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 *3rd* 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 consulatation-** 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

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2. Business standard- India as Pharmacy of the world
3. IBEF- Status of Pharma sector in India

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