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Safety concerns related to global biosimilars drug development

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This session will focus on safety-related aspects of biosimilars development; noting that the global biosimilars market includes monoclonal antibody biosimilars, insulins, interferons, erythropoetins, filgrastim, somatropin and follicle stimulating hormone. As of April 2014, biosimilars have been on the market for eight years and around 300 million patient days have been generated. The session notes that while European and Canadian regulatory authorities still hold a global leadership role in biosimilar drug development, with no biosimilars approved to date in the United States, these products are widely used in the EU, Canada, Japan and Australia, and have the potential for price discounts of 10 to 50 percent of reference product prices. The author notes that although an untoward safety event occurred in the 1990s, early in the development of biologics, that was due to a change in formulation of erythropoietin, since then, biosimilar drug development has proven safe over a significant time span. Nonetheless, this session cautions that with the existing diversity of regulatory sophistication between markets, there is the possibility for a problematic safety signal to result from five scenarios:

- Marketing approvals based on small clinical trials
- outsourcing of manufacturing
- pressure for speed to market
- trials in emerging markets
- lack of specific regulatory guidance and biosimilar approvals in the US. All five scenarios will be discussed in greater detail during the session.

Biography

Nigel Rulewski holds an MB and BS from St. Bartholomew's Medical School, University of London, a Diploma in Child Health from the Royal College of Physicians and a Diploma from the Royal College of Obstetricians and Gynecologists. He has over 25 years of experience in drug development and regulatory affairs in both large and small pharmaceutical companies and has worked in venture capital and pharmaceutical business development. He currently serves as Head of Quintiles Global Biosimilar Unit.

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