Getting a Biosimilar Drug Approved in Europe – Updated Guidance

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The European Medicines Agency ("EMEA") has updated its 2005 guideline on principles for establishing biosimilarity between an innovator product and a biosimilar ("Guideline on similar biological medicinal products"; CHMP/437/04 Rev 1). The purpose of the document is to provide regulatory guidance to biosimilar manufacturers that are going to be referencing innovator product data as part of their submission for regulatory approval. Similarity to the reference product needs to be established for quality characteristics, biological activity, safety and efficacy as part of a comprehensive regulatory comparability evaluation. The release of the finalized guideline follows circulation of a draft updated guideline in 2013 for industry comments (CHMP/437/04 Rev. 1). The new guideline is in effect on April 30, 2015.

The latest revisions appear intended to provide more regulatory certainty on standards, and to make it easier, in some cases, to use non-European reference products. The guideline explains how biosimilarity is judged with respect to the key issues of safety, efficacy, quality and biological activity. In general, comparability studies are needed to generate evidence substantiating the similar nature, in terms of quality, safety and efficacy, of the similar biological medicinal product and the chosen reference drug already authorised in Europe. In some cases the reference product may be one that is approved elsewhere, such as the US, not Europe, if justifiable to regulators. For example, bridging studies may be sufficient to permit use of a non-European reference product. This is significant, since it may permit biosimilar manufacturers to avoid redoing clinical trials in Europe, making it simpler to approve a biosimilar.

This Guideline is to be read in conjunction with more specific guidelines that may be applicable on issues such as quality issues with biotechnology derived proteins (EMA/CHMP/BWP/247713/2012), and clinical/non-clinical issues (EMEA/CHMP/BMWP/42832/2005 Rev). There are also guidelines specific to particular protein categories as monoclonal antibodies, and specific proteins, such as filgrastim. Where there is a gap in regulatory guidance, biosimilar companies are invited to contact Regulatory Authorities in the EEA to obtain further advice on their development, whenever there is a need for more detailed information than provided in the guidelines already available.

The EMEA updated guidance also has significance for biosimilar approvals in other countries. Since Europe is a leader in developing biosimilar guidance, regulators such as Health Canada often take European guidance documents into account.

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