



SUBJECT:	EMEA guidelines on similar biological medicinal products containing biotechnology-derived proteins as active substances	DATE:	03 September 2008
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Executive Summary

A couple of previous papers (EXCO/NL07/CET/1502 and EXCO/ES07/CET/1502) dealt with the problem of the authorisation to market generic drugs containing a biotechnological active substance (so called biogenerics). In particular, EXCO/ES07/CET/1502 related to this problem in Europe and pointed out that the feature a biogeneric should have in order to be authorised is the biosimilarity with the already approved reference drug.

In this paper EMEA guidelines will be analysed, which allow to set criteria for assessing biosimilarity.

In order to develop a new biological medicinal product claimed to be similar to an original, reference medicinal product, a comparison in terms of quality, safety and efficacy is necessary.

Legal basis is Directive 2001/83/EC, as amended and Part II of Annex I of Directive 2001/83/EC, as amended.

Two sets of characteristics can define the product: features related to the characteristics of the molecule and features related to the process for its synthesis.

Comparability should be addressed for both the medicinal product and the active substance in the medicinal product. First of all, the reference medicinal product must be authorised in the Community.

A clear scientific justification of the criteria followed to select the reference medicinal product should be provided, with specific attention to its critical parameters and

quality attributes.

The purity and impurities profiles of the active substance and medicinal product should be assessed both quantitatively and qualitatively by a combination of analytical procedures.