

share nonproprietary names with the respective innovator products. For example, Remicade, which is the reference product for Inflectra as well as Remsima, share the same international nonproprietary name infliximab. At present, INN names distinguish between glycosylated and nonglycosylated biosimilar products by adding a Greek letter suffix for glycosylated products as with epoetin (epoetin α , epoetin β , epoetin θ , and epoetin ζ) (US FDA, 2015b). The INN system has been very effective in the pharmacovigilance of drugs but poses a challenge in product identification and tracking of biosimilars. To prevent inadvertent substitution of products sharing the same INN name and to accurately track the biological products once they are marketed, the naming of biosimilar products and how they are prescribed becomes crucial. With several biosimilar products for a same reference product, it becomes essential that these are clearly identified by their brand names in order to clearly distinguish them from the innovator as well as other biosimilars. An adverse event associated or reported with the biosimilar product identified only by nonproprietary name may be incorrectly attributed to the reference product or to another product that is a biosimilar.

The INN for biosimilars is a topic of much ongoing discussion. The WHO is working to develop a harmonized set of product identifiers that can be used to trace the products more effectively. Health Canada will follow WHO's guidance on the INN naming of the product once it is released.

So far, various regulatory jurisdictions have some guidance in place to address the issues pertaining to naming and tracking the adverse drug reactions associated with biosimilar products. In Canada, the guidance document mentions that biosimilar products have to be prescribed by their brand names which are unique, in order to trace the adverse event to the correct product. In the EU, it is recommended that the product be prescribed by its brand name and batch number. In the US, the FDA is recommending a routine use of designated suffixes to identify biological products in order to improve pharmacovigilance and to differentiate among biological products that have not been determined to be interchangeable (US FDA, 2015a). In a notice issued in August 2015, the FDA proposed that for biological products, a nonproprietary name that includes a unique suffix composed of four lowercase letters will be designated. This naming convention is applicable to both previously licensed and newly licensed biological products. The FDA has implemented this rule for some of the filgrastim products, epoetin alfa, and infliximab. Based on this new naming convention the official names and proper names of these products would be filgrastim-bflm, filgrastim-jcwp, filgrastim-vkzt, pegfilgrastim-ljfd, epoetin alfa-cgkn, and infliximab-hjmt (US FDA, 2015b).

The WHO guidelines mention that, as for all biotherapeutics, an adequate system is necessary to ensure specific identification of the subsequent biologic products (i.e., traceability). It further states that the "national regulatory authority (NRA) shall provide a legal framework for proper pharmacovigilance surveillance and ensure the ability to identify any biotherapeutics marketed in their territory which is the subject of adverse reaction reports." This implies that an adverse reaction report for any biotherapeutic should include, in addition to the INN, other important indicators such as proprietary (brand) name, manufacturer's name, lot number, and country of origin (WHO, 2009).