28 April 2016
EMA/CHMP/302883/2016

CHMP List of questions

To be addressed by the applicants/marketing authorisation holders for medicinal products for which clinical and bioanalytical parts of the bioequivalence studies were performed at the Semler Research Center (SRC) Private Limited located at SRC Private Limited, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India (also known as JP Nagar site) and Semler Research Center (SRC) Private Limited PA Arcade, No 21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India (also known as Sakar Nagar Clinical site)

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1443

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The Semler Research Center (SRC) Private Limited, 75A, 15th Cross, 1st Phase, JP Nagar, Bangalore 560 078, Karnataka, India (also known as JP Nagar site) and Semler Research Center (SRC) Private Limited PA Arcade, No 21, 22, 23, Kodigehali Main Road, Sahakaranagar Post, Bangalore 560 092, Karnataka, India (also known as Sakar Nagar Clinical site) were subject to recent GCP inspection carried out by the WHO and the US FDA where critical findings were identified on the inspected studies, as well as serious deficiencies in the quality management system in place at the sites (covering clinical and bioanalytical activities), which affect the trustworthiness of the data generated by the sites and cast doubt on the reliability of the corresponding bioequivalence studies conducted 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.Therefore it is 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.