1 April 2016
EMA/CHMP/228248/2016

CHMP List of questions

To be addressed by Alkem Laboratories Limited, Department of Bioequivalence, C-17/7, MIDC Industrial estate, Taloja, Dist. Raigad – 410 208, India

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.

Alkem is invited to provide any relevant and substantiated information to be considered by the Committee for Medicinal Products for Human Use (CHMP) when determining the impact of the inspection findings on the benefit-risk balance of medicinal products authorised, as well as for pending marketing authorisation applications, on the basis of trials performed at the site between March 2013 and March 2015.