



CURRENT AFFAIRS



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GENERIC DRUGS

This article covers "Daily Current Affairs" and the topic details "GENERIC DRUGS". The topic "GENERIC DRUGS" has relevance in the Social Justice section of the UPSC CSE exam.

Relevance:

For Prelims:

What are Generic Drugs?

What is compulsory licensing?

For Mains:

GS 2: Social Justice

Benefits of Generic Drugs?

Challenges for India in Adopting Generic Drugs?

Why in the News?

Generic drugs for diabetes, gastric issues, cardiovascular ailments see high demand. The Jan Aushadhi Kendras selling generic drugs at affordable prices have seen their sales rise more than 170 times over the last nine years

What are Generic Drugs?

Generic drugs are pharmaceutical products that are equivalent to brand-name drugs in terms of active ingredients, dosage form, strength, route of administration, quality, safety, and intended use. They are typically produced and marketed after the patent protection of the original brand-name drug expires. Generic drugs contain the same active ingredients, have the same pharmacological effects, and provide the same therapeutic benefits as their brand-name counterparts.

Regulatory authority: The regulatory authority responsible for ensuring the quality, safety, and efficacy of drugs in India is the Central Drugs Standard Control Organization (CDSCO). CDSCO approves and regulates generic drugs through a comprehensive evaluation process.

What is compulsory licensing?

Compulsory licensing is a legal mechanism that allows a government to grant permission to a third party to produce, use, or sell a patented invention without the consent of the patent holder. It is a measure used to balance the exclusive rights granted to patent holders with public health needs or other societal interests.

The primary objective of compulsory licensing is to ensure access to essential goods or services, particularly in situations where patent-protected products are priced high, unaffordable, or in short

supply. By issuing a compulsory license, the government can authorize other manufacturers or entities to produce and distribute a patented product or technology.

Benefits of Generic Drugs?

- **Cost savings:** Generic drugs are generally more affordable than brand-name drugs. The competition among multiple manufacturers once the patent protection expires leads to price reductions. This cost savings makes healthcare more accessible and can significantly reduce prescription drug expenses for individuals and healthcare systems.
- **Equivalent effectiveness:** Generic drugs must demonstrate bioequivalence to brand-name drugs, meaning they have the same active ingredients, dosage forms, strengths, and route of administration. They provide the same therapeutic benefits as their brand-name counterparts when used as prescribed. Regulatory authorities rigorously test generic drugs to ensure their safety, quality, and efficacy.
- **Increased access:** The affordability of generic drugs enhances access to medications for a broader population. Lower prices make it more feasible for patients to afford necessary treatments, particularly for chronic conditions that require long-term medication use.
- **Promote competition:** The introduction of generic drugs into the market promotes healthy competition. Brand-name drug manufacturers face competition from generic manufacturers, which can help drive down prices of both generic and brand-name drugs. This competition fosters innovation and efficiency within the pharmaceutical industry.
- **Availability of therapeutic alternatives:** Generic drugs offer therapeutic alternatives to brand-name drugs. When a patent expires and generic versions become available, patients have more options to choose from, allowing them to make informed decisions based on factors such as cost and personal preferences.
- **Regulatory standards and oversight:** Generic drugs undergo stringent regulatory scrutiny to ensure their safety, quality, and effectiveness. Regulatory authorities set standards and guidelines for the approval and manufacturing of generic drugs, providing assurance to patients and healthcare professionals.
- **Support for healthcare systems:** The availability of cost-effective generic drugs helps healthcare systems manage their budgets more efficiently. By substituting brand-name drugs with generics, healthcare providers and payers can allocate resources more effectively and provide access to a broader range of treatments.

Challenges for India in Adopting Generic Drugs?

- **Perception and awareness:** One of the primary challenges is the perception and awareness of generic drugs among patients and healthcare professionals. Some patients may still have reservations about the quality and efficacy of generic drugs compared to brand-name drugs. Lack of awareness and understanding about bioequivalence and regulatory standards can contribute to this perception.
- **Brand loyalty:** Brand loyalty is another challenge. Patients who have been using a particular brand-name drug for a long time may be hesitant to switch to a generic alternative, even if it is more cost-effective. Strong brand loyalty and trust in specific brands can make it challenging for patients to accept or consider generic options.
- **Lack of trust and misinformation:** Trust plays a crucial role in the adoption of generic drugs. In some cases, instances of substandard or counterfeit generic drugs have eroded public trust. Additionally, misinformation or rumors about the quality or effectiveness of generic drugs can further hinder their acceptance and adoption.
- **Prescription practices:** Prescription practices by healthcare professionals can impact the adoption of generic drugs. If doctors are more inclined to prescribe brand-name drugs or are not proactive in

suggesting or prescribing generics, it can limit their usage. Factors such as incentives or relationships between healthcare professionals and pharmaceutical companies may also influence prescribing patterns.

- **Regulatory challenges:** While India has a robust regulatory framework for generic drugs, ensuring consistent adherence to quality standards across all manufacturers remains a challenge. The quality control and surveillance of the entire supply chain, including manufacturing, distribution, and dispensing, need continuous monitoring and enforcement to maintain quality and build trust in generic drugs.
- **Price differentials:** While generic drugs are generally more affordable than brand-name drugs, the price differentials between generic and brand-name drugs in some cases may still be substantial. Patients who have limited financial resources may find it challenging to afford even the lower cost of generic drugs, leading to barriers in their adoption.
- **Intellectual property concerns:** Intellectual property rights and patent-related issues can create challenges for the availability of certain generic drugs. Patents granted to brand-name drugs may limit the immediate entry of generic versions into the market. Although compulsory licensing provisions exist in India, the complexity of patent laws and litigation processes can impact timely access to affordable generic alternatives.

Addressing these challenges requires a multi-faceted approach involving awareness campaigns, education for patients and healthcare professionals, effective regulation and monitoring, and fostering trust in the quality and efficacy of generic drugs. Collaboration between government agencies, pharmaceutical industry stakeholders, healthcare providers, and patient advocacy groups can help overcome these challenges and promote the wider adoption of generic drugs in India.

Source:

<https://www.thehindu.com/sci-tech/health/no-plans-to-take-jan-aushadhi-kendras-online-says-ceo/article66976870.ece>

Q.1 Which of the following is a key benefit of generic drugs?

- (a) They have a lower risk of adverse effects compared to brand-name drugs.
- (b) They are exclusively available in specialized dosage forms.
- (c) They offer cost savings compared to brand-name drugs.
- (d) They have a longer patent protection period than brand-name drugs.

Answer: (c)

Q.2 Which of the following is a significant challenge in the adoption of generic drugs?

- (a) Limited availability of generic drugs for commonly prescribed medications.
- (b) Lower effectiveness and safety risks compared to brand-name drugs.
- (c) Lack of regulatory oversight for generic drug manufacturing.
- (d) Higher cost of generic drugs compared to brand-name drugs.

Answer: (a)

Q.3 Discuss the challenges and opportunities in promoting the widespread adoption of generic drugs in healthcare systems. How can these challenges be addressed to enhance access, affordability, and quality of healthcare?

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