

12:00 AM, March 10, 2018 / LAST MODIFIED: 01:30 PM, March 14, 2018

Developing our own biologic drugs



Eva Rahman Kabir

The increase in the burden of chronic diseases globally has called for greater measures in ensuring safe and effective patient treatment. Biologic drugs, or biologic response modifiers, (biologics for short) are a branch of drugs that have greatly aided in this regard and have revolutionised the way clinicians can treat diabetes, autoimmune diseases, cancers and other medical conditions. Biologics are genetically engineered from a living organism, such as a virus, gene or protein, to simulate the body's natural response to infection and disease. They target proteins, cells and pathways responsible for the symptoms and damage of specific diseases.

The high demand for and resulting financial success of these biopharmaceutical products over the last three decades have seen the door open for close copies of these biological products. Popularly termed as “biosimilars”, these products hold immense potential for the pharmaceutical industry in terms of their applications and benefits. Biosimilars pose to be of great promise to the pharmaceutical industry, irrespective

of the level of economic development in each country, with the commitment of drastically reducing a country's dependence on foreign imports to meet local demand. They have the additional advantage of requiring an abbreviated and streamlined approval process by a recognised regulatory body and are commercialised only after they have undergone clinical evaluation to verify that they are highly similar to already approved reference products.

Bangladesh holds a prominent position as a pharmaceutical manufacturer in South Asia, meeting both domestic and international demand. Similar to most other countries in the region such as Pakistan and India, it possesses well-structured regulatory pathways for the approval of pharmaceuticals. The pharmaceutical industry in Bangladesh benefits from the Trade-Related Aspects of Intellectual Property Rights (TRIPS) waiver on pharmaceutical products for developing nations, which will expire in 2033. In order to sustain growth after 2033, the industry will need to innovate and identify new opportunities.

Over recent years, the positive progress in Bangladesh's economic development, drug expertise and pharmaceutical drug policies have favourably positioned it as a hub for biosimilar drug development. Biosimilars possess unique characteristics with regard to small molecule generic drugs which pharmacists and clinicians are required to understand in order to ensure these medications are used safely and optimally. Critical variables that are necessary to be considered with regard to biosimilars include the evaluation of their clinical parameters (interchangeability, immunogenicity, clinical data), information on product manufacture, product characteristics (naming, labelling) and institutional considerations (pharmacovigilance, patient education).

As of now, although the country meets about 98 percent of its local pharmaceutical demand, it still relies on foreign imports for costly biotherapeutic products. The level of technology, expenditure, time consumption, etc. of biosimilar development from scratch may result in a challenge for companies to take up such operations without any aid from the government or foreign investments. An intelligible policy targeting to solve the shortcomings in infrastructure and funding could significantly facilitate biotechnological research. Similar to the API Park which is being developed within the country, the government could take steps to install its own “Biotech Park” and “Genome Valley” similar to those established in India. Furthermore, academia-industry collaboration could be encouraged in order to promote research into the development of biotech molecules.

With the patent expiration of most first-generation biologics internationally in 2004, and new biologics having a patent period of just 20 years, prospects for developing biosimilars are brighter than ever.

Eva Rahman Kabir (PhD) was Professor, Department of Pharmacy, BRAC University.

The author would like to acknowledge Shannon Sherwin Moreino for his valuable inputs in compiling this article.