Europe Developing More Specific Criteria for Biosimilar Drug Safety Data

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Immunogenicity of biosimilar medicines has been a key concern for regulators. They want to minimize risk that a patient receiving a biosimilar medicine will be at risk of having an adverse immune response to the biosimilar. It has also been a key potential patient safety issue in the often polarized discussion between innovator and biosimilar manufacturers.

The European Medicines Agency intends to revise a Guideline that provides recommendations for the immunogenicity assessment of a biosimilar protein drug. This Guideline is of interest to biosimilar manufacturers that intend to submit an application for marketing authorization. As an initial step, the EMEA released a draft concept paper in March 2014, which has a deadline for comments on **June 30, 2014**. The concept paper is a precursor to the release of draft revised guideline that would eventually update the current Guideline that has been in effect since 2008. A primary goal of the eventual revisions is to define more specifically the requirements of immunogenicity assays. The concept paper states that EMEA feels that many past marketing authorizations lacked a clear strategy to approach immunogenicity.

The EMEA intends to further address the following topics:

- More specific guidance for the presentation of immunogenicity data;
- Requirements of data on antibody assays;
- Role of in vitro and in vivo non-clinical studies;
- Risk-based approach to immunogenicity;
- Clinical data to study the correlations of the induced antibodies to allergic and anaphylactic/anaphylactoid reactions, delayed immunological reactions, pharmacokinetics, lack of efficacy;
- Comparative immunogenicity studies; and
- Post-licensing immunological studies.