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US FDA moves to accelerate biosimilar development and lower drug costs

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Driving market competition and expanding patient options

The US Food and Drug Administration (FDA) has announced significant action to make it faster and less costly to develop biosimilar medicines, which are lower-cost “generic” alternatives to biologic drugs that treat serious and chronic diseases.

In a new draft guidance, the FDA proposes major updates to simplify biosimilarity studies and reduce unnecessary clinical testing. The agency through a separate initiative also plans to make it easier for biosimilars to be developed as interchangeable with brand-name biologics, helping patients and pharmacists choose lower-cost options more easily.

Expensive biologic medications make up only 5% of prescriptions in the US but account for 51% of total drug spending as of 2024. FDA-approved biosimilars are as safe and effective as the branded drugs, yet their market share remains below 20%.

To date, FDA has approved 76 biosimilars, corresponding to a small fraction of approved biologics. By contrast, there are more than 30,000 approved generics, exceeding the number of approved brand drugs. Only about 10% of biologic drugs expected to lose patent protection in the next decade currently have a biosimilar in development.

Commenting on this development, Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance said, "The recent announcement by the USFDA and CMS is a welcome step that will accelerate biosimilar development and lower drug costs for patients. The simplification of interchangeability guidelines and approval pathways will create a more enabling environment for the industry to diversify in large-molecule space. India already has nearly 130 approved biosimilars, and over the next seven years, more than 55 blockbuster drugs are expected to lose exclusivity in the US. India has long been a trusted partner in ensuring access to quality-assured, affordable medicines for American patients. These reforms will further strengthen the US–India partnership and our shared goal of improving healthcare access and affordability."