EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2023
EMA/CHMP/304426/2023

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 Synapse Labs Pvt. Ltd., a contract research organisation (CRO) located in Kharadi, Pune, India

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1529

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1. Background

Synapse Labs Pvt. Ltd., located in Kharadi, Pune 411 014, India, was subject to a GCP inspection in November 2020 and November 2022 by the Spanish competent authority where critical findings were identified that cast serious doubts on the reliability of the analytical and clinical data generated by the CRO. The severity and the extent of the findings of the inspection raise serious concerns relating to the suitability of the quality management system at Synapse Labs Pvt. Ltd. and about the overall reliability of data generated by this CRO and submitted to support the marketing authorisations (applications) for medicinal products in the EU.

2. Questions

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 and applicants 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.