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Biosimilars

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Biosimilars can be defined as products with comparable quality, efficacy and safety to medicines made using –or derived from- living organisms using biotechnology, once that their patent has expired[1].

After the first biosimilar for somatotropin approved in 2006, the number of biosimilars is impressively increasing, to include blood products such as Factor VIII, substances derived from tissues and cell cultures such as interferons, gene and cell therapies or tissue engineered products. Following the marketing authorization of the first biosimilar monoclonal antibody infliximab, monoclonal antibodies are becoming the largest class of candidate biosimilars, representing the object of 37% of all Scientific Advice procedures at the European Medicine Agency (EMA) between 2003 and 2011[2].

In Europe, biosimilars are authorized with a centralized procedure by EMA, that published guidelines for these products[3] with special reference to their quality assessment[4], non-clinical and clinical evaluation[5], immunogenicity[6]. Specific guidelines are also available for monoclonal antibodies[7] and specific biosimilar products such as low-molecular-weight heparins, interferons, recombinant erithropoietins, FSH, G-CFS and recombinant insulins[2]. At more global level, the issue of biosimilars has also been addressed by the WHO[8].

The main advantage of biosimilars is to allow alternative cost-effective options which favor patient access - and affordability for HTA boards- to drugs with very high costs. However, biosimilars are not simple generics. Their complex structure and manufacturing requires adequate evaluation not only of similarity and bio-equivalence, but also of a safety and efficacy profile for each therapeutic indication.

References

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