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GOVERNMENT OF INDIA
भारत सरकार

Economic Times , Delhi
Wednesday 18th November 2015, Page: 7
Width: 23.85 cms, Height: 10.21 cms, a4r, Ref: pmin.2015-11-18.45.61

Biosimilar Drug Rules May Be Revamped

Change in norms only after consultations with industry, academic institutions

A Welcome Change

- The rules are aimed to sync with fast evolving global regulatory norms
- Additional comparability studies with reference drug
- Greater focus on post-marketing surveillance and pharmacovigilance to report adverse events
- Focus on non-inferiority of biosimilar from initial stages

Key Indian Contenders: Biocon, Dr. Reddy's, Zydus Cadila, Intas, Cipla

₹2000 cr Estimated size of biosimilar drug mkt in 2014

20%: CAGR of domestic biosimilar drug mkt

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Mumbai: The health ministry plans to revamp guidelines for approving biosimilar drugs to make the regulatory pathway more robust and sync it with the rapidly evolving global landscape. The guidelines were released three years ago.

Biosimilars are copies of complex drugs, which are based on living cells and 'similar' to an original biologic manufactured by the innovator. These drugs stand distinct from the chemical-based generic drugs that are 'identical' to the originator's compound.

Officials say the new norms are expected to build further on the existing rules. They will be finalised after consultations with the industry, academic institutions and stakeholders like the civil society. "We will put up the draft in public domain and seek views prior to giving a final shape to the new rules," a senior health ministry official said, adding that the ministry aims to finalise the rules by year-end. "A large number of future products will be from biologics origins and it is important to be geared up to examine those filings with clear rules."

The new rules are intended to drill specifically on areas like comparability tests with the reference drug and also address issues such as pharmacovigilance and post-marketing surveillance to report any adverse events.

The existing proposals, called Guidelines on Similar Biologics, were released by the department of biotechnology in 2012. They offer a broad roadmap for lab tests, clinical trials and manufacturing processes. The new norms may set the threshold for the minimum number of patients needed for clinical trials and depending on the drug, the number may be increased. "Some key issues were not specified in the first guidelines, which had created scope for interpretations," an industry executive said.

Biocon chairman Kiran Mazumdar Shaw told **ET** that the Association of Biotech-led Enterprises (ABLE) is looking forward to the pathway that enables safe and dependable biosimilars. ABLE is the local industry group of biotech players.

Shaw advocated the use of new innovative technologies to ensure patient safety and better treatment outcomes, in line with the efforts followed by drug regulators in developed markets. She said stress should be on establishing a pathway for robust molecular characterization from the initial stages, mitigate risks and assess efficacy to demonstrate non-inferiority of tested compound.

Leading Indian drug makers like Biocon, Dr. Reddy's, Cipla, Zydus Cadila and Intas are pursuing ambitious programmes to tap the emerging global biosimilars market.

Regulatory