27 January 2022
EMA/CHMP/27672/2022

CHMP List of questions

To be addressed by Synchron Research Services 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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The US Food and Drug Administration (FDA) recently rejected all clinical and bioanalytical studies conducted by Synchron Research Services 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 in the EU.

Synchron Research Services is invited to provide the following information:

1. Any relevant and substantiated information to be considered by the Committee for Medicinal Products for Human Use (CHMP) when determining the impact of the findings on the benefit-risk balance of medicinal products authorised, as well as for pending marketing authorisation applications, on the basis of studies performed since the set-up of the CRO.
2. A list of marketing authorisations/ marketing authorisation applications in the European Union for which Synchron Research Services has been involved in the clinical and/or bioanalytical activities in the context of bioequivalence studies.