Biosimilars-2013
OMICS Group Conferences
Accelerating Scientific Discovery
2nd International Conference and Exhibition on
Biowaivers & Biosimilars
September 23-25, 2013 Raleigh, North Carolina, USA

Biosimilar: Myth or Reality

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Abstract

The market for biologics is growing at nearly twice the rate of pharma as a whole. Given their often high costs compared to chemical-based, traditional pharmaceuticals, this trend is placing increasing financial pressure on healthcare budgets. Against this context, biosimilar medicines offer a major opportunity to provide greater access to affordable health care. Regulations for biosimilars are currently evolving in Europe, the US and many emerging countries. The EU has established a mature infrastructure

of legislation, regulation, and scientific and technical guidance that supports the development of biosimilars and their marketing authorization. The process has been well tested as demonstrated by approvals and non-approvals. As of September 2013 EMA has approved 18 biosimilar applications (5 ESAs, 7 Filgrastims, 3 Somatotropins, 2 Infliximabs and one Follitropin) and 2 Insulins and one Interferon biosimilar applications were withdrawn due to deficiencies. In the US the Biologics Price Competition & Innovation Act (BPCIA) created the New Pathway 351(k) that became available 23Mar 09 for Biosimilars and Interchangeable Biosimilars. The FDA published three draft guidance documents for the industry on 9th February 2012. The guidance gives an overview of the FDA's approach to determining biosimilarity, consistent with a longstanding agency approach to the evaluation of scientific evidence. Overall, the broad scope of the FDA's draft guidance documents for biosimilar approval provides minimal advice for trial pathways as compared to the EMA. In this respect, abbreviated program development may prove to be timely and costly particularly because the FDA's position is that there will not be a "one-size-fits-all" assessment for products across all classes. Despite the uncertainties surrounding product specific considerations for clinical trials, as of August 2013 according to one report FDA "continues to meet with sponsors interested in developing biosimilar products," and as of the last week of August 2013, the Agency "had received 57 meeting requests for an initial meeting to discuss biosimilar development programs for 13 different reference products and held 47 initial meetings with sponsors." However no biosimilar applications have been received by the FDA.

Biography

Rodeina Challand B.Sc., Executive Director, Biosimilars Development, Scientific Affairs, has 25 years of experience in healthcare, cancer research, and the pharmaceutical industry across a wide range of roles. As director of clinical projects at Hospira Inc., her responsibilities included creating clinical development strategies for biosimilars and serving as head of clinical operations in Europe. For over 10 years, she directed the conduct of Phase I-IV clinical trials, including large pivotal biosimilar multi-national, multi-center trials and several post-authorization safety studies for biosimilars. She was the lead in the development of Hospira's first biosimilar, Hospira GCSF, from lab to clinic. She has experience in all aspects of biosimilar development including study design and regulatory agency discussions (Europe, US, Japan, Australia, Singapore, and South Korea) and has worked on six biosimilar molecules. She was also the company's representative in several EMA consultations with regard to the development of the EMA biosimilar guidelines and was a member of the European Biopharmaceutical Group, which is a sector of the European Generic Association. More recently in her role in PRA, she has worked on 7 biosimilar programs in various capacity including consulting, strategy, feasibility, IMP management and study delivery. She has also represented PRA as a speaker in several international biosimilar conferences across the Globe.