



## Rules to Prescribe Generic Drugs

### Why in news?

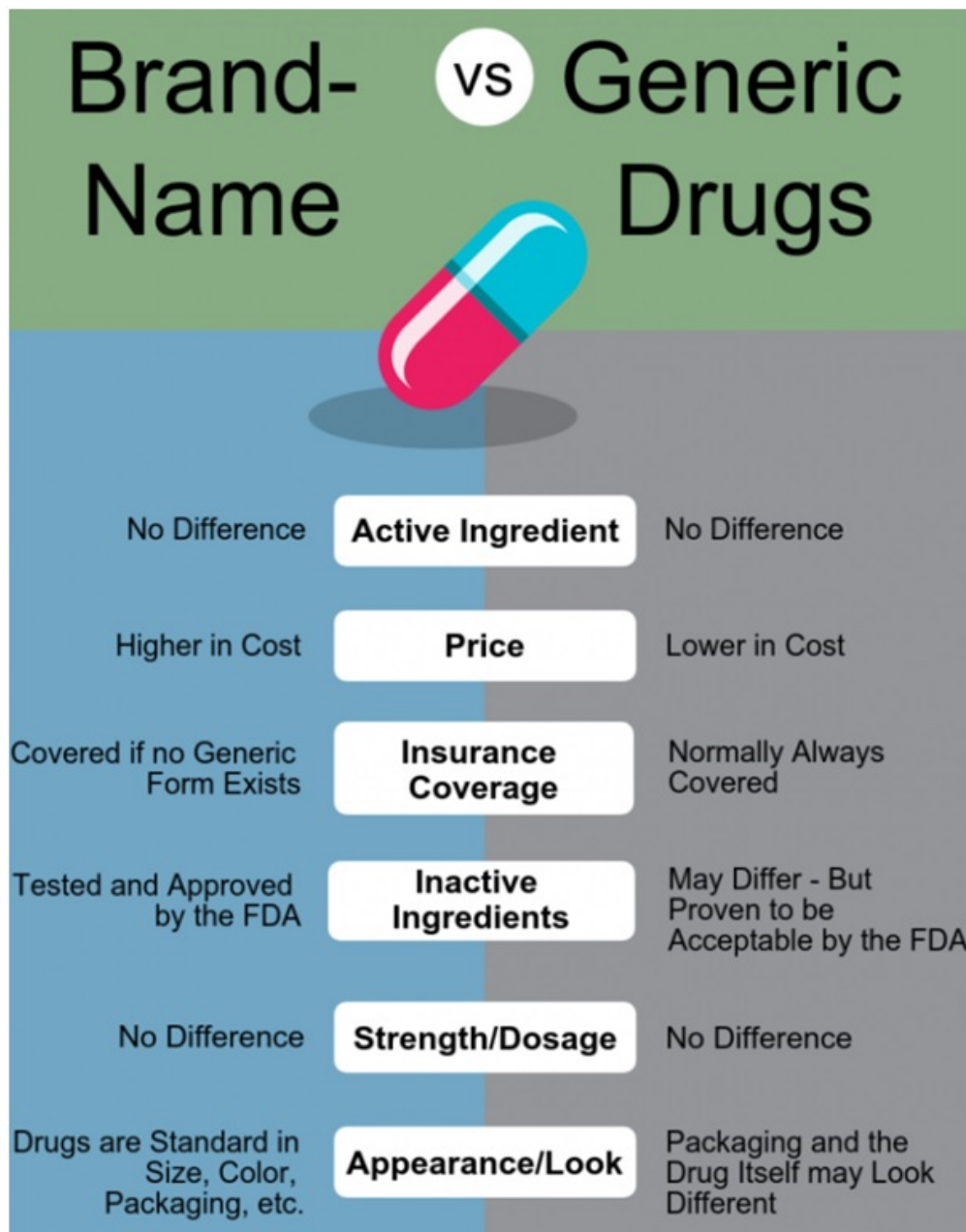
Doctors have been protesting on new guidelines for professional conduct to use generic names of medicines on the prescription instead of a particular brand name.

### Picture of India's Pharma Industry

- India is known as the "pharmacy of the world" due to the low cost and high quality of its medicines.
- The Indian pharmaceutical industry is among the largest in the world.
- India is the *largest producer of generic drugs* globally and is known for affordable vaccines and generic medications.
- According to a recent report by Asian Lite, India accounts for 13 % of the global pharma market.
- The Indian Pharmaceutical industry is currently ranked 3<sup>rd</sup> in pharmaceutical production by volume.
- The Pharma sector currently contributes to around 1.72% of the country's GDP.

### What is a generic medicine?

- A generic drug is a medication that has exactly the same active ingredient as the brand name drug and yields the same therapeutic effect.
- It is the same in dosing, safety, strength, quality, the way it works, the way it is taken, and the way it should be used.
- They do not involve repetition of extensive clinical trials over the years, unlike brands that undergo extensive R&D procedure.



### What is the new guidelines about?

- Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations prescribes that every registered medical practitioner should prescribe drugs using generic names written legibly.
  - For example, a doctor will have to prescribe paracetamol for fever, instead of Dolo or Calpol.
- Exemption-**
  - Narrow therapeutic index medicines** -Drugs where a small difference in dosage may lead to adverse outcomes
  - Biosimilar** -A different version of biologic products that are manufactured in living systems
  - Similar other exceptional cases.

*On an average, generic medicines are 30% to 80% cheaper than the branded*

versions and hence likely to bring down healthcare costs.

### What are the steps taken to promote generic drugs?

- **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)**- It is implemented by Ministry of Chemicals and Fertilizers to provide quality generic medicines at affordable prices.
- Prices of medicines sold through these outlets are 50-90% less than that of branded medicine prices in the open market.
- Pharmaceuticals and Medical Devices Bureau of India procures medicines only from World Health Organization - Good Manufacturing Practices (WHO-GMP) certified suppliers.
- Each batch of drug is tested at laboratories accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL).
- Only after passing the quality tests, the medicines are dispatched to PMBJP Kendras.
- **Janaushadhi Sugam**- It is a mobile application that provides information to public about location of kendras.
- It helps them search Janaushadhi medicines and compare the maximum retail price of generic vs. branded medicines.
- **Free drug initiative**- It is implemented under National Health Mission (NHM).
- It aims to provide essential generic drugs free of cost in public health facilities.
- **New guidelines**- Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prescribes that every physician should prescribe drugs with generic names legibly and preferably in capital letters.

### Why doctors are protesting over new guidelines?

*Indian Medical Association (IMA) is the largest body of doctors in the country*

- **Uncertainty about quality**- Doctors, drug manufacturers, and the government all agree that there is quality issues with generic medicines.
- The quality control in the nation being very weak, prescribing drugs without assured quality would be detrimental to patient health.
  - Union health ministry shows that around 3% of all medicines tested over the last 3 years — including generics, branded generics, and branded medicines — were found to be not of standard quality.
- **Issues with testing**- Doctors said that only 0.1% medicines are tested for quality checks.
- Manufactures said it is not possible for the government to test every batch for quality.
- **Lack of studies**- Experts from the pharmaceutical sector admit that there are drugs still in the market that never underwent the below studies.
  - **Bio-equivalence studies** -It is done to show that the generic drug elicits the same response as a branded version.
  - **Stability studies**- It is done to see how the quality of the drug varies over a period under specific environmental conditions.

- **Absence of consultation-** The guidelines were notified without consultation with stakeholders.
- **Pharmacist over doctor-** If a pharmacy does not have a generic version of a medicine because of very low profit margins, the responsibility to substitute it with a branded medicine will shift to the pharmacist instead of the doctor.
- This will promote brands that have good profit margins, irrespective of how good they are.
- **Ineffective treatment-** The doctors say it will also take away their choice of prescribing the medicine they think is the best for a patient, hampering the doctor's reputation.

### What lies ahead?

- IMA has asked for "one drug, one quality, one price" system where all brands should be either sold at the same price, which should be controlled or banned.
- Only generic medicines allowed while ensuring the highest quality of these drugs.

### References

1. [Indian Express- Doctors protesting rule to prescribe generic drug](#)
2. [Business standard- India as Pharmacy of the world](#)
3. [IBEF- Status of Pharma sector in India](#)



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