



CURRENT AFFAIRS



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Date - 1 August 2023

BIOSIMILARS

This article covers "Daily Current Affairs" and the topic details "Biosimilars". The topic "Biosimilars" has relevance in the "Science and Technology" section of the UPSC CSE exam.

For Prelims:

What are Biosimilars?

For Mains:

GS3: Science and Technology

Why in the news?

A collective of scientists and medical professionals has requested the Union Health Ministry and the Department of Biotechnology to uphold strict regulations for biosimilars.

What is Biologics?

- **Biologics are pharmaceuticals derived from natural systems, such as humans, animals, or microorganisms. Due to their intricate nature, they offer treatment options for various conditions where alternative therapies are not yet accessible.**
- Examples of such medicines include gene therapies, transplant tissue, recombinant proteins, stem cell therapies, and monoclonal antibodies. They are frequently used in the treatment of severe and life-threatening illnesses.
- In contrast to traditional drugs, biologics differ in terms of their source materials, structural complexities, manufacturing processes, and regulatory requirements. Due to these differences, biologics can sometimes be more expensive, leading to accessibility challenges for certain patients.
- To address this issue and enhance access to biological therapies, biosimilars were developed. The purpose of biosimilars is to increase accessibility to these treatments and consequently improve patient outcomes.

What is a Biosimilar?

- **A biosimilar product is a type of biologic product that receives approval by demonstrating its high similarity to an already approved biologic product, known as a reference product.**
- The biosimilar must also prove that there are no clinically significant differences in terms of safety and effectiveness compared to the reference product. Minor differences are allowed only in clinically inactive components of biosimilar products.
- Biosimilars are derived from the same sources, such as living cells or microorganisms, as their reference products. Additionally, they possess comparable levels of safety and effectiveness, ensuring they are a reliable alternative to their reference counterparts.

How are biosimilars different from generic medicines?

- While identical generic versions of small molecules can be chemically synthesised, it is not possible to create identical versions of reference biologic medicines, due to their complexity.
- As a result, the methodologies utilized for creating generic medicines are not applicable to the development of biosimilar medicines.

Differences between Biologics, Biosimilars and Generics:



Feature	Biologic	Biosimilar	Generic
Representation			
Origin	Living organisms	Similar to the reference biologic	Identical to the brand-name drug
Manufacturing process	Complex	Complex	Simple
Regulatory approval process	More rigorous	More streamlined	Similar to biologics
Safety and efficacy	Same standards	Same standards	Same standards
Time Investment	8-10 years	7-8 years	2-3 years
Cost	More expensive	Less expensive	Less expensive
Savings	Less savings	More savings	More savings than the brand-name drug

Prospects:

- The biosimilar market is projected to reach sales between \$14 billion and \$31 billion in 2023, accounting for approximately 4% of the biopharmaceuticals market in 2018.
- Biosimilars have demonstrated their ability to capture market share, especially in Europe, and the overall upward trend in the pharmaceutical sector provides a solid basis for their growth.
- The high cost of biologics has made biosimilars attractive to payors and regulators as a way to reduce healthcare spending while still benefiting patients.
- Biosimilars are expected to compete favorably as 12 major biologic products with combined global sales of over \$67 billion will face biosimilar competition by 2020 after their patents expire.
- Some companies have exited the biosimilars market, creating potential opportunities for investors in legacy programs at attractive price points.
- The growing demand for lower-cost biologics and the overall growth in the pharmaceutical market driven by population, age, and wealth factors support a positive outlook for biosimilars, with the potential for significant returns on investment.

Challenges in Biosimilars:

- **Development risks** for biosimilars are estimated to range from 50% to 75% in terms of successfully bringing the product to the market. This stands in contrast to small molecule generics, which boast a higher success rate of around 95%. The extent of biosimilar development risks fluctuates based on factors such as the particular product, production cell line, and regulatory demands.
- **Market Dynamics:** Each biosimilar and market have unique characteristics and dynamics. Launch and marketing plans must be tailored to individual biosimilars, considering therapeutic areas, patient populations, and geographical drivers.
- **Price Competition:** Biosimilars often enter the market with immediate price drops compared to reference products. Price wars and aggressive pricing strategies can erode margins and profitability.
- **Brand Identity:** Establishing a brand identity can mitigate the negative effects of a later market entry and improve adoption by emphasizing quality.
- **Limited Awareness and Knowledge:** Despite biosimilars being in the EU market for over a decade, awareness and knowledge among physicians, pharmacists, and patients remain relatively limited.
- **Resistance to Switching:** Patients on long-term biologic treatments may resist switching to biosimilars due to perceived risks or new delivery mechanisms
- **Intellectual Property Challenges:** Originators use intellectual property portfolios and marketing strategies to defend against biosimilar competition, resulting in fewer launched products in the US.

Indian Regulatory Framework

- Under the Indian regulatory system, biosimilars are referred to as “similar biologics.”
- The regulatory framework for biosimilars in India is governed by the Central Drugs Standard Control Organization (CDSCO) in collaboration with the Department of Biotechnology (DBT).
- In 2012, they developed the “Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorization in India” to address the challenges associated with the development of similar biologics.
- This guideline was revised in 2016.
- Regulation of similar biologics are also governed by the Drug and Cosmetic Act (1940), Drug and Cosmetic Rules (1945), and the Rules for Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells (1989). These regulations were notified under the Environmental (Protection) Act, 1986.

India has become a key global player in producing similar biologics, benefiting from its large market. However, to maintain leadership, Indian pharmaceutical companies must upgrade technology and enhance workforce skills, requiring support from the government and regulatory agencies.

Sources:

‘Relaxing norms for biosimilars risks safety’ – The Hindu

Q1. With reference to Biosimilars, consider the following statements:

1. Similar to generic medicines compared to their brand-name counterparts, biosimilars are identical to reference biologic products.
2. Biologics are medications created from living organisms, encompassing sources such as humans, animals, or microorganisms.
3. The purpose of biosimilars is to enhance the accessibility of biological therapies and make treatments more cost-effective.
4. Biosimilars are not suitable for treating severe or life-threatening illnesses.

Which of the statements given above is/is/are correct?

- (a) Only one
- (b) Only two
- (c) Only three
- (d) All Four

Answer: (b)

Q2. Which of the following organisations regulates biosimilars in India?

- (a) World Health Organization (WHO)
- (b) Food and Drug Administration (FDA)
- (c) Central Drugs Standard Control Organization (CDSCO)
- (d) Department of Science and Technology (DST)

Answer: (c)

Q3. What are biosimilars, and how do they differ from generic medicines? Discuss the challenges associated with them in the context of India.

Rishabh

WHITE LABEL ATMS (WLAS)

This article covers “Daily Current Affairs” and the topic details “White Label ATMs (WLAs)”. The topic “White Label ATMs (WLAs)” has relevance in the Economy section of the UPSC CSE exam.

For Prelims:

About White Label ATMs (WLAs) ?

Types of ATM?

For Mains:

GS 3: Economy

Major Functionalities of an ATM?

Advantages of an ATM?

Limits of an ATM?

Why in the news?

White Label ATMs (WLAs) are expected to drive ATM spread across India with a greater focus on tier III to VI centres, said Union Minister of State for Finance, Bhagwat Kisanrao Karad

White Label ATMs (WLAs)

Definition and Ownership:

- ATMs set up, owned, and operated by non-banks are called White Label ATMs (WLAs).
- Non-bank ATM operators are authorized under the Payment & Settlement Systems Act, 2007 by the RBI.
- WLAs provide banking services to customers using debit/credit/prepaid cards issued by banks.

Steps to Enhance WLA Presence and Viability:

Cash Sourcing Flexibility:

- WLAs are allowed to source cash from retail outlets, Reserve Bank, currency chests, and any scheduled bank, including Cooperative Banks and Regional Rural Banks.
- This addresses cash sourcing constraints faced by WLAs, especially after demonetization.

Expanded Services and Partnerships:

- White Label ATMs (WLAs) are allowed to provide bill payment and interoperable cash deposit services
- They can display advertisements for non-financial products/services, increasing revenue streams.

On-Tap Authorization:

- RBI introduced on-tap authorization for WLAs, simplifying the approval process to encourage more non-bank players to enter the ATM industry. This fosters greater competition and expansion of the WLA network.

Driving ATM Penetration:

- WLAs have a vital role in attaining this goal, as they provide convenient banking services to a wider range of customers. It focuses on expanding ATM penetration in Tier III to VI centers to improve banking accessibility in underserved areas. WLAs play a crucial role in achieving this objective, offering convenient banking services to a broader customer base.

Facilitating Consumer Complaints and Protection:

- The Consumer Education and Protection Department of the Reserve Bank of India (RBI) is responsible for handling complaints related to White Label ATMs (WLAs).
- Initiatives like the National Strategy for Financial Education (NSFE) 2020-2025 promote education and financial literacy.



Major Functionalities of an ATM:

- **Cheque Deposition:** Some ATMs allow customers to deposit cheques directly into their bank accounts, making it convenient for them to perform this banking task without visiting a branch.
- **Cash Withdrawals:** One of the primary functions of ATMs is to dispense cash to customers, allowing them to withdraw money at any time.
- **Transferring Funds:** Many ATMs enable fund transfers between the customer's accounts linked to the ATM card.
- **Verify Account Balance:** Customers can check their account balances through the ATM, providing them with real-time information about their finances.
- **Additional Services:** ATMs often offer additional banking services like mobile recharges, bill payments, ticket booking, and more, providing convenience to users.
- **Security:** ATMs ensure secure transactions through encrypted channels, protecting customers' financial data during transactions.
- **Customer Authentication:** Each transaction at an ATM requires customer authentication through individual PINs and card numbers, ensuring security.

Advantages of an ATM:

- **Time-Saving:** ATMs offer quick and efficient banking services, saving customers' time by providing access to cash and various banking functionalities 24/7.
- **24/7 Availability:** ATMs operate round the clock, allowing customers to access banking services even outside regular banking hours.
- **Security:** ATMs maintain high-security standards, protecting customer data and transactions with encryption and secure authentication measures.
- **Authentic Accessibility:** Customers can access their accounts securely using their unique PINs and card details, ensuring only authorized users perform transactions.
- **Wide Network:** ATMs are widely available, creating a vast network of banking services that customers can access conveniently.

Limits of an ATM:

- **Technical Errors:** ATMs may occasionally encounter technical issues, leading to service disruptions or transaction failures.
- **Transaction Limits:** There are limits on the amount of money that customers can withdraw or transfer in a single transaction or within a specific time frame.
- **Limited Functionalities:** While ATMs offer essential banking services, some complex transactions may require visiting a bank branch or using online banking platforms.
- **Transaction Charges:** Customers may incur transaction charges for certain types of ATM transactions, especially when using ATMs of other banks or exceeding transaction limits.

SOURCE:

<https://www.livemint.com/news/india/expansion-of-white-label-atms-to-drive-atm-spread-in-india-promoting-financial-inclusion-and-banking-services-11690289848533.html>

Q.1 Which of the following statements are true regarding White Label ATMs (WLAs) and their enhancement in India?

1. WLAs are owned and operated by non-bank entities.
2. WLAs are not allowed to offer bill payment and cash deposit services, limiting their revenue streams.
3. WLAs primarily focus on expanding ATM penetration in metropolitan cities to improve banking accessibility.

Select the correct answer from the options given below:

- (a) 1 only
- (b) 1 and 3 only
- (c) 2 and 3 only
- (d) 1, 2 and 3

Answer: (a)

Q.2 Match the types of ATMs with their respective descriptions:

1. Orange Label ATM
2. Yellow Label ATM
3. Pink Label ATM
4. Green Label ATM

Descriptions:

- (A) Used for share transactions; Mainly for buying and selling stocks and securities.
- (B) Used for e-commerce transactions; Primarily for online shoppers and merchants.
- (C) Set up to provide safety and convenience to women customers.
- (D) Provided for agricultural transactions.

Options:

- (a) 1-A, 2-C, 3-B, 4-D
- (b) 1-C, 2-B, 3-A, 4-D
- (c) 1-A, 2-B, 3-C, 4-D
- (d) 1-C, 2-B, 3-D, 4-A

Answer: (c)

Q.3 Discuss the significance of ATMs in facilitating financial inclusion and the challenges faced in achieving widespread ATM penetration, particularly in rural and underserved areas.