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Editorial OMICS International

Biosimilars and Safety Issues

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Editorial

Nowadays there is ongoing interest in the development of biosimilars, as biosimilars are anticipated to lead to price competition and to lower healthcare costs The first biosimilar, Omnitrope®, a biosimilar agent of the Recombinant Human Growth Hormone [rhGH]; was approved in Europe by the European Medicines Agency in 2006. Since then, 20 biosimilars have been approved in Europe including hematopoietic growth factors, insulin, monoclonal antibodies.

Biosimilars are biologics that are highly similar to approved biologics. According to European Medicines Agency, a biosimilar is a biological medicine that is similar to another biological medicine that has already been authorized for use. Thus, in contrast to generic drugs, biosimilars are similar but not identical to their reference products. Production of an identical copy of a biologic is quite difficult, due to a number of differences that exist between biologics and small molecules. Biologics are protein based drugs that can be thousands of times larger than small molecule drugs, are more complex and have higher immunogenic potential in comparison with small molecule drugs.

In addition, the manufacturing process for biologics is more complex and demanding in comparison with the manufacturing process for small molecule drugs. Multiple steps are required for cloning and protein expression, protein production, purification and validation. Some of these steps may vary between manufacturers resulting in differences between the biosimilar and the reference biologic drug. Small molecule drugs are manufactured through chemical reactions that can be safely reproduced by other manufactures leading to identical copies.

In clinical practice, at the moment, there is experience with the first monoclonal antibody biosimilar already approved the tumour necrosis factor-alpha inhibitor Remsima® (CT-P13). The drug has been approved for all the indications of the original drug infliximab (Remicade®). Approval of this biosimilar was based in part on extrapolation of clinical trial data from two indications (rheumatoid arthritis and ankylosing spondylitis) to all other indications, including inflammatory bowel disease [1,2]. Although the drug is available in a number of European countries since 2013, and it is currently prescribed for biologics naïve patients with inflammatory bowel disease, gastroenterologists express reservations about the extrapolation of indication and about the safety profile. A Post-marketing study of the biosimilar CT-P13 published from a Korean researcher's reports tolerability and efficacy in patients treated for Crohn's Disease and Inflammatory Bowel Disease and followed for 30 weeks. At the moment, there are ongoing clinical trials that investigate the clinical efficacy and safety profile of CT-P13 in inflammatory bowel disease. The example of CT-P13 reflects the impact of the approval of biosimilars in clinical practice.

Conclusion

In conclusion, the whole complexity in the manufacturing process of biosimilars renders the evaluation of the safety profile of biosimilars rather difficult. A regulatory pathway has been developed for the approval of biosimilars and this pathway is evolving. However, at the time of approval of a biosimilar agent, the knowledge on the safety profile of the agent is quite limited. Therefore extensive post-marketing surveillance is of paramount importance. Extrapolation of safety data from the reference product to the biosimilar is not straightforward.

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