceptable, "switch ability" is not guaranteed for all therapeutic categories.

The 10th Edition of the Indian Pharmacopoeia (IP 2026) continues to uphold standards for drug quality, while recent Indian regulatory updates (Revised Schedule M, Feb 2025) focus on tightening manufacturing standards to improve consistency.

Key Risks of Mid-Treatment Switching

- **Variability in Drug Exposure**: Although active pharmaceutical ingredients (API) are the same, inactive ingredients (excipients), binders, and manufacturing processes can differ. These differences may affect the rate of absorption and overall efficacy.
- **Reduced Therapeutic Effect:** Unplanned brand switches can lead to a dip in efficacy or increased adverse events.
- **Generic-to-Generic Switches**: Research indicates that switching between different generic brands (generic-to-generic) is more problematic than switching from a brand to a generic.
- **Lower Adherence**: Changes in color, shape, or packaging can confuse patients, leading to non-compliance or reduced adherence.

2. High-Risk Categories for Switching

Certain medicines have a Narrow Therapeutic Index (NTI)- where a small difference in dose or blood concentration can cause treatment failure or toxicity- and should not be switched without medical supervision.

- **Anti-epileptic Drugs (AEMs):** Phenytoin, carbamazepine, and valproic acid require consistent brands to maintain therapeutic stability.
- **Thyroid Medications:** Levothyroxine, especially due to its complex Pharmacokinetic profile.
- **Cardiovascular Drugs:** Digoxin, warfarin, and amiodarone.
- **Psychotropic Medications:** Anti-psychotics and anti-depressants.
- **Biologics/Biosimilars:** These are more complex to replicate than generic drugs, requiring careful, intentional, physician-led switching rather than automatic, pharmacist-level substitution.

Guidelines on "Switchability"

- **Maintain Consistency**: Clinicians should aim for a consistent supply of the same brand, especially during the maintenance phase of chronic, high-risk diseases.
- **"Do Not Substitute"**: Prescribers should write "Use Same Brand" or "Do Not Substitute" on prescriptions for critical, narrow-therapeutic-index drugs.
- **Patient Education**: If a switch is necessary, the patient should be fully aware of the change in appearance to prevent confusion.
- **Monitor Symptoms**: If a patient experiences a deterioration in symptoms, an unplanned brand switch should be considered a potential cause.

Regulatory Trends (2025- 2026)

- **QR Code Mandate**: As of late 2025, India has mandated that certain drugs (vaccines, antimicrobials, anti-cancer drugs) carry a QR code to enhance supply chain tracking and authentication, helping to manage quality and reduce counterfeits.
- **Strict Manufacturing Standards**: Revised Schedule M (2024-2025) in India aims to align with international GMP (Good Manufacturing Practices) standards, enhancing the quality of generic products.
- **Changed Formulation Rule**: The Central Drugs Standard Control Organisation (CDSCO) has instructed that if the API composition of a drug changes, the manufacturer cannot retain the same brand name, preventing misleading, unintended, and unauthorized substitution.

Best Practices for Clinicians and Pharmacists

For the majority of medicines (e.g., painkillers, antibiotics), switching brands is safe. For narrow-range or chronic care drugs, **unnecessary, unplanned switching between brands or generics should be avoided to maintain optimal treatment effectiveness.**

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04 Prescription Writing Mistakes That Confuse Pharmacies

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COMMON ERRORS

1. Illegible Handwriting and Ambiguous Details

Poor Handwriting: Despite the rise of electronic prescribing, handwritten notes are still a significant issue. Pharmacists may misinterpret drug names or dosages, particularly with look-alike/sound-alike drugs.

Missing or Unclear Strength: Failing to specify the strength (e.g., Cefuroxime without mentioning 250mg, 500mg) forces pharmacists to call the prescriber.

Omitted Dosage Form: Not specifying if a medication is immediate-release (IR) or extended-release (ER/XR/XL/LA) can lead to the wrong medication being dispensed.

Missing Quantity/Duration: Not defining how many tablets to dispense or how long to take the medication (e.g., "5 days" vs. "10 days").

2. Dangerous Abbreviations and Symbols

Misinterpreted Units: Using "U" for units can be mistaken for "0" (zero), leading to a 10-fold overdose (e.g., 10U interpreted as 100).

Decimal Point Errors: A trailing zero (e.g., 5.0 mg) can be misread as 50 mg, while a leading decimal point (e.g., .5 mg) can be read as 5 mg instead of 0.5 mg.

"QD" or "OD" for Daily: These can be mistaken for "QID" (four times a day) or "right eye" (OD), respectively.

"Ug" or "mcg": Using "Ug" for micrograms can be mistaken for "mg" (milligrams).

3. Incomplete Information

No Diagnosis/Indication: Failing to include the purpose (e.g., "for blood pressure") makes it difficult for pharmacists to verify if the drug is appropriate, especially if the handwriting is poor.

Missing Patient Details: Leaving out age or weight is critical, as dosage requirements differ significantly between children, adults, and the elderly.

No Refill Information: Forgetting to specify the number of refills creates ambiguity.

4. Electronic (E-Prescribing) Errors

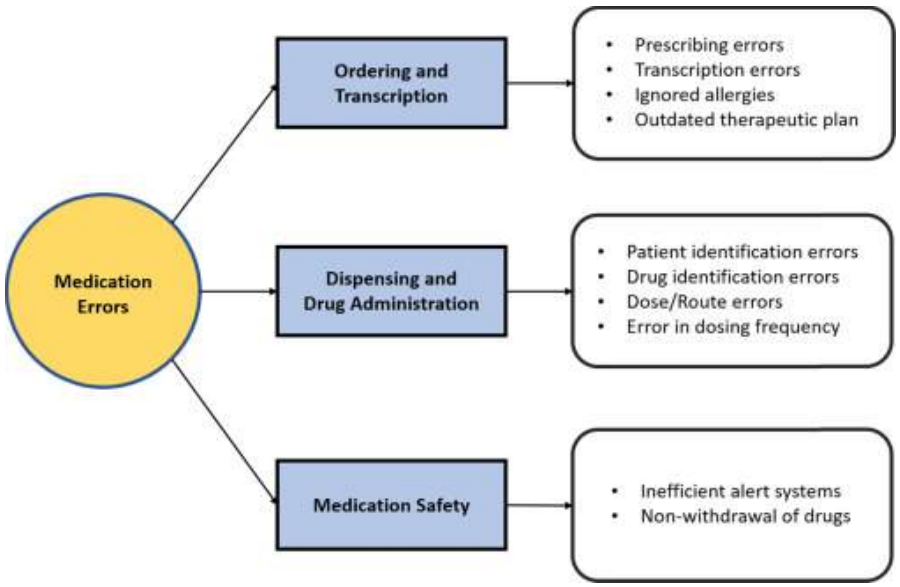
Wrong Drug/Dose Selection: Using dropdown menus, prescribers may select a drug with a similar name, or the system may default to an incorrect strength.

Drop-down Menu Errors: Inadvertently selecting the wrong medication from a computerized list.
Incompatible Systems: Technology, such as auto-populate features, can input conflicting, incorrect, or outdated instructions.

5. Common "Sound-Alike/Look-Alike" Mix-ups

Drug Name Confusion: Prescriptions for drugs like celecoxib (Celebrex) and citalopram (Celexa) can be easily mixed up.

Brand vs. Generic: Using brand names (e.g., "Jupitor") for a drug that the pharmacist might only know by its generic name (atorvastatin) can cause confusion.



NMC GUIDELINES

Based on recent directives (2025-2026) from the National Medical Commission (NMC) in India, improving prescription legibility and accuracy is a critical patient safety mandate. The NMC has instructed medical colleges to form special committees to monitor prescriptions, specifically to eliminate errors caused by poor handwriting, ambiguous abbreviations, and improper drug naming.
Here are the specific prescription writing mistakes that confuse pharmacists and violate NMC guidelines:

1. Illegible and Poor Handwriting

- **The Mistake**: Using hurried, cursive, or messy handwriting that makes drug names or dosages unreadable.
- **NMC Guideline**: Prescriptions must be written in clear, legible, and, wherever possible, capital letters.
- **Pharmacy Impact**: Causes immense difficulty for pharmacists to accurately identify the medicine, leading to dangerous substitution or dispensing errors.

2. Failure to Use Generic Names

- **The Mistake:** Writing brand names instead of the generic (pharmacological) name of the drug.

- **NMC Guideline:** The National Medical Commission encourages the use of generic names wherever possible.
- **Pharmacy Impact:** Restricts substitution with cheaper alternatives and can lead to confusion if the branded drug is unavailable, as pharmacists may not easily identify the pharmacological equivalent.

3. Vague or Ambiguous Directions

- **The Mistake:** Using vague instructions like "take as directed," "use as needed," or failing to specify the duration of therapy.
- **Pharmacy Impact:** Prevents pharmacists from providing effective patient counseling and makes it hard to verify the intended total dosage.

4. Dangerous Abbreviations and Unit Mistakes

- **The Mistake:** Using unsafe abbreviations (e.g., U for units, Q.D. for every day, D/C for discontinue) and improper decimal usage (e.g., .4 mg instead of 0.4 mg).
- **NMC Guideline:** Avoid abbreviations that can be misinterpreted. The metric system should be used, and leading zeros must be used for decimals (0.5mg, not .5mg).
- **Pharmacy Impact:** "U" can be read as "0" or "4" (causing 10-fold overdoses), and "Q.D." can be mistaken for "QID" (four times a day), leading to overdosing.

5. Omission of Crucial Details

- **The Mistake:** Omitting the patient's age (especially for children/geriatrics), weight, or the doctor's registration number/signature.
- **NMC Guideline:** Prescriptions must include the patient's age and weight (for, e.g., pediatric dose calculations) and the practitioner's name and registration number for authenticity.
- **Pharmacy Impact:** Makes it difficult to verify if the drug dose is safe for the patient or if the prescription is genuine.

6. Similar-Sounding or Similar-Looking Drug Names

- **The Mistake:** Writing names of drugs that look or sound alike (e.g., Celecoxib vs Celexa or Arkamine vs Artamine) without clarity.
- **Pharmacy Impact:** High risk of dispensing the wrong medication entirely.

NMC Recommendations for Improvement:

- **Capital Letters:** Using block letters for all prescriptions.
- **Digital Prescriptions:** Moving towards e-prescriptions to eliminate handwriting issues.
- **Monitoring:** Medical colleges are required to monitor prescriptions for these errors.

Violations of these guidelines can result in professional misconduct proceedings against the practitioner by the State Medical Council or the NMC.

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05 Patients Mistrust In Generic Drugs And How To Counsel Without Losing Confidence

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Introduction- There are two types of drugs available in the market,1.Generic2.Branded Generic drugs are the back-bone of affordable care, in the modern health care system,but patients perceive them differently ,not giving them importance as

per their clinical equivalence. A major percentage of patients view them with skepticism relating cheaper with inferior.
If patients don't trust their medication,their compliance is likely to be less leading to poor health outcomes .So addressing this issue is a clinical necessity and it is not merely about saving cost

1. WHY PATIENTS MISTRUST

There are many psychological and sociological factors behind mistrust in generic drugs.

- **The cheaper is inferior myth**

As in every market lower price correlates with poor quality, this 'Thought process' drives the patient mindset equating a cheaper drug with inferior ingredient

- **Dissimilarity in Appearance**

Due to trademark, a generic drug cannot look the same as a branded counterpart.
Due to difference in colour, shape etc the placebo- nocebo' effect comes into play and patients tend to think that generic drug is not going to be as effective or is going to have more side effects

- **systematic Distrust -**

There is skepticism towards pharmaceutical companies, which often transforms into mistrust in generic medicines. Reports of 'Research molecules' or 'Foreign companies' often amplifies it.

- **Lack of knowledge**

A large portion of people are not aware of the term 'generic'.They don't understand what 'Bioequivalence' means

- **Burden of chronic illnesses**

Patients with chronic illness are very particular about their 'stable' brand name and are hesitant to change the brand name leave aside generics.

2 Strategies for Counselling

Patients are influenced by their healthcare people, doctors and pharmacists. If doctors themselves cannot show confidence in ‘generic drugs’, how will the patients believe in it!

A. The‘Bio-equivalent’standard

It is important to explain to the patients that FDA and other regulatory bodies require the generic drugs to be ‘Bio-equivalent’. This means the generic must deliver the same amount of active ingredient into the blood stream at the same rate as the branded one.

B.Address Inactive Ingredients

The branded and generics differ only in the inactive ingredients (fillers, dyes,
binders). This convinces the patient that even if the pill looks different, it doesn't work differently

C. The financial point

Tell the patient that the generic offers better value for money This is due to the fact that generic manufactures don't have to repeat expensive clinical trials which the original company did and hence the saving

D. Endorsement

Patients often believe their health care providers’.personal choice. Telling them ‘I take generic version of ‘Heart medicine’ goes a long way in infusing faith in the generic version

3. When to Exercise Caution

While generics are suitable for the vast majority,clinicians should be mindful of Narrow
Therapeutic Index (NTI) of drugs .(e.g.,Levothyroxine,Warfarin,Lithium). For these specific cases, counselling should focus on:

- **C**onsistency in the specific generic manufacturer.
- Monitoring for small shifts in blood levels during a transition.
- Encouraging the patient to report any subtle changes immediately

Summary table: **Myths vs facts**

Patient Myths	**Clinical Fact**
“Generics take Longer to Work.”	Bioequivalence laws Require identical onset of action
“They are Made in Unsafe Factories.”	Generic plants must Meet the same GMP (Good manufacturing practices) as brand Plants.
“The different Color means It's a different drug.”	Color/shape differences are due to trademark laws, not chemistry

“It has more Side effects.”	Active ingredients and Safety profiles are the Same; Rarely an Inactive Dye may cause a reaction.

Take Home Message

It is about addressing misconceptions that patients may have about generic medicines; that generic and branded have the same 'Bioequivalent' Drug as their ingredient. It requires a blend of empathy and hard science to tell them that they differ only in physical appearance but have the same active ingredient. Generics are definitely more pocket friendly and give value for money.

EXPLAIN AND DON'T COUNTER

Acknowledge that “bioequivalent” does not mean “identical”. Differences in excipients (filters) or pill appearance can cause real psychological or physiological transitions. Validating these concern builds more rapport than a lecture on FDA standards.

THE SAME ENGINE ANALOGY: Explain that while the “packaging” (colour, shape binders) might change, the “engine” (the active pharmaceutical ingredient) is strictly regulated to perform in the same way.

PROACTIVE COUNSELLING: Shifting a patient to a generic is a clinical intervention . Design the switch as a way to increase long-term adherence by reducing financial toxicity. Explain them that it is more pocket friendly rather than a cost- cutting measure by the pharmacy or insurer.

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06 Are All 'Same-Salt' Drugs Really the same?

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Problem

The increasing availability of multiple pharmaceutical brands containing the same active pharmaceutical ingredient (API) has significantly improved affordability and accessibility of medicines worldwide. Generic substitution policies have been widely promoted to reduce healthcare costs and improve equity in drug access. However, alongside these benefits, a persistent and often incorrect assumption has emerged- that all same-salt drugs are therapeutically identical and fully interchangeable under all clinical circumstances. Even when the active ingredient is the same, formulation differences may influence drug absorption in certain clinical situations.

At first glance, this assumption appears logical. If two products contain the same API in the same strength and dosage form,they should theoretically produce the same clinical effect.Regulatory authorities such as the World Health Organization(WHO), Central Drugs Standard Control Organization (CDSCO, India), U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMA) require demonstration of bioequivalence before approving generic medicines. Bioequivalence ensures comparable rate and extent of absorption between a generic product and its reference (innovator) product.

However, bioequivalence does not automatically guarantee universal clinical interchangeability. Therapeutic outcomes may be influenced by

- Formulation characteristics
- Excipients
- Release mechanisms
- Stability profiles
- Manufacturing quality standards
- Drug- device interface
- Patient-specific physiological variables

In most cases, generics perform equivalently and safely. Yet in specific clinical scenarios- particularly narrow therapeutic index (NTI) drugs, modified-release formulations, biologics, chronic therapies, and device-dependent medications- small variations can translate into meaningful clinical consequences.
This distinction between chemical sameness and therapeutic equivalence is critical for rational prescribing, patient safety, and regulatory policy.

Common Mistakes

1. Equating Chemical Identity with Therapeutic Equivalence

The most frequent misconception is assuming that identical APIs automatically ensure identical therapeutic outcomes.
Chemical sameness establishes pharmaceutical equivalence- but therapeutic equivalence requires comparable bioavailability, stability, and manufacturing quality.

WHO prequalification guidelines emphasize that multisource (generic) products must demonstrate bioequivalence under stringent regulatory standards and adhere to Good Manufacturing Practices (GMP). The API alone does not determine drug performance; the formulation matrix,
dissolution characteristics, and stability under real- world conditions significantly influence clinical behaviour.
Thus, while most generics are clinically effective, therapeutic equivalence cannot be inferred solely from API identity.

2. Uncontrolled Brand Switching in Narrow Therapeutic Index (NTI) Drugs

NTI drugs have a small margin between therapeutic and toxic concentrations.
Even minor variations in systemic exposure can lead to toxicity or therapeutic failure.
Examples include:

- Levothyroxine
- Warfarin
- Phenytoin
- Carbamazepine
- Lithium
- Tacrolimus

Although bioequivalence studies accept a typical 80-125% confidence interval for pharmacokinetic parameters, even variations within this permitted range may be clinically significant for NTI drugs. Frequent brand switching without monitoring may result in unstable drug levels breakthrough seizures, altered INR, or thyroid dysfunction.
Clinical prudence requires careful monitoring when switching brands in such cases.

3. Interchanging Different Release Mechanisms

Not all formulations containing the same API are interchangeable. Immediate-release (IR), sustained-release (SR), controlled-release (CR), and extended-release (ER) products are designed with different pharmacokinetic profiles.
Modified-release systems alter:

- Time to peak concentration (Tmax)
- Maximum concentration (Cmax)
- Duration of action

- Fluctuation index
- Switching from IR to SR (or vice versa) without dose adjustment may result in subtherapeutic response or adverse effects. For example:
- SR metformin reduces gastrointestinal intolerance
- ER antihypertensives maintain smoother blood pressure control
- Modified-release opioids carry overdose risks if misused

Thus, release mechanism is a clinically relevant property, not atrivial pharmaceutical distinction.

4. Overlooking the Role of Excipients

Excipients are often considered pharmacologically inert, yet they influence:

- Drug dissolution and absorption
- Stability and shelf life
- Palatability
- Tolerability
- Allergenicity

Differences in fillers, binders, dyes, preservatives, or lactosecontent may affect patient adherence and tolerability. Pediatricand geriatric populations are particularly sensitive to excipient variations.
In rare cases, hypersensitivity reactions or intolerance occur due to excipients rather than the API itself.

5. Ignoring Device Variability

For device-dependent medications, therapeutic equivalence depends not only on formulation but also on the performance characteristics of the delivery system.
Examples include:

- Metered-dose inhalers (MDIs)
- Dry powder inhalers (DPIs)
- Insulin pens
- Transdermal patches
- Prefilled syringes

Variations in aerosol particle size, inspiratory resistance, plumegeometry, or injection force may influence drug deposition andabsorption. Even subtle changes in inhaler design can alterpulmonary drug delivery and asthma control. Patient familiarity with a specific device also affects adherenceand technique. Automatic substitution without training maycompromise outcomes.

6. Misunderstanding Regulatory Guidance

In India, the National Medical Commission (NMC) encourages prescribing by generic names to promote affordability and transparency. However, this policy does not mandate blind substitution without clinical consideration.

Similarly:

- FDA assigns therapeutic equivalence ratings (e.g., “AB”rating) in the Orange Book.
- EMA provides product-specific bioequivalence guidance while leaving substitution policies to member

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- FDA assigns therapeutic equivalence ratings (e.g., “AB”rating) in the Orange Book.
- EMA provides product-specific bioequivalence guidance while leaving substitution policies to member states.

- CDSCO mandates BA/BE studies for many generics before approval.Regulatory approval supports interchangeability in most cases, but clinical judgment remains paramount- particularly in high-risk drug categories.

Practical Guidance

When Same-Salt Drugs Can Usually Be Interchanged

Interchangeability is generally safe when:

- The drug has a wide therapeutic index
- Treatment is short-term or symptomatic
- Pharmacokinetic variability has minimal clinical impact
- The formulation is simple (immediate-release oral tablets)
- The condition is non-critical

Examples include:

- Paracetamol
- Ibuprofen
- Antacids
- Most uncomplicated oral antibiotics
- Simple antihistamines

In such settings, generic substitution improves affordability without compromising safety.

When Caution Is Required

Heightened vigilance is warranted in:

- Narrow therapeutic index drugs
- Chronic therapy requiring stable plasma levels
- Modified-release formulations
- Biologics and biosimilars
- Device-dependent medications
- Elderly patients
- Pediatric populations
- Pregnancy
- Renal or hepatic impairment

In these cases:

- Avoid frequent brand switching
- Monitor clinical and laboratory parameters
- Counsel patients regarding potential changes

Regulatory Context

WHO

WHO prequalification standards require:

- Demonstration of pharmaceutical equivalence
- Bioequivalence studies
- Stability data under climatic conditions

- Compliance with GMPWHO recognizes multisource products as interchangeable when these criteria are rigorously satisfied, especially in public health procurement systems.

CDSCO (India)

CDSCO defines bioequivalence as comparable rate and extent of absorption between test and reference products. BA/BE studies are required for many immediate-release oral generics and selected other dosage forms.

India's regulatory framework continues to strengthen post-marketing surveillance and quality assurance mechanisms to ensure confidence in generics.

FDA (USA)

The FDA classifies therapeutically equivalent generics in the Orange Book. Products rated "AB" are considered bioequivalent and substitutable.For biologics, FDA guidance on interchangeability requiresrobust analytical similarity and clinical data. In certain cases, switching studies may not be necessary if scientific justification is adequate.

EMA (EU)

EMA provides detailed product-specific bioequivalence guidance and harmonized regulatory standards across member states. While EMA evaluates generics centrally, national policies determine pharmacy-level substitution.

Counselling and Documentation

Patient Counselling

Effective communication reduces confusion and non- adherence.

Clinicians should:

- Explain that generics are generally safe and effective
- Clarify that minor differences may exist in appearance or excipients
- Advise reporting of any change in symptoms after switching
- Emphasize proper device technique
- Reassure patients about regulatory oversight

For NTI drugs, patients should be instructed not to change brands without medical advice.

Documentation

Good clinical practice requires:

- Writing both generic and brand name when clinically relevant
- Documenting reasons for selecting a particular brand (especially NTI drugs)
- Recording counselling provided
- Monitoring and documenting therapeutic response after switching
- Reporting adverse drug reactions Clear documentation protects both patient safety and medico-legal integrity.

Take Home Points

- Same-salt drugs are chemically identical but not always clinically identical in every situation.
- Bioequivalence supports- but does not universally guarantee interchangeability.
- Excipients, release mechanisms, stability, manufacturing quality, and device performance influence outcomes.
- NTI drugs, chronic therapy, modified-release products, biologics, and device-dependent medications require caution.
- Regulatory agencies (WHO, CDSCO, FDA, EMA) provide structured frameworks to ensure quality and safety of generics.
- Rational prescribing integrates regulatory evidence, pharmacological principles, and individualized clinical judgment.

Conclusion

Generic medicines are essential for sustainable healthcare systems and are safe and effective in the vast majority of cases.However, the simplistic belief that all same-salt drugs are universally interchangeable overlooks important pharmacokinetic, pharmaceutical, and clinical nuances.

The goal is not to discourage generic prescribing- but to promote informed, evidence-based substitution. Clinicians must balance affordability with patient safety, guided by regulatory science, pharmacology, and individualized care.

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07 Biologics in Women's Health: What Every ObGyn Must Know

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Introduction

The term 'biologics' encompasses a wide variety of biologic molecules that include both human and murine monoclonal antibodies and soluble cytokine receptors. Commonly available examples that obstetricians may come across include infliximab, adalimumab, etanercept and rituximab; all of these are commonly used to treat women with rheumatic diseases and other immune-mediated conditions, including Crohn's disease, thrombocytopenic purpura, psoriasis and asthma. As many of these conditions disproportionately affect women during their peak reproductive years, the management of biologics in the context of pregnancy, breastfeeding, and neonatal health has become a cornerstone of modern obstetric practice.

Biologics in Reproductive-Age Women

Biologics, primarily monoclonal antibodies, are large protein molecules that target specific pathways in the immune system. Unlike small-molecule drugs, they do not cross the placenta during the first trimester via passive diffusion. In India, the Central Drugs Standard Control Organization (CDSCO) oversees the approval of these agents, emphasizing the need for robust safety data in the Indian population through post-marketing surveillance and clinical investigations [1].

The primary challenge in women of reproductive age is managing the active disease, which itself is a risk factor for adverse pregnancy outcomes. Uncontrolled systemic inflammation is associated with higher rates of miscarriage, preterm birth, and low birth weight. Consequently, contemporary guidelines emphasize that for many women, the benefits of continuing biologics outweigh the theoretical risks [2]. Biologic use often declines throughout pregnancy, falling from nearly 100% pre-conception to under 50% by the third trimester, only partially rebounding post-partum. This, in part, follows recommendations to discontinue some anti-TNF agents (like adalimumab, infliximab) in the third trimester, though IBD guidelines often recommend continuing them to prevent maternal flares.

Pregnancy Planning and Management

Preconception counselling is paramount. The World Health Organization (WHO) and other global bodies advocate for achieving disease remission for at least 3- 6 months before conception [3]. During this phase, OBGYNs must review the patient's medication profile.

The primary concern regarding biologics in pregnancy is their ability to cross the placenta. Most biologics are IgG1 monoclonal antibodies. Unlike small-molecule drugs, these large proteins cannot cross the placenta via simple diffusion during the organogenesis phase of the first trimester.

However, from the late second trimester onwards, the neonatal Fc receptor (FcRn) on the syncytiotrophoblast actively transports IgG antibodies from the maternal circulation to the fetus. This mechanism is designed to provide the neonate with passive immunity but also results in the active transfer of biologic medications. According to the U.S. Food and Drug Administration (FDA), this transfer increases significantly after 28 weeks of gestation, often leading to fetal drug concentrations that exceed maternal levels at the time of delivery.

TNF-alpha Inhibitors: Agents like adalimumab and infliximab are well-studied. While they are actively transported across the placenta starting in the late second trimester, they are not considered teratogenic.

1.Certolizumab Pegol: This agent is unique because it lacks the Fc region required for active transport across the placenta. Data endorsed by the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) indicate minimal to no fetal exposure throughout pregnancy, making it a preferred choice for women requiring treatment into the third trimester [4, 5].

2.Rituximab and Other Biologics: B-cell depleting agents like rituximab are generally discontinued before pregnancy due to the risk of neonatal B-cell depletion, although they may be used in life-threatening maternal situations [2].

3.Common Biologics Management in Pregnancy

Biologic Agent	**Target**	**Pregnancy Category / Strategy**	**Recommended Discontinuation Timing**	**Neonatal Live Vaccine Delay**
Certolizumab pegol	TNF-α	Preferred (No active placental transfer)	Continue throughout pregnancy	None (Standard schedule)
Adalimumab	TNF-α	Continue to control disease	Discontinue at 34–36 weeks	6–12 months
Infliximab	TNF-α	Continue to control disease	Discontinue at 30–32 weeks	6–12 months
Etanercept	TNF-α	Low placental transfer	Discontinue at 34–36 weeks	6 months

Rituximab	CD20	High risk of B-cell depletion	Discontinue 6 months preconception	6–12 months
Ustekinumab	IL-12/23	Limited data	Discontinue at mid-2nd trimester	6–12 months
Secukinumab	IL-17A	Limited data	Discontinue at conception	6–12 months
Abatacept	T-cell	Potential for immune modulation	Discontinue 10-14 weeks preconception	6–12 months

Infection Risk and Maternal-Fetal Safety

The immunosuppressive nature of biologics necessitates vigilant screening for latent infections. Before initiating therapy, patients should be screened for Tuberculosis (TB), Hepatitis B, and HIV, as biologics can trigger reactivation of these conditions.

Maternal infection risk does not appear significantly higher than that of the general population when disease is well-controlled; however, the neonate remains a primary concern. Because most biologics (except certolizumab) are actively transported to the fetus after 20-28 weeks of gestation, neonatal serum levels at birth can exceed maternal levels. This prolonged exposure can persist for up to six months postpartum, potentially increasing the infant's vulnerability to infections in the first year of life [6].

Vaccination Issues

Vaccination protocols for both the mother and the infant must be carefully adjusted:

- **Maternal Vaccination**: Inactivated vaccines, such as those for influenza and Tdap, are safe and recommended. Live vaccines (e.g., MMR, Yellow Fever) are contraindicated during pregnancy [7].

- **Neonatal Vaccination**: This is a critical safety point. Infants exposed to biologics (except certolizumab) in utero must avoid live vaccines for the first 6–12 months of life [2]. In particular, the BCG vaccine- routine in many regions- must be delayed to prevent disseminated infection. The National Medical Commission (NMC) emphasizes that practitioners must stay updated on these protocols to ensure neonatal safety [8].

Conclusion

Managing biologics in women’s health requires a multidisciplinary approach involving the obgyn, rheumatologist, or gastroenterologist. The goal is to maintain maternal health while ensuring a safe environment for the developing fetus. By understanding the timing of placental transfer and the specific risks associated with neonatal immunosuppression, we can provide evidence-based care that supports both mother and child.

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08 Tender Drug And Market Drug

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Safety and Accountability Issues

Rising healthcare costs have forced health systems to explore mechanisms that make medicines more affordable while maintaining quality and continuity of treatment. One widely used method is **tender procurement**, where medicines are purchased in bulk through a competitive bidding process.

At the same time, doctors routinely prescribe medicines available through the **open pharmaceutical market**, where multiple manufacturers sell branded versions of the same molecule.

Both systems operate simultaneously in India. Understanding their differences helps clinicians make safe prescribing decisions while maintaining accountability to patients.

What Are Tender Drugs?

Tender drugs are medicines procured through a **competitive procurement process** conducted by government departments, hospitals, or large healthcare institutions. Pharmaceutical companies submit bids, and contracts are usually awarded to suppliers who meet quality standards and offer the most competitive pricing.

The purpose of tender procurement is primarily **cost reduction and assured supply of essential medicines**.

Because medicines are purchased in very large quantities, prices obtained through tenders are often significantly lower than those available in the retail market. For this reason, tender procurement is widely used in **public hospitals, government health schemes, and institutional healthcare systems**.

This system plays an important role in improving **access to essential medicines**, particularly in resource-constrained settings.

What Are Market Drugs?

Market drugs are medicines supplied through the **regular pharmaceutical distribution system**. They are manufactured and marketed under specific brand names and are available through pharmacies, hospitals, and distributors.

Multiple companies may manufacture the same molecule, resulting in several brands in the market. Pricing is influenced by competition, manufacturing costs, and distribution networks.

Doctors are generally more familiar with market brands because they are commonly used in routine clinical practice and are easily available through retail pharmacies.

Tender Drugs vs Market Brands

Aspect	Tender Drugs	Market Brands
Procurement	Purchased through competitive government or institutional tenders	Sold through regular pharmaceutical market
Pricing	Usually lower due to bulk purchase	Higher due to distribution and marketing costs
Supply	Often supplied by one contracted manufacturer	Multiple manufacturers available
Availability	May fluctuate if tender supplier changes	Generally stable due to multiple suppliers
Accountability	Monitored by procurement authorities and regulators	Shared between manufacturers, pharmacies and clinicians

Quality Considerations

A common question raised by clinicians is whether medicines supplied through tenders differ in quality from widely used market brands.

In principle, **all medicines approved for use in India must comply with standards laid down by the Central Drugs Standard Control Organisation (CDSCO) and the Indian Pharmacopoeia.** Manufacturing facilities are expected to follow **Good Manufacturing Practices (GMP).**

Therefore, medicines supplied through tender systems are required to meet the **same regulatory quality standards** as medicines sold in the market.

However, large procurement systems require **strong quality monitoring**, because a single supplier may provide medicines for a large population. In such situations, consistent batch testing and pharmacovigilance become particularly important.

Many institutions therefore conduct **pre-supply testing and periodic quality audits** before distributing tender medicines.

Clinical Considerations

For most medicines, switching between approved brands or generic versions does not affect clinical outcomes. However, doctors should remain aware that **frequent switching of products may create confusion for patients**, especially those on long-term therapy.

Patients treated in government hospitals may receive tender medicines during admission, but obtain medicines from private pharmacies after discharge. Differences in packaging, colour, or brand name can sometimes cause uncertainty.

In certain therapeutic categories, maintaining product consistency is advisable. These include medicines with a **narrow therapeutic index**, where small variations in blood concentration can affect treatment response.

Examples include:

- Thyroid hormone preparations
- Anti-epileptic medicines
- Anticoagulants
- Certain hormonal therapies

In such situations, continuity of the same product helps maintain treatment stability.

Storage and Handling

Drug quality is influenced not only by manufacturing but also by **storage and handling conditions**.

Medicines transported through large procurement chains may pass through multiple storage points before reaching patients. Exposure to heat, humidity, or improper storage conditions can affect drug stability.

Hospitals and pharmacies should therefore ensure:

- Proper temperature control during storage
- Regular monitoring of expiry dates
- Appropriate transport conditions
- Clear batch traceability

These precautions apply equally to tender medicines and market brands.

Professional Responsibility

The prescribing decision must always be guided by **clinical evidence, patient safety, affordability, and availability.**

Doctors practice within healthcare systems where medicines may be supplied through institutional procurement programmes, government schemes, insurance systems, or private pharmacies. Each of these systems has its own operational framework.

Educational meetings, scientific conferences, and continuing medical education programmes remain important avenues for clinicians to stay updated about advances in pharmacology and therapeutics. These platforms support dissemination of scientific knowledge and exchange of clinical experience.

Professional integrity requires that **clinical judgement remains independent and evidence-based**, with patient welfare as the central consideration.

Practical Approach for Clinicians

When prescribing medicines, clinicians may consider a few simple precautions:

1. Prescribe medicines that comply with national regulatory standards.
2. Maintain consistency of product when treating conditions requiring stable drug levels.
3. Inform patients if a change in brand or manufacturer occurs.
4. Encourage patients to report unexpected changes in response to treatment.
5. Document medicines clearly when managing long-term therapies.

Conclusion

Tender procurement and market-based pharmaceutical supply represent two different approaches to delivering medicines within healthcare systems.

Tender systems improve affordability and access to essential medicines, especially in public healthcare programmes. Market brands provide broader availability and multiple manufacturing sources.

For clinicians, the key concern is not the procurement pathway but the **quality, safety, and continuity of the medicine used.**

With appropriate regulatory oversight, institutional monitoring, and responsible prescribing practices, patients can receive safe and effective treatment irrespective of whether medicines originate from tender procurement or the open pharmaceutical market.

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09 Storage & Handling Errors That Reduce Drug Effectiveness

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Storage is an important activity in the medicines supply chain management. Good Storage Practices help ensure the quality, safety, and identity of pharmaceutical products up to their point of use. Improper storage of medicines can lead to misplacement of stock and expiry, stock-outs, and deteriorated quality of medicines, leading to interruption of crucial treatment and waste of financial resources.

The most common errors in drug storage:

1. Not having an exclusive place to store medicines

Storing drugs close to or together with other cleaning products, perfumery, or food. Sharing the refrigerator of thermolabile medicines with any type of food (or bottle of water). Contamination may reduce efficacy

2. Not monitoring the temperature conditions of the storage location

Temperature, humidity, ventilation, and luminosity must be controlled even when the stock is not only of thermolabile drugs.

3. Lack of control over access to the medication storage location: Unrestricted access to medicine storage sites may lead to contamination, temperature disturbances, and loss due to theft.

4. Carelessness in the handling of products: A Very common mistake in stocking medicines.

Can interfere with the physicochemical stability of the drugs. Improper handling and misuse are common with medicines presented in multidose vials, which are opened and used more than once. These must be kept in their original packaging and closed again after every use.

5. Ignorance of technical standards by staff

6. Inefficient validity control and management: Drugs lose their function and quality after the expiration date and, therefore, must be distributed and marketed within the indicated period. A strict inventory validity control is essential.

Essentials of drug storage:

- Appropriate space and space utilisation
- Cleanliness
- Appropriate temperature

- Humidity and Light control
- Measures to prevent pests, fire, and thefts
- Special storage conditions

Storage area

- The storage area should be appropriately sized so that no more than 60% of its space is utilized.
- It should have sufficient space for stock handling and should not hinder the cleaning
- Stacking should not damage due to excessive vertical stacking height
- **If using pallets, stack cartons on pallets** keep things off the floor:

At least 10cm off the floor
At least 30cm away from the walls and other stacks
Generally, not more than 2.5m high

- Monitor store security and safety.
- Inspect the storage structure for damage, including the walls, floors, roof, windows, and doors.
- Check the store roof for leaks, especially during the rainy season and during or after a storm
- Visually inspect fire extinguishers and regularly run generator to ensure the system is working correctly

Maintain clean storage conditions

- Clean receiving, storage, packing, and shipping areas.
- Sweep or scrub floors.
- Remove garbage.
- Clean bins, shelves, and cupboards.

Arrangement of products:

- Ensure there is sufficient storage space
- Ensure that products are stacked correctly and cartons are not crushed.
- Follow the manufacturer or shipper's directions when stacking, and follow labels for storage conditions
- Place liquid products on the lower shelves or on the bottom of stacks.
- Where special storage conditions are required on the label (e.g. temperature, relative humidity) these should be provided, checked and monitored and recorded.

Shelf-life and expiry:

- Shelf-life is the time for which a given product stored under reasonable conditions, is expected to remain stable (>90%potency)
- Arrange cartons so the arrows point up, and the identification label, manufacturing, and expiry dates are visible. If this is not possible, write the product's name and expiry date clearly on the visible side so stock can be sent to facilities well in advance of expiry.
- Arrange products in the storage area to facilitate the first-to-expire, first-out (FEFO) and first-in-first-out (FIFO) procedure: Place products that will expire first in front
- Drugs should not be administered, and products and equipment must not be used beyond their expiry dates.
- Sterility must be preserved; single-use devices are intended for single use only and must not be reused.

Humidity control and Ventilation:

- The Label “protect from moisture” indicates storage in a space with no more than 60% relative humidity.
- Open the windows or air vents in the storeroom to promote airflow. Ensure all windows have screens to keep out insects and birds
- Use a fan to circulate fresh air
- Put boxes on pallets and ensure there is space between pallets and the wall of the storeroom.
- **Air conditioners:** Costly, depend on a constant supply of electricity, and require regular maintenance.
- **Dehumidifier** may be a less costly option, but it needs a constant supply of electricity and requires regular attention to empty the water containers.

Sunlight

- Some health products, like multiple vitamins, furosemide, chloropheniramine maleate, hydrocortisone, and latex products (such as male condoms) are photosensitive and will be damaged if exposed to light.
- Shade the windows or use curtains.
- Keep products in cartons.
- Use opaque plastic or dark glass bottle

Appropriate temperature

The chemical composition of some drugs can change when exposed to different temperatures. For temperature-sensitive medications, a refrigeration chain (a system for storing, handling, and transporting pharmaceuticals at controlled temperatures) is critical.

- Hormone-containing drugs, chemotherapy drugs, anti-seizure medications, and antibiotics become less effective when exposed to temperatures outside their recommended storage temperature.
- For vaccines, biologics, insulin, and similar drugs, proper refrigeration is essential to maintain their effectiveness, prevent degradation, and reduce risks for both healthcare providers and patients.
- Heat melts ointments and creams, rendering other products useless.

It is important to follow the manufacturer’s recommended storage conditions for all products.

- **Store frozen**: some products, such as certain vaccines, require storage at -20˚C (4˚F) and transport within a cold chain
- **Store at 2˚-8˚C (36˚-46˚F)**: some heat-sensitive products must not be frozen. These are usually kept in the first and second parts of the refrigerator (never the freezer).
- **Keep cool:** store between 8˚-15˚C (45˚-59˚F).
- **Store at room temperature:** store at 15˚-25˚C (59˚-77˚F)
- If the product has no specific storage instructions, then recommended to store in a clean, dry, ventilated space with a temperature of 15 to 25 °C (59- and 77-degrees F), and depending on conditions, up to 30C

Keep direct sunlight out of the storeroom

Refrigerators and freezers

- Refrigerators that open on the top are more efficient than vertical ones; The coldest part of vertical refrigerators is at the bottom.
- Store products that are sensitive to freezing or very low temperatures on the upper shelves.
- Always have enough frozen icepacks to transport items requiring cold storage.
- If space allows, then place a few plastic bottles of water in the refrigerator. This will help maintain the temperature of a longer period of time if the power is cut off.
- Place refrigerators and freezers about 20 to 40cm away from the wall to increase the air circulation.

- Under ideal conditions, rooms with multiple refrigerators and/ or freezers should have air conditioning.
- Use calibrated thermometers or electronic monitors to check the refrigerator temperature
- Alarm system: warns of temperature fluctuations, door openings, and power outages.

SPECIFIC STORAGE CONCERNS:

Vaccines

Vaccines are highly sensitive to temperature fluctuations and demand consistent refrigeration to maintain efficacy. Exposure to freezing temperatures or excessive heat can alter the chemical structure of vaccines, compromise the efficacy, increasing the risk of preventable disease outbreaks.

- Vaccines must be stored within the temperature range specified by the manufacturer
- NEVER store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances
- Vaccines to be used at an off-site or satellite facility should be transported in a Portable vaccine storage unit, such as a portable refrigerator.
- Every vaccine storage unit and transport unit must have a temperature monitoring device.

– Alarm for out-of-range temperatures
– Low-battery indicator
– Current, minimum, and maximum temperature display
– Recommended uncertainty of +/-0.5° C (+/-1° F)
– Temperature logging interval that can be programmed to record temperatures at least every 30 minutes

Storage temperatures fall within a narrow range for most vaccines, including COVID-19 vaccines, Diphtheria, Tetanus, and Pertussis (DTaP) vaccines, Hepatitis B vaccines, Hib vaccines, Influenza vaccines, Measles and HPV vaccines, Pneumococcal and Rotavirus vaccines. Polio vaccines, Tuberculosis (BCG) vaccines

Biopharmaceuticals

Other biologics that require precise temperature control include: Blood clotting factors (t-PA), Interferons, Erythropoietin, and Cytokines (G-CSF), Monoclonal antibodies (anti-TNF, anti-HER2, anti-PD-1), and Stem cells. These products are sensitive to temperature variations, risking denaturation and loss of efficacy when improperly stored.

Hormonal Medications (e.g., Insulin)

- Insulin must be stored between 2°C and 8°C to avoid denaturation. After opening, some insulin formulations may be stored at room temperature for limited periods. Freezing may cause insulin to crystallize.
- Other hormone-based treatments, such as growth hormones, fertility drugs, and GLP-1 analogs, also require cold storage.

Other Pharmaceuticals that require refrigeration:

Medications prone to melting at room temperature, such as suppositories, Prevention of microbial contamination: eye drops and injectable antibiotics After reconstitution, Certain antibiotics must be stored between 2°C and 8°C and used promptly.

Drugs to be stored in an access-controlled environment:

- Narcotic drugs: Morphine, Oxycodone, Tramadol, Codeine, Opium preparations.
- Psychotropic substances: Diazepam and other medicines in the Essential Medicines List, Carbamazepine, strong tranquilizing medicines, such as chlorpromazine.

Storage area should be a separate locked room, cabinet, or safe, with a warning system/ alarm in place to check unauthorised access.

Flammables: Acetone, anesthetic ether, alcohols (before dilution) and kerosene:

- Store large supplies in a separate location away from the main storeroom, and not less than 20m away
- Fire-fighting equipment should be easily available.
- A small stock of flammables may be kept in a steel cabinet in a well-ventilated area, away from open flames and electrical appliances. Mark the cabinets with a hazard symbol.
- The cabinet shelves should be designed to contain and isolate spills.
- Always store flammables in their original container.
- Flash point is the minimum temperature at which the liquid gives off vapor in sufficient concentration to form an ignitable mixture with air. It is not necessary to store flammables below their flash point, but it is very important to store them in the coolest location possible and never in direct sunlight.

How to safely carry medicine while traveling

- Keep medicine in the cabin of your car with you.
- Never leave medications in a very hot or cold car, and don’t store them in your trunk.
- Medications that require refrigeration, such as insulin and EpiPens, should be kept in a cooler with a cool-pack.

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10 Ethical Prescribing In The Age Of Discounts & Incentives

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Prescribing medicines is one of the most important responsibilities entrusted to a physician. Every prescription reflects a clinical judgement that directly affects patient safety, treatment outcomes, and financial burden on the patient.

In modern healthcare systems, medicines are produced and distributed within a large and complex pharmaceutical ecosystem that includes manufacturers, distributors, healthcare institutions, and regulatory authorities. Within this environment, doctors are expected to maintain **independent clinical judgement** while selecting the most appropriate therapy for their patients.

The challenge for clinicians is therefore to balance **scientific evidence, patient affordability, and availability of medicines**, while maintaining the highest ethical standards of medical practice.

The Changing Landscape of Pharmaceutical Practice

Over the last few decades, the pharmaceutical sector has expanded rapidly. Multiple brands of the same molecule are now available in the market, and newer therapeutic agents are continuously being introduced.

Doctors often receive information about new medicines through several channels, including:

- Scientific journals
- Clinical guidelines
- Continuing medical education programmes
- Academic conferences and workshops
- Medical representatives and product information

These sources play an important role in keeping clinicians updated about advances in pharmacology and therapeutics. At the same time, it is essential that clinical decisions remain **guided primarily by evidence and patient interest**.

Ethical Foundations of Prescribing

Medical ethics has traditionally been guided by four fundamental principles:
Beneficence - acting in the best interest of the patient.
Non-maleficence - avoiding harm to the patient.
Autonomy - respecting the patient's right to make informed decisions.
Justice - ensuring fair and equitable access to healthcare.

Ethical prescribing requires that these principles remain central to clinical decision-making.
A medicine should therefore be selected based on:

- Clinical effectiveness
- Safety profile
- Suitability for the patient's condition
- Affordability and accessibility

Cost and Affordability

In many countries, including India, a large proportion of healthcare expenditure is borne directly by patients. The cost of medicines therefore has a significant impact on treatment adherence.

Prescribing medicines that are **clinically appropriate and reasonably affordable** helps ensure that patients complete the recommended course of therapy. In some situations, doctors may prefer cost-effective alternatives when therapeutic outcomes are comparable.

Balancing cost with clinical effectiveness is therefore an important aspect of responsible prescribing.

Transparency and Professional Integrity

Modern healthcare systems encourage transparency in professional interactions and decision-making. Maintaining clear ethical boundaries strengthens public confidence in the medical profession.

Doctors must ensure that prescribing decisions are based on **scientific knowledge, clinical experience, and patient needs**. Transparency in professional conduct helps maintain trust between patients and healthcare providers.

Professional bodies and regulatory authorities have therefore issued guidelines that emphasise responsible interactions between healthcare professionals and industry stakeholders.

These guidelines aim to ensure that **educational and scientific activities continue to support medical learning**, while preserving professional independence.

Rational Use of Medicines

Rational prescribing involves selecting medicines that are:

- Appropriate for the clinical condition
- Supported by scientific evidence
- Safe for the patient
- Used in the correct dose and duration

Overuse of medicines, unnecessary polypharmacy, or inappropriate use of expensive drugs can increase healthcare costs and expose patients to avoidable risks.

Doctors therefore play a crucial role in promoting the **rational and judicious use of medicines**.

Maintaining Patient Trust

Trust is the foundation of the doctor-patient relationship. Patients rely on their physicians to recommend treatments that are safe, effective, and in their best interest.

When prescribing medicines, clear communication helps strengthen this trust. Explaining the reason for choosing a particular medicine, its expected benefits, and possible side effects enables patients to participate actively in their treatment.

Such communication improves treatment adherence and helps patients feel confident about their care.

Practical Steps for Ethical Prescribing

Clinicians can follow a few practical steps to maintain ethical prescribing practices:

1. Base prescribing decisions on clinical evidence and accepted guidelines.
2. Consider patient affordability while maintaining therapeutic effectiveness.
3. Avoid unnecessary changes in medication when a patient is stable on treatment.
4. Document prescriptions clearly and accurately.
5. Maintain transparency in professional interactions.

These measures help ensure that prescribing practices remain consistent with professional standards.

Conclusion

Ethical prescribing is an essential component of good medical practice. In a healthcare environment where therapeutic options and pharmaceutical information continue to expand, maintaining independent clinical judgement is increasingly important.

By focusing on **evidence-based medicine, patient welfare, affordability, and transparency**, doctors can ensure that prescribing decisions remain aligned with the fundamental principles of medical ethics.

Ultimately, ethical prescribing strengthens the credibility of the medical profession and supports the delivery of safe and effective healthcare.

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APPENDIX

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CLINIC- SAFE PRESCRIBING & DRUG- HANDLING TOOLKIT

Section	What Must Be Written	Example / Notes
Doctor Identification	Doctor name, qualification, registration number, clinic/hospital name, address, contact number	Dr XY, MD (ObGyn), Reg No XXXXX
Date of Prescription	Clearly mention date	12 Mar 2026
Patient Identification	Patient name, age/DOB, sex	Mrs SS, 32 yrs
Weight (when relevant)	Especially for children or weight-based drugs	65 kg
Patient Contact / ID	Address, phone, hospital ID	Helps trace prescription
Clinical Diagnosis / Indication	Brief diagnosis or reason for prescribing	Iron deficiency anaemia
Drug Name	Prefer pharmacological / generic name	Ferrous ascorbate
Strength	Strength must be specified	100 mg
Dosage Form	Tablet / capsule / syrup / injection / cream	Tab / Inj / Cap
Dose & Frequency	Exact dosing schedule	1 tablet twice daily
Duration of Treatment	Number of days / weeks	For 30 days

Special Instructions	Before/after food, bedtime dose, etc.	After meals
Substitution Note (if required)	Mention if brand consistency required	“Use same brand”
Follow-up Advice	When to review	Review after 4 weeks
Doctor Signature	Signature + stamp	Mandatory
Registration Number	Should be clearly visible	NMC/State registration
Prescription Safety Check	Name, drug strength, dose, duration, signature all present	Quick final review

2. Ten Prescription Errors That Invite Trouble

Error	Why It Is a Problem	Safe Practice
1. Illegible handwriting	Pharmacists may dispense wrong drug	Use clear block letters
2. Drug strength not mentioned	Multiple strengths exist	Always specify mg/mcg
3. Dose not specified	Leads to incorrect dosing	Mention dose + frequency
4. Duration missing	Patients continue indefinitely	Always write number of days
5. Dangerous abbreviations	Can cause overdose	Avoid U, QD, OD etc
6. No patient details	Difficult to verify prescription	Always write name + age
7. No doctor registration number	May be considered invalid prescription	Always include registration number
8. Brand name only without drug clarity	Pharmacist confusion if brand unavailable	Prefer pharmacological name
9. Decimal point errors	Risk of 10-fold dose error	Write 0.5 mg not .5 mg
10. Missing signature	Prescription legally incomplete	Sign every prescription

Quick Rule
A safe prescription must clearly show:
Patient → Drug → Dose → Duration → Doctor identity

3. Generic vs Branded vs Biosimilars

One-Page Decision Guide for ObGyns

Feature	Generic Drug	Branded Drug	Biosimilar
Definition	Same active ingredient as original drug	Marketed brand of the drug	Highly similar version of a biologic drug
Manufacturing	Chemical synthesis	Chemical synthesis	Produced from living cells
Regulatory requirement	Bioequivalence studies	Full clinical trials initially	Comparability studies + clinical evaluation
Cost	Usually lowest	Higher due to branding and marketing	Lower than innovator biologic
Interchangeability	Usually interchangeable	Depends on availability	Switching requires clinical judgement
Examples in ObGyn	Metformin, iron salts	Multiple market brands	Recombinant FSH, monoclonal antibodies
When appropriate	Most routine conditions	When brand consistency needed	ART, oncology, specialised therapy
Clinical caution	Narrow therapeutic index drugs	Maintain consistency	Monitor after switching

Practical Clinical Rule

Situation	Preferred Approach
Routine treatment (infection, anaemia, pain)	Generic or cost-effective brand
Chronic therapy	Maintain same product
Narrow therapeutic index drugs	Avoid frequent switching
Biologic therapy	Physician-guided switch only

Key Message
Generics improve **affordability**,
Brands offer market **familiarity**,
Biosimilars improve **access to biologic therapy**.

Clinical judgement should guide the choice.

04 - RED FLAGS

20 Drug Storage Mistakes Seen During Clinic Inspections

Common Storage Errors

No	Storage Mistake	Why It Is a Problem	Safe Practice
1	Drugs stored near windows or sunlight	Heat and light degrade medicines	Store in shaded cupboards
2	No temperature monitoring	Some drugs lose potency outside recommended range	Maintain temperature log
3	Mixing expired and usable drugs	Risk of accidental dispensing	Separate expired stock clearly
4	No expiry date check	Outdated drugs may be dispensed	Monthly expiry audit
5	Loose strips without packaging	Batch number and expiry not traceable	Keep original packaging
6	Emergency drugs not separated	Delay during emergencies	Dedicated emergency tray
7	Vaccines stored in normal refrigerator compartment	Temperature fluctuation	Use designated vaccine compartment
8	Refrigerator without thermometer	Cannot monitor storage conditions	Install refrigerator thermometer
9	Frequent opening of drug refrigerator	Causes temperature variation	Restrict unnecessary opening
10	IV fluids stored directly on floor	Risk of contamination and damage	Store on shelves or racks

11	Mixing paediatric and adult drug stocks	Risk of dosing errors	Label shelves clearly
12	No batch record maintained	Difficult to trace recalls	Maintain batch documentation
13	High-alert drugs not identified	Risk of medication errors	Label high-alert medicines
14	No stock rotation	Older drugs expire first	Follow FIFO (First In First Out)
15	Heat-sensitive drugs kept outside refrigeration	Potency may reduce	Follow storage instructions
16	Injections stored in open trays	Risk of contamination	Use closed storage trays
17	Drug cupboards not locked	Risk of misuse or theft	Lock cabinets when not in use
18	Schedule drugs not separated	Regulatory violation	Maintain separate storage
19	No documentation of drug disposal	Improper disposal risk	Maintain disposal register
20	Biomedical waste mixed with usable stock	Infection risk	Follow BMW rules

05 Monthly Drug Storage Self-Audit

Clinic staff should verify the following once every month:

- Temperature log maintained
- Expiry dates checked
- Emergency drugs available and labelled
- Refrigerator temperature monitored
- Expired drugs removed from usable stock
- Stock rotation followed (FIFO)

06 - FDMSE COMMITTEE RECOMMENDATIONS

FEBRUARY 2026 ACTION POINTS

1. Prescribe medicines using **generic names with full details**
2. Brand switching must be **documented and explained**
3. SR/ER formulations should **not be substituted casually**
4. Biosimilars must be **CDSCO- approved products only**
5. Ensure **traceability** for biologics and similar biologics
6. Maintain **drug storage temperature logs** in all clinics
7. Conduct **monthly expiry and batch checks**
8. Tender drugs must follow **quality assurance SOPs**
9. Ethical prescribing should be **free of inducement influence**
10. Patient counselling and documentation are **essential medicolegal safeguards**

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02 - Biosimilars, Generics & Brand Confusion

FDMSEC INSIGHTS- February- 2026

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