Editorial

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Biosimilars: The Road Ahead

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Editorial

Biosimilars came into existence with the sole ideology of affordable medication for chronic illnesses in the therapy areas of immunology and oncology. The increasingly austere measures and continuous cuts in healthcare budget by many countries forced pharmaceutical companies to develop low cost biologics without compromising on quality. Numerous players have entered this field sensing the wide range of opportunities in multiple therapy areas. The first generation biosimilars emerged, applying the phenomenon of incremental innovation, categorized under hormones (somatropin). Later, the copies of complex mAbs (monoclonal antibodies) were developed. Presently, multiple biosimilars exist for somatropin and epoetin. Recently, the biosimilar of infliximab (Remicade) was approved by the EMA. The Remicade biosimilar, known as Inflectra/Remsima, was jointly developed by Celltroin and Hospira.

Only few countries have a concrete set of guidelines for biosimilar mAbs. They are yet to decide on critical issues like interchangeability and substitution. Also, innovator companies pose a serious threat, challenging the efficacy and safety of biosimilars. The key stakeholders involved in the system viz. (regulators, physicians, patients, reimbursement agencies etc.) play a crucial role in determining the future of biosimilars and their persistence in the market to sustain competition against innovator companies.

The definition of "Stakeholder" has constantly evolved and new stakeholder groups have emerged in recent years, with non-clinical stakeholders becoming increasingly important. The decision-making landscape in the healthcare system has become complex, with intertwined relationships between various advocacy groups. Due to microheterogeneity and other technical hindrances, certain issues on interchangeability and substitution at pharmacy level are yet to be resolved. The biosimilar manufacturers need to gain trust and acceptance of these multiple stakeholders to gain access into the market. The involvement of different stakeholders in the process varies by therapeutic area. Therefore, knowing the relevant players, and their needs and interdependencies are critical to the success of a biosimilar.

Key stakeholders involved in governing access to biosimilars:

- Pharmaceutical companies: Numerous players from the generic and biotechnology background have joined the race of biosimilars. Their success and survival extensively depends of the perception and support of other stakeholders.
- Physicians: Physicians and their associations are still the key partners in achieving access for a product/ portfolio across countries.
- Payers: Increasing healthcare costs are forcing payers to install cost control mechanisms, leading to new/additional hurdles for patient access.
- Advocacy groups: Advocacy groups are non-profit organizations working in various fields. They often exert direct influence on policy shaping.
- Patients: The patient is the ultimate consumer of the product and the final decision maker while purchasing.
- Pharmacies: Pharmacies regularly influence drug access by controlling availability of the product and are crucial for biosimilars while addressing issues on interchangeability and substitution.

Conclusion

In emerging economies, the healthcare policies are often unstructured. Biosimilar companies must adopt new ways to influence healthcare policies to improve access to patients. Policy changes can only be established through a scientific approach, e.g., by generating local data to convince the stakeholders.

Biosimilars are the need of the hour to address the cost issue with originator products. However, customized comparability studies and more sophisticated analytical tools are needed to prove their efficacy while overcoming the cost barrier.

