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Biosimilars: Regulatory approval pathway

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The expiration of patents for a number of blockbuster biologics, increasing pressure for lower cost versions of biological Medicines, ushered in an era of the subsequent production of biosimilar products. A biosimilar medicinal product is a biological medicine which is similar to another biological medicine that has already been authorized for use, the "reference medicinal product" expected to have the same safety and efficacy profile. The EMA has taken the lead in the regulatory approval framework for biosimilar products, and WHO has published guidelines on the evaluation of biosimilars in order to facilitate the global harmonization. Biosimilarauthorization poses a number of substantial scientific and regulatory challenges for regulatory authorities. Committee for Medicinal Products for Human Use (CHMP) has also issued several product class-specific guidance that sets out product requirements in greater detail. The basic concepts and main principles of approving biosimilars are similar among various nations, notwithstanding some differences in regard to the scope, the choice of reference product, and the data requirement.