27 February 2020
EMA/CHMP/106145/2020

CHMP List of questions

To be addressed by the Clinical Research Organisation (CRO) for medicinal products which have been authorised or are pending approval based on clinical trials performed at Panexcell Clinical Laboratories Priv. Ltd

Referral under Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1494

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

Panexcell Clinical Laboratories Priv. Ltd., located in Navi Mumbai 400 701, India, was subject to a GCP inspection in October 2019 by the Austrian and German competent authorities where critical findings were identified that cast serious doubts on the reliability of the data of the study inspected.

The following critical observations were made during the inspection of a bioequivalence study:

- The reported PK profiles of several subjects were found to be exceptionally similar. From the verification done during inspection it is apparent that study samples could not have been mixed-up accidentally. The similarities of the profiles are of such extent that they cannot be explained and there are serious doubts whether the reported concentrations of the subjects do actually originate from these. Moreover, the confidence interval, which was >125% after the samples of the first 32 subjects were analysed showed a downwards trend and appeared to be only within the acceptance limit after the affected subject samples were analysed.
- During the inspection, study personnel intentionally documented the wrong room temperature in order to pretend that room temperature in the sample processing area was within the acceptance range.

The severity and the extent of the findings of the inspection raise serious concerns relating to the suitability of the quality management system at Panexcell Clinical Laboratories Priv. Ltd. and about the overall reliability of data generated by this CRO and submitted to support the marketing authorisation applications for medicinal products in the EU.

Panexcell Clinical Laboratories Priv. 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 trials performed since the set-up of the site under the name Panexcell Clinical Laboratories Priv. Ltd.
2. A list of marketing authorisations/ marketing authorisation applications in the European Union for which Panexcell Clinical Laboratories Priv. Ltd has been involved in the context of clinical studies.