Vermeer et al. published a cross-sectional study using the FDA's FAERS and EudraVigilance and found that, in the spontaneous reports available in these databases, batch numbers are not recorded for 76% and 79% of reports, respectively. Furthermore for 96.2% of the biopharmaceuticals for which a biosimilar was available in the EU, the product name could be identified. It has been found that the traceability of biopharmaceuticals, especially for those that have a biosimilar product, was much higher than that for generic products due to higher reporting of batch numbers (Vermeer et al., 2013).

How the biosimilar products are prescribed (i.e., by brand name or by INN name) and whether the lot number is recorded on the prescription will be critical in monitoring the adverse events associated with these products. Educational material for the health care providers informing them of the need to include brand names and lot numbers in the prescription will go a long way to address this issue and to maintain the standard of patient safety.

13.4 CONCLUSIONS

Postmarket surveillance of biotherapeutics is essential to monitor the safety and effectiveness of drugs under real-world conditions. Introduction of biosimilars has presented a whole new set of challenges for pharmacovigilance. Biosimilars are biological products that are similar to previously approved respective reference biotherapeutics. Biosimilars are authorized based on a reduced nonclinical and clinical data package compared to those of respective reference biologic products; therefore, their benefit–risk profiles may not be fully characterized. It is known that even minor changes in the manufacturing process of biologicals can significantly affect their benefit–risk profiles, and, of greatest concern for biosimilars, is the risk of immunogenicity. Authorized biosimilars are regulated as new drugs and have the same pharmacovigilance requirements as their respective reference products. A risk management plan is required at the time of marketing authorization application. Depending on the known safety profile of the reference product and the data provided for the biosimilar product, the MAH may be required to include additional pharmacovigilance activities such as certain postmarket safety studies, including registries. Once authorized, the manufacturer of the biosimilar product is required to submit PSURs on a regular basis. Since the safety profile of the reference product is usually well established, it is expected that the safety information included in the RMP for the biosimilar would mirror that of the reference product, in addition to the safety data generated for the biosimilar during clinical trials, to reflect a more comprehensive safety profile of the biosimilar product.

Due to the naming convention, difficulties may arise if the products are prescribed by the INN names and where the lot numbers of the products are not adequately captured. Guidelines to address this issue and the issues pertaining to naming biosimilars are still under consideration by the WHO. It is very important that biosimilar products are clearly identified in order to specifically distinguish them from the respective reference products and other biosimilar products in the class, so that the adverse reactions associated with each product can be clearly identified or traced.