Europe Continuing to Develop Biosimilar Guidance

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The European Medicines Agency (“EMEA”) continues to be a leader in developing guidance to industry on biosimilar approvals. The EMEA is currently preparing a Reflection Paper to try to review the limitations of biosimilar data comparison methodologies to evaluate biosimilarity. The Reflection Paper initiative was triggered by questions from industry about biologic development. This type of statistical analysis is used to assess data comparisons between two different biologics as well as between different batches of the same drug. Alternative approaches will be considered in the Reflection Paper. This initiative may result in a dedicated guidance document for industry in future.

The EMEA also continued its work on reviewing and updating earlier guidance. For example, it circulated a draft updated guideline on biosimilars (CHMP/437/04 Rev. 1). The protein drug, clinical and non-clinical, issue guidance was also reviewed and opened for comment (EMEA/CHMP/BMWP/42832/2005 Rev. 1). Comment periods for both these documents closed in late 2013.