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India, a potential market for budding biosimilar cos
Thursday, November 25, 2010 08:00 IST
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In India, the guideline (under the aegis of Department of Biotechnology (DBT)) is underway to create a pathway for biosimilars approvals, which are comparable versions of biologics to enter the drug market. These bio-drugs will create a wave of lower cost competition in the Indian biotech industry, which has already heightened the competition in the field of biologics as a fast growing area of drug therapy. Moreover, the biosimilars will compete with leading R& D-based biopharmaceutical makers.

Some of the significant competitive drugs are human growth hormones, recombinant insulins, epoetin alfa, leukine and interferon-alfa etc which has come up as biosimilars in the market. It has been anticipated that the new regulatory pathway for biosimilars could be a catalyst to spur competition in the biotech industry, which eventually may drive the biopharmaceutical industry to deliver qualitative and affordable patient care

World Health Organization (WHO) has come up with guideline that has an EU-modelled 'biosimilar pathway'. As a WHO member state,India needs to implement the WHO guidelines on Similar Biotherapeutics Products (SBP) for evaluation of SBPs in the regulatory and manufacturers' practice and facilitate development for approval of SBPs of assured quality, safety and efficacy.

The European Union has a European Medicines Agency Evaluation of Medicines for Human Use (EMEA) guideline for biosimilars, published with amended version in 2004. A reference product requires the use of a reference product authorized in the EU to be used for the entire comparability exercise. The United States Food & Drug Administration (USFDA) has taken further steps towards implementing guidelines on the approval pathway for biosimilars by holding a public meeting on the matter.

In USA, Biologics Price Competition and Innovation Act of 2009 (BPCI Act) establishes an abbreviated approval pathway for biological products that are demonstrated to be 'highly similar' (biosimilar) to, or 'interchangeable' with, a FDA-licensed biological product. In India though DBT has

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set up discussion with stakeholders in order to obtain input on specific issues and challenges associated with the implementation of the biosimilar guidelines, there should be a public hearing before finalizing the guidelines as a feedback.

Once the pathway for biosimilars comes in force, the biosimilars will have to undergo analytical studies to demonstrate the highly similar or sameness to the reference product despite minor differences in clinically inactive components. Furthermore, it needs to follow the same prescribing instructions and indications as the reference product with regard to safety, purity and potency. The important task for the Drug Controller General of India (DCGI) would be to determine cross-over studies such as interchangeability of a biosimilar.

Although there is no significant protection of a reference product like data exclusivity in India; submission of reference product data is necessary part of filing biosimilar to gain approval from the regulatory authority. India has, by far, demonstrated the greatest acceptance of biosimilars. In recent years many biosimilars have been approved for marketing in India. Further, as part of the initiative the Department of Biotechnology is inviting proposals from Indian companies working on biosimilars under its Biotechnology Industry Partnership Programme (BIPP). The proposal means that the Indian government will give support to biotech companies on a cost-sharing basis for development of novel and high risk futuristic technologies and to enhance existing R & D capacities specifically for biosimilars.

In the meanwhile, with the approval of several biosimilars, India has joined the biogenerics band wagon and has hit the trail on Europe and the US. India is one of the major players getting ready to take advantage of this opportunity, thereby expected to reinforce India's position as a major player in the biosimilars market.

As India is aiming to grab the major share in the global biosimilars market in the future, it needs to keep pace with big, eminent players and create financial back-up and manufacturing know-how to establish strong R&D capabilities. Increased use of biologic drugs is expected to help the region to emerge as a potential market for budding biosimilar companies.

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