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Pharmacovigilance of Biosimilars

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Biotech industry forms the backbone of the current pharmaceutical products. Seven out of top ten anticipated drugs of the industry in 2014 will be biologics [1]. Considering the fast pace growth of the biotechnological products, there is a parallel demand of biosimilars. As defined by FDA, "A biosimilar is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" [2]. Thus these biosimilar products become affordable alternatives to several biotechnological products, which are going off-patent. Along with the benefit of cost-effective therapy and scope of further research leading to the possibility of bio-superiors, biosimilars have led to formation of a whole new branch of biotech industry. However, there are various other concerns that require these biosimilars to be monitored closely.

The European Medicines Agency (EMEA) issued a guideline on "similar biological medicinal products" in October 2005 and since then 14 biosimilar products have been approved by EMA for the European market. These include biologics of three major classes: human growth hormone, granulocyte colony-stimulating factor and erythropoietin [3]. Considering the need for biosimilars for the current market, U.S. FDA has also issued draft guidance, recently in 2010, in an attempt to provide licensure pathway for biosimilars. The guidance aims to assure the safety, purity and potency of these biosimilars before approval.

Unlike the generic drugs for small molecules, the biosimilars will undergo stringent regulatory processes. As the biosimilars can be manufactured in multiple different ways and have human/animal origin, they can yield to the formation of biological product with similar efficacy but varied adverse effects to the reference. Thus, unlike small molecule generics, a biosimilar approval requires clinical studies to ensure that small manufacturing changes have not altered the therapeutic efficacy of the biological drug. Further, pharmacovigilance allows monitoring of adverse effects associated with a particular marketed biosimilar [4].

World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" [5]. Once a drug is released in the market by FDA, it is monitored for its safety profile. Further, the adverse effects caused by the drug are reported to generate post-marketing surveillance data. Post-marketing pharmacovigilance becomes even more critical in case of biosimilars as there is limited information available regarding them. Additionally, the effect of such biosimilars on diverse patient populations with respect to the dosage and duration of therapy needs to be closely monitored. Due to these reasons, biosimilars are required to undergo same pharmacovigilance regulations as its reference product. Thus biosimilars approved by EMEA are required to submit a risk management plan (RMP) along with the marketing application and have to provide regular safety update reports after the product is in the market. The RMP includes the safety profile of the drug and proposes the prospective pharmacovigilance studies [6].

Currently, the approved biosimilars of European market are under strict pharmacovigilance to assure patient safety. Ebbers et al. [7] reports various pharmacovigilance activities that have been conducted to monitor the safety of such approved biosimilars. These efforts includes cohort studies and surveys to monitor the adverse effects of erythropoietin biosimilars, pharmacovigilance programs and safety follow-up for long term data regarding the use of granulocyte colony-stimulating factor and a check on immunogenicity data for human growth hormone administered to the younger population [7]. Along with these studies spontaneous monitoring of the adverse effects serves to be useful. Spontaneous reports originating from the healthcare providers assist in identifying the biologic responsible for it, target patient population, severity of the adverse effect and the need of intervention. Overall, these surveillance studies are capable of generating information that will not only be useful for the patient population in Europe but will also provide supporting data to the scientists in other countries like the U.S. where several biotech/pharmaceutical companies plan to venture in the field of biosimilars.

In conclusion, pharmacovigilance is an integral part of biosimilar approval due to the fact that these biologics are unlike small molecule generics. Pharmacovigilance studies will continue to assist biotechnological companies to bring safe and efficacious biologics to the market as the information pool grows regarding the safety profile of some of the approved biologics.

References

1. Malik NN (2012) Biologics: Personalized drugs should cut care costs. Nature 485: 582.
2. Information for consumers (Biopsimilar). U.S. Food and Drug Administration, USA.
3. Biosimilars use in Europe (2011) Generics and Biosimilars Initiative.
4. Mellstedt H, Niederwieser D, Ludwig H (2008) The challenge of biosimilars. Ann Oncol 19: 411-419.
5. Pharmacovigilance. World Health Organization, Geneva, Switzerland.
6. Giezen TJ, Staus SMJM, Mantel-Teeuwisse AK (2009) Pharmacovigilance of biosimilars from a regulatory point of view: Is there a need for a specific approach? Int J Risk Saf Med 21: 53-58.
7. Ebbers HC, Crow SA, Vulto AG, Schellekens H (2012) Interchangeability, immunogenicity and biosimilars. Nat Biotechnol 30: 1186-1190.

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