

Dopuszczanie do obrotu produktów leczniczych biopodobnych

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Marketing authorization of biosimilar medical products

Summary

Biosimilars present a new category of products when compared with conventional generics. While the demonstration of a pharmacokinetic similarity is the main method to demonstrate therapeutic equivalence of generic medicinal products, a number of issues will make the approval of biosimilars more complicated. Therefore, the centralised procedure of marketing authorization is the only procedure allowed for these products in EU.

New manufacturers will need to ensure that their biopharmaceutical has similar efficacy and safety profile to the reference product through more extensive clinical trials than the limited testing done for generic versions of low-molecular-weight chemical medicines. The primary issue of concern for the safety of these agents is the potential for immunogenicity.

This review presents background information on the differences between biosimilars and low-molecular-weight generic drugs and the current regulatory situation, and provides information on the main sources of variability of biosimilars.

Key words:

biosimilars, generics, commercialization, immunogenicity

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