

# Pharmacovigilance for Biosimilars<sup>1</sup> (Post-marketing surveillance)

*Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on adverse effects or any other drug related problem to protect patient safety. Established procedures that enable the clear identification of each medicinal product use 1) the distinct brand name of a product and/or 2) the name of its manufacturer/sponsor in combination with 3) the International non-proprietary name (INN), together with 4) the batch and lot number. While this information is available for any medicinal product, adverse event reports are often missing some of the information, making the tracing of individual products to individual patients tedious and time-consuming.*

*Based on their size, complexity and variability, biopharmaceuticals can have comparable therapeutic effects while having slightly different structures (e.g. glycosylation profiles). This can be the case for different batches of the same originator product, especially after manufacturing changes, as well as between originator and biosimilar products. In rare cases, this might lead to a difference in safety profile (e.g. immunogenicity), which needs to be traced back to the responsible product/batch.*

## Novartis perspective

Novartis supports and commits to robust pharmacovigilance (PV) and traceability of all medicinal products, including biosimilars. PV processes should be designed to adequately address the specificity of the respective type of medicinal product (e.g. small molecule vs. biopharmaceutical).

To improve patient safety through enhanced pharmacovigilance, Novartis supports the recent initiative in the European Union to review and improve the pharmacovigilance system of medicinal products in Europe.

Valid pharmacovigilance procedures should be mandatory for all products of a certain category (e.g. biopharmaceutical) and not depend on if the relevant brand is an originator or a biosimilar product.

1. Biosimilars are biopharmaceutical products that were approved after the patent expiry of the originator product. Biosimilars are judged by the same quality, efficacy and safety standards as the original biologic.

We do not support applying different safety standards for biosimilars (e.g. black triangle in the UK). A biosimilar is not a completely new treatment since by the time a biosimilar is approved the knowledge about the entire class of products is much greater than at the time of the first approval of the originator product.

Novartis fully supports that for biopharmaceuticals not only the INN (International Non-proprietary Name), but also the manufacturer's name and the batch number are reported. In addition, biosimilars are already now (as originator biological products and all new medicinal products) required to supply a stringent Risk-Management-Plan, which is evaluated and approved with the market authorization. This risk management plan has to describe and justify the post-marketing surveillance of the biosimilar products, e.g. including Phase IV studies and patient registries.