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Naming requirements for Biosimilars

A Biosimilar Medicinal Product, (also referred to as "biosimilar") or Follow-on Protein Product (FOPP) as it is called in the United States, is a follow-on version of a previously approved recombinant biotechnology product, which is produced by a different manufacturer after patent expiry of the original. The advent of biosimilars has caused a debate as to whether the current INN (International Non-proprietary Name) system for medicines should be revised to assign each biological product a distinct INN. The INN system was established by the World Health Organization in 1953 to «provide health professionals with a unique and universally accepted available designated name to identify each pharmaceutical substance». Novartis believes the INN should continue to identify the active substance and not the medicinal product, which is defined by the active substance together with its formulation.

Novartis Position

Novartis Pharmaceuticals and Sandoz, the generic division of Novartis (both hereafter "Novartis"), develop and manufacture, among others, branded and biosimilar biopharmaceuticals, respectively. Novartis is unique among pharmaceutical companies in that it has large investments in both branded and generic drugs, and is therefore not advocating a particular position based on the commercial interests of a particular product. Instead, Novartis strongly supports a balanced position which advocates that the same standards of high quality and science consistently be applied to all medicines, that intellectual property be provided full protection, while recognizing the role that generic and biosimilar drugs can play in the health care system.

Novartis supports the existing WHO INN system and its application to all pharmaceutical, including biological, substances as it facilitates clear identification, safe prescription and dispensing of medicines to patients. Novartis believes that the INN should remain to identify the active substance and not the medicinal

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product, which is defined by the active substance together with its formulation. Novartis advocates that only scientifically substantiated criteria should be used to allocate INNs, such as the current criteria for biological substances which are based on their molecular characteristics and distinguish according to e.g. differences in amino acid sequence.

The biosimilar concept is based on the recognition that a biosimilar has been systematically developed using state-of-the-art analytical technology and process science combined in sound Quality by Design concepts designed to create a product that matches, i.e. is highly similar to, the reference product. Minor differences in the profiles of product-related substances and impurities (as classified in ICH guideline Q6B on "Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products") are natural and to be expected. The relevance of such minor differences must be systematically evaluated using information available in the scientific literature as well as state-of-the-art analytical, biological and/or pre-clinical studies. Any such evaluation should follow the principles laid out in ICH guideline Q5E ("Comparability of Biotechnological/ Biological Products Subject to Changes in Their Manufacturing Process"): "The demonstration of comparability does not necessarily mean that the quality attributes [...] are identical, but that they are highly similar and that the existing knowledge is sufficiently predictive to ensure that any differences in quality attributes have no adverse impact upon safety or efficacy [...]." Finally, safety and efficacy of biosimilar products are confirmed in clinical studies. These have to be designed in line with relevant guidelines or in consultation with the competent authorities.

Novartis advocates that, if the main active component(s) is (are) identical and if the biosimilar product is approved to be similar to its reference product in all aspects required for its market authorization, it should be allocated the same INN. As the regulatory authority that evaluates the market authorization application of the biosimilar product possesses the technical expertise and the relevant information, it should equally assess, whether or not the biosimilar substance fulfills the requirements to justify the allocation of the INN used for the reference substance.

1. Quality by Design means designing and developing products and manufacturing processes to ensure predefined quality. In the case of biosimilars, product quality is predefined by the reference product.

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Novartis supports robust pharmacovigilance and traceability of all medicinal products, including biosimilars. Established procedures that use the distinct brand name of a product and/or the name of its manufacturer/sponsor in combination with the INN, together with the batch and lot number enable the identification of each medicinal product.

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