

# Generic Medicines

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## Manifest Pedagogy

Pharmaceuticals is one big subtopic under health. And there are many which have been in news under it like generic drugs, IPR issues, Medical Devices as drugs, Drug Pricing etc. Hence this subtopic needs to be prepared holistically.

## In news

Generic Drugs after the establishment of Jan Aushadhi Stores

## Placing it in the syllabus

Indian Polity (explicitly mentioned)

Indian Society Society

## Static dimensions

- Definition of Generic drugs
- Difference between Generic and Branded drugs
- **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) 2008**

## Current dimensions

- Supreme Court verdicts on Generic drugs
- Guidelines of Medical Council of India on them

## Content

### Definition of Generic drugs

- A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form,

safety, strength, route of administration, quality, and performance characteristics.

- It works in the same way and provides the same clinical benefits as its brand-name version.
- Approved generic medicines are generally sold only after patents and exclusivities protecting the brand-name version end.

### **Difference between Generic and Branded drugs**

- Generic medicines tend to cost less than their brand-name counterparts because they do not have to repeat animal and clinical (human) studies that were required of the brand-name medicines to demonstrate safety and effectiveness. Unlike brand companies, generic manufacturers compete directly on price, resulting in lower prices for consumers
- Generic drug may also be slightly different in colour, shape, or markings compared to brand one.

### **Facts About Generic drugs**

#### **☒ Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) 2008**

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a campaign launched by the Department of Pharmaceuticals to provide quality medicines at affordable prices to the masses. PMBJP stores have been set up to provide generic drugs, which are available at lesser prices but are equivalent in quality and efficacy as expensive branded drugs.

**It was launched by the Department of Pharmaceuticals in November 2008 under the name Jan Aushadi Campaign. Bureau of Pharma PSUs of India (BPPI) is the implementation agency for PMBJP.**

### **Vision**

To bring down the healthcare budget of every citizen of India

through providing Quality generic Medicines at Affordable Prices.

## **Mission**

- Create awareness among the public regarding generic medicines.
- Create demand for generic medicines through medical practitioners.
- Create awareness through education and awareness program that high price need not be synonymous with high quality.
- Provide all the commonly used generic medicines covering all the therapeutic groups.
- Provide all the related health care products too under the scheme.

## **Objective**

Making quality medicines available at affordable prices for all, particularly the poor and disadvantaged, through exclusive outlets “Jan Aushadhi Medical Store”, so as to reduce out of pocket expenses in healthcare

## **Jan Aushadhi Store**

- These stores have been launched across the country.
- All therapeutic medicines are made available from Jan Aushadhi Stores.
- In addition to medicines and surgical items supplied by BPPI, Jan Aushadhi stores also sell allied medical products commonly sold in chemist shops so as to improve the viability of running the Jan Aushadhi store.
- OTC (Over-the-counter) products can be purchased by any individual without a prescription. A prescription from a registered medical practitioner is necessary for the purchase of scheduled drugs.
- BPPI (Bureau of Pharma Public Sector Undertakings of India) has been established under the Department of

Pharmaceuticals, Govt. of India, with the support of all the CPSUs for co-coordinating procurement, supply and marketing of generic drugs through the Jan Aushadhi Stores.

- The quality, safety and efficacy of medicines are ensured by getting each batch of medicines procured from CPSUs as well as private suppliers tested from NABL approved laboratories and conforming to the required standards before the same are supplied to Supers stockists /Jan Aushadhi Stores from the Warehouse of BPPI.

### **Supreme Court directive/ verdicts on Generic drugs**

In a ruling that was cheered by both activists and Indian pharma companies, the Supreme Court rejected German drugmaker Bayer's last-ditch attempt to block the sale of a cheap generic version of its cancer drug Nexavar in the country in 2014. Following are the highlights of the verdict;

- The SC upheld an earlier ruling by the Bombay High Court, and is being seen as a "momentous" win for public health as well as a blow to global drugmakers' efforts to protect their high-price medicines in India.
- This brings to an end the legal challenge to the country's first-ever compulsory license, issued in 2012 to Indian generics group Natco Pharma, that allowed it to sell a copycat version of Nexavar, which is used to treat kidney and liver cancer.
- This verdict highlights India's "critical role" in balancing intellectual property and public health

In another high profile case in 2013, **Swiss drugmaker Novartis's** attempt to win patent protection for its **cancer drug Glivec** was also dismissed by the Supreme Court.

### **The Medical Council of India (MCI) guidelines to Doctors(2017)**

- It has warned the doctors of action if they fail to

adhere to its guidelines of prescribing the drugs only in generic names and writing prescriptions legibly.

- MCI has also asked the medical practitioners to ensure that there is rational prescription and use of drugs, failing which “strict disciplinary action” will be taken if they fail to adhere to its orders.
- It has asked the medical community to follow its 2016 notification in which the MCI had amended the clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 mandating the doctors to prescribe medicines by generic names in place of brand names.
- All the Registered Medical Practitioners under IMC Act are directed to comply with the aforesaid provisions of the Regulations without fail.
- States are requested to give wide publicity of the above regulation to ensure that all the doctors practising medicine to comply with the regulation.