

Biosimilar Medicine

A biosimilar medicine is a biological medicine which is similar to another biological medicine that has already been authorised for use. Biosimilar medicines are commonly known as biological generic medicines. The existing biological medicine is known as the 'reference medicinal product'. Biosimilars may only be marketed after the patent for the reference medicinal product has expired, although they may be developed earlier. A biosimilar medicine and its reference medicinal product are expected to have the same safety and efficacy profile.

Biosimilar medicines are developed to have the same mechanism of action, and to treat the same diseases as the reference medicinal product. Standards of the EU Good Manufacturing Practice (GMP) apply to the manufacture of biosimilar medicines in the same way as for any other biological medicinal product. Biosimilar medicines may offer a less costly alternative to existing biological medicinal products that have lost their exclusivity rights.