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Challenges in assessing therapeutic equivalence of nanosimilars

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Showing therapeutic equivalence of nanomedicine follow on products to a reference drug is like for biosimilars more challenging than for low molecular weight drugs. The pharmacokinetics and especially the bio-distribution can be among other parameters which depend on the size/size distribution and composition of the nanoparticle, having implications on the efficacy and safety of the drug. Today, the interaction of these nanoparticles with the body is not fully understood and the clinically meaningful physicochemical parameters are only partially identified. In two clinical studies of chronic kidney disease patients depending on hemodialysis, a lack of therapeutic equivalence was demonstrated for the first time for a nanomedicine, namely Venofer® (iron sucrose), a nano particulate iron preparation for i.v use and it follows on products or better called iron sucrose similars (ISS)-approved on a generic pathway in Europe. Upon switching from the originator iron sucrose to the ISS, a rapid drop in Hb level and iron parameters was observed and higher doses of i.v iron as well as ESA was required to stabilize the patient's Hb levels. Further clinical reports also showed different safety outcomes such as increased levels of inflammation markers in hemodialysis patients and a significantly higher number of adverse events in gynecology patients. The generic paradigm, lacks the clinical and non-clinical safety and efficacy requirements, is therefore not appropriate to assess nanomedicine follow-ons. Although ISS share the international nonproprietary name with the originator, they can exhibit clinically meaningful differences. Alarmed by these findings, the FDA and EMA have issued draft guidelines and reflection papers that propose a multi-step in vitro, non-clinical and clinical testing to evaluate the extent of similarity as a pre-requisite to define the therapeutic position and the interchangeability or switchability of such nanomedicines.

Biography

Beat Flühmann is a Pharmacist, completed MBA and PhD in Molecular Biology. Presently, he is the Director of Vifor Pharma and steering committee member of the Non-Biological Complex Drugs Working Group hosted at Lygature (a non for profit organization). Previously, he had worked for Hoffman La Roche R&D in the area of diabetes and lipid metabolism. His current interest is in regulatory science aspects of nanomedicines.

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