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Beat Flühmann

Vifor Pharma Ltd., Switzerland

Nanomedicines: An emerging regulatory challenge

Today, up to 23 nanomedicines are approved and approximately 50 are in clinical development. In the past, first follow-on products also referred to as nanosimilars have entered the European market through the generic approval pathway. But upon substitution, significant differences have been observed in clinical practice raising doubt about their therapeutic equivalence. Today, leading regulatory authorities such as FDA and EMA as well as the regulatory science community are aware of these challenges and discuss regulatory requirements. Particularly, demonstration of pharmaceutical equivalence and bioequivalence prerequisites for generic approval according to 505(j), is extremely difficult if not impossible. While nanomedicines share lots of communalities such as heterogeneity, complexity, and the large molecular size with biologics, they are synthetic products and therefore, not eligible for the 505(k) biosimilar pathway. Hence, today generic manufacturers seeking for regulatory approval of follow-on products face challenges due to the nature of these nanomedicines and lack of an appropriate regulatory pathway following the principle of similarity. Based on data from the introduction of biosimilars in Europe, we estimate potential health care expenditure savings of EUR 280 million in France, Germany, Italy, Spain and UK, and USD 2'002 million in the US for the year 2020 from an approval pathway for nanosimilars. The biosimilar legislation that has successfully facilitated patient access to save and cost-effective medicine could serve as a model for a yet to establish nanosimilar approval pathway.

Speaker Biography

B Flühmann is a Pharmacist by training and holds a PhD in Molecular Biology from ETH Zürich, Switzerland on "Structural analysis and characterization of cell surface receptors" and a MBA of the University of St. Gallen Switzerland. He is working in various positions in the field of Pharmaceuticals and Functional Nutrition. He has been leading a global multidisciplinary research and development team at Roche/DSM nutritional products developing novel compounds for the prevention and treatment of diabetes. At Vifor Pharma Ltd., he has been acting as Global Brand Director defining global strategic product plans across all functions (medical, marketing, market research, regulatory, life cycle management, logistics) and ensuring the operational execution. In his current position at Vifor Pharma Ltd, he is Global Lead of Non-Biological Complex Drugs with a main interest in regulatory aspects of nanomedicines. He is a Steering Committee Member of the Non-Biological Complex Drugs Working Group hosted at Lygature a non-for-profit organization. The mission of the Non-Biological Complex Drugs Working Group is to work on appropriate and harmonized science-based approval and post-approval standards for Non-Biological Complex Drugs to ensure patient benefit and safety.

e: Beat.Fluehmann@viforpharma.com

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