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TITLE

EUROPEAN REGULATIONS IN THE CONTEXT OF BIOSIMILARS

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The drugs derived from biotechnology are now at a turning point in their relatively recent history. The extinction of patents protecting some innovative recombinant medicines introduced during the last two decades creates a new situation: manufacturers with the skills and technology needed to develop alternative products and to seek permission marketing. In this context, the European Medicines Agency (EMEA) has established a specific directive issued in 2004, which clarifies the definition of a biological drug similar to a biological drug reference and the content of the dossier to demonstrate equivalence of biotechnology drug [biosimilar] interchangeability with the original product. This legislation clearly distinguishable "biosimilar drugs" from "generic drugs". While for generic drugs, the equivalence is taken for granted when the copy has the same quality and the same bioavailability than the original, biosimilars medicines must demonstrate comparability to the reference in terms of quality, safety and efficacy. Bioequivalence studies as for generics are not sufficient and the security of the biosimilar in comparison with the reference product should be assesses through specific pre-clinical and clinical trials. This demonstration is supplemented by a folder containing comprehensive quality and more studies comparability of the active substance and the finished product. The interchangeability is the major problem for physicians and pharmacists. The interchangeability is a therapeutic act comprising the knowledge of the patient and its story, the pathology, the indication, the dosage and the product complexity.