1 April 2016
EMA/CHMP/228189/2016

CHMP List of questions

To be addressed by the applicants/marketing authorisation holders for medicinal products for which the clinical and/or bioanalytical parts of the bioequivalence studies were performed at Alkem Laboratories Limited, Department of Bioequivalence, C-17/7, MIDC Industrial estate, Taloja, Dist. Raigad – 410 208, India site between March 2013 and March 2015

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1436

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Alkem Laboratories Limited, Department of Bioequivalence, C-17/7, MIDC Industrial Estate, Taloja, Rigad – 410 208 India, was subject to GCP inspection carried out in March 2015 by the Dutch and German competent authorities where critical findings were identified on the inspected studies, as well as serious deficiencies in the quality management system in place at the site (covering clinical and bioanalytical activities), which affect the trustworthiness of the data generated by the site between March 2013 and March 2015 and cast doubt on the reliability of the corresponding bioequivalence studies conducted during this period to support a marketing authorisation.

The marketing authorisation holders (MAHs) and applicants are invited to comment on the impact of the above on their marketing authorisation(s) or application(s). Demonstration of bioequivalence to the EU reference medicinal product (RMP) is a requirement of Article 10 of Directive 2001/83/EC, MAHs are therefore requested to provide evidence of bioequivalence (e.g. bioequivalence trials) with the EU reference medicinal product, in order to demonstrate a positive benefit-risk balance of the concerned medicinal products.