EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2023
EMA/CHMP/304427/2023

CHMP List of questions

To be addressed by Synapse Labs Pvt. Ltd., located in Kharadi, Pune, India

Referral under Article 31 of Directive 2001/83/EC

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 the CRO and submitted to support marketing authorisations (applications) for medicinal products in the EU.

Synapse Labs Pvt. Ltd. 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 inspection 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 Synapse Labs Pvt. Ltd. has been involved in the clinical and/or bioanalytical activities in the context of bioequivalence studies.