Concerns with Generic Medicine

Why in news?

Patients in India rely on the advice of unqualified medical shop sellers instead of doctors when buying medicines.

What is the difference between generic and branded medicines?

About	Branded drugs	Generic drugs
Definition	They are also called as the *"Innovator drugs"* and are at first available in the market as new chemical entities	It is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents
Trade name	Sold under the manufacturer's name	Not sold under the manufacturer's name
Affordability	High Cost	Low cost
Patent protection	Produced by a company which holds the patent	Available at the market by the pharma companies only after the patent protection period expires
Animal and clinical study	Essential to perform tests	Not required
Features	The company formulates the chemical composition and establishes the dosage, strength, efficacy, administration etc.	The active ingredients, dosage, efficacy and administration are exactly same as that in branded drug
Competition	Little competition as patent protected	Competition is heavy due to price variation

What are the challenges associated with generic medicines?

- **Deciding authority**- The doctors don't have the freedom to choose the brand of generic medicine for the patient, only salesperson decides the brand.
- **Unethical practices-** There is a corrupt link between pharmaceutical companies and doctors who can be influenced to give in to unethical marketing and promotional offers or kick-backs.
- **Counterfeit marketing** - Big pharma companies focus on profit rather than quality and promote their costly propaganda against generic medicines.

Hathi Committee in 1975 recommended for the gradual elimination of brand names.

- **Lack of accountability**- There is no clarity about who will ensure the compliance to the quality standards of drugs.
- **NMC directive**- National Medical Commission's (NMC) notification asking registered medical practitioners to prescribe only generic medicines but was later suspended due to protests.
- **Poor quality**- Unauthentic and sub-standard medicines stands at 4.5% and 3.4%, which will directly impact patients' health.
- **Lack of essential medicine-** Non essential medicines like vitamin tonics, cough syrup etc., are available in pharmacy but the rate of essential medicine is low.

Issues	Challenges	Benefits
Pharmaceutical companies	Big pharmaceutical companies that invented the drug will lose business Quality control in smaller manufacturers	Small companies can manufacture generic drugs
Doctors	Lose control over which company product to write. Accountability if the drug dispensed by the chemist is substandard	Do not need to know all brand names of a pharmaceutical compound and not influenced by promotional activity of some companies,
Chemist	Decreased profit margins in generics as compared to branded drugs	Get chose different company drugs to dispense (some may be of doubtful quality)
Patients/ Public	May run the risk of getting sub-standard medicines	Reduced patient expenses for medication
Quality of drugs	Quality control standards are the same for all manufacturers. India is the largest manufacturer and exporter of generic drugs which meet international standards. However smaller companies may not be as robust.	With generic drugs, it is easier to regulate dosage of individual drugs which is not possible in Fixed Drug Combinations (FDCs) of branded drugs. The government also bans many irrational FDCs from time to time.
Inducements and promotional activities	Those who receive inducements (as pharma companies make less money hence cannot offer inducements)	State and Central Governments: Spend less on reimbursement of medical expenditure on their employees entitled to medical care such as CGHS, Railways, Defence, ESI, RSBY etc.
Access to treatment	Market share of big pharma companies shrinks	Access and affordability of medical care increases benefitting especially the poor.

Steps taken by India 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 price.
• Each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories (NABL).
• **Pharmaceuticals and Medical Devices Bureau of India**- It procures medicines only from *World Health Organization – Good Manufacturing Practices (WHO-GMP)* certified suppliers.
• **Janaushadhi Sugam-** It is a mobile application that provides information to public about location of Jan Aushadhi Kendra's.
• **Free drug initiative**- Implemented under *National Health Mission (NHM)*, it aims to provide essential generic drugs free of cost in public health facilities.
• **National Pharmaceutical Pricing Authority** – It fixes the ceiling price of Scheduled medicines specified in the Schedule-I (essential medicines) of the *Drugs (Prices Control) Order, 2013.*

What lies ahead?

- **Quality assurance-** Government must ensure the quality of medicines produced, procured, and supplied through its Universal Health Coverage system as well as the private health-care network.
- **Periodic testing**- The medicines that fail periodic quality test must be banned, with punitive action taken against manufactures.
- **Rules for generic drugs**- Government should assure that the medicines in the markets are of standard quality, this would ensure confidence in doctors.
- **Proper monitoring-** To ensure affordable medicines for all under Universal Health Care, free medicines and diagnostics are acceptable, but implementation needs to be monitored.
- Promoting generic drugs nationally builds on the rich experience across states especially Rajasthan and Tamil Nadu who are pioneers in introducing generic drugs in public health system.

In India, annually, about 32 million people get pushed below poverty line because of expenditure on medical care.

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