27 January 2022
EMA/CHMP/25663/2022

CHMP List of questions

To be addressed by the applicants and marketing authorisation holders for medicinal products which have been authorised or are pending approval based on studies performed at Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, Gujarat, India

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1515

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1. Background

The US Food and Drug Administration (FDA) recently rejected all clinical and bioanalytical studies conducted by Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, Gujarat, India, on the ground that inspections and analyses of study data indicated that the company was 'responsible for the creation of false data' and that all their studies were therefore 'unacceptable'. Similar concerns have been previously raised in study data supporting marketing authorisation applications in the EU. The available information and data raise serious concerns related to the suitability of the quality management system and the overall reliability of data generated at Synchron and submitted to support marketing authorisation applications.

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.