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Editorial

Insight of Biologics and Biosimilar Drugs

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Approval of more than 18 recombinant drugs by European Union and nine recombinant drugs by Food and Drug agency in 2019, highlights the emergence and competition in the field of marketing of new therapeutic biological medical products. Biologics or biopharmaceuticals or biological medical product are the pharmaceutical drugs which mimics natural biological substances produced in living cells through biological process. Biologics includes various pharmaceutical products derived from living cells using biotechnology. After approval and successful marketing of first biologic named humulin (Recombinant insulin) in 1982, recombinant erythropoietin, recombinant somatotrophin and granulocyte colony-stimulating factor were also soon launched in global market and were historical for the management of respective chronic conditions. Till 1980, more than 150 biologics has been approved and marketed around the globe. These biologics becomes very popular since their introduction inspite of involved high prices as they are major breakthrough in the treatment of many chronic fatal diseases. Even various biologics has been approved for marketing in the field of Veterinary drugs too. These includes recombinant interferon omega for canine parvoviral enteritis and feline leukaemia, protamine zinc insulin for diabetes, feline interleukin-2 for feline sarcoma and pegbovigrastim for prevention of bovine clinical mastitis. USDA approved veterinary immunostimulant preparation are Propionibacterium acne (Eqstim) and polyprenyl (Vetimmune). Lokivemetab is only biologic monoclonal antibody approved for veterinary use in treatment of canine atopic dermatitis. Approaching expiry of patent of biologics which were marketed in 1980s, leads to the introduction of second generation biologics which are copy drugs of these generic biologics and intends to offer comparable quality, efficacy, safety that too at low prices. These drugs are popularly known as Biosimilar drugs or similar biological product (SBP) or follow on biologic (FOB) or subsequent entry biological (SEB). Biosimilar approved for therapeutic use includes recombinant proteins, monoclonal antibodies, hormones, interleukins, antitoxin and vaccines.

European medicine agency (EMA) defines Biosimilar drugs as biological medicine similar to another already authorized biological medicine. According to WHO, Biosimilar drugs are biotherapeutic products with quality, efficacy and safety similar to licensed reference biological products. Since biologics mimic natural biological substances, even a minor change in its attribute can result in serious safety and quality concerns and can be fatal at times. After expiry of patent of first generation biologics, different firms start producing and applying for approval of different Biosimilar drugs. Biosimilar drugs with the same therapeutic effect were produced from different sources and reported to have variations in quality, efficacy and safety. These variation compels thorough safety clinical trials for each drug. European medicine agency (EMA) of European Union was the first agency around the world who published regulatory guidelines for approval of biosimilar drugs in 2006. Biosimilar somatotrophin named Omnitrope was the first biosimilar to be approved in 2006 and infliximab is the first biosimilar monoclonal antibody to be approved in 2013. Till date, EMA has approved more than 50 biosimilar drugs. Later on WHO and FDA also published their regulatory guidelines for the approval of biosimilar drugs. Filgrastim-sndz is a biosimilar to generic filgrastim (granulocyte colony stimulating factor) and is the first biosimilar to be approved in 2013. In 2000, the first biosimilar for the treatment of hepatitis B was marketed in India but regulatory authorizations for marketing of biosimilar drugs in India were framed in 2012 and revised in 2016. Till date there is no biosimilar drug developed in the field of Veterinary sciences.

Major challenges with biosimilar drugs are safety concerns associated with the immunogenicity of foreign molecules. Clinical use of approved biosimilar epoetin-α results in such immunogenic reactions producing antibodies against native and recombinant erythropoietin precipitating pure red cell aplasia in patients. However, emergence of biosimilar drugs will increase the competitive and innovative urge in the field of therapeutics which will aid in bringing down the sky high cost of treatment associated with biologic therapeutics. Current success in the field of biologics and biosimilar drugs are a strong indication that their market is going to steadily increase in future and will provide mankind with new and more effective therapeutic products.

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