biologics (SEBs) in Canada. In 2010, Health Canada issued *Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs)* whose objective is to provide guidance on how to satisfy the data and regulatory requirements under the Food and Drugs Act and Regulations for the authorization of SEBs in Canada (HC, 2010).

The concept of an SEB applies to all biological drug products, but there are additional criteria to determine whether the product will be eligible to be authorized as SEBs:

1. A suitable reference biological drug exists that was originally authorized based on a complete data package, and has significant safety and efficacy data accumulated.
2. The product can be well characterized by state-of-the-art analytical methods.
3. The SEB can be judged similar to the reference biological drug by meeting an appropriate set of predetermined criteria.

With regard to the similarity of products, Health Canada requires the manufacturer to evaluate the following factors:

1. Relevant physicochemical and biological characterization data.
2. Analysis of relevant samples from the appropriate stages of the manufacturing process.
3. Stability data and impurities data.
4. Data obtained from multiple batches of the SEB and reference to understand the ranges in variability.
5. Nonclinical and clinical data and safety studies.

In addition, Health Canada has stringent postmarketing requirements, including an adverse drug reaction report, periodic safety update reports, suspension or revocation of NOC (notice of compliance). Canada's guidance shares similar concepts and principles, as indicated in the WHO guidelines since the guidance clearly mentions that Health Canada seeks to harmonize as much as possible with other competent regulators and international organizations.

8.2.4 Asian Pacific Region (Japan, Korea, China)

8.2.4.1 Ministry of Health, Labour and Welfare

The Japanese Ministry of Health, Labour and Welfare (MHLW) has also been confronted with the new challenge of regulating biosimilar/follow-on biological products. Based on the similarity concept outlined by the EMA, Japan published a guideline for the quality, safety, and efficacy of biosimilar products in 2009 (MHLW, 2009). The scope of the guideline includes recombinant plasma proteins, recombinant vaccines, PEGylated recombinant proteins, and nonrecombinant proteins that are highly purified and characterized. Unlike the EU, polyglycans such