The expiration of patents for biological drugs will lead us to the golden age of biosimilars and provide a competitive edge to medium-sized pharmaceutical manufacturers and contract research organizations. Biosimilars are three-dimensional versions of biological products that share an identical protein sequence and common amino acid sequence with the originals (biological drugs) and have demonstrated a high degree of similarity in physicochemical characteristics, efficacy, safety (including immunogenicity) and quality, but with differences in their manufacturing process in the structure of the active protein. However, these biological medicines offer lower-cost alternatives to the original drugs. The paper reviews the literature on biosimilar drugs and covers their therapeutic status, approved biosimilars, and regulatory guidelines in Australia, Brazil, Malaysia, Japan, Singapore and South Korea. The literature suggests that biosimilars are comparable but not identical to the reference product. They are not a generic version of an innovative product and do not ensure therapeutic equivalence. Each country has its own regulatory guideline for biosimilar drugs.

Biography

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