



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Start of review concerning the conduct of studies at Panexcell Clinical Laboratories Priv. Ltd, India

The European Medicines Agency (EMA) has started a review of medicines for which studies have been conducted by Panexcell Clinical Laboratories Priv. Ltd at its site in Mumbai, India. This follows a good clinical practice (GCP) inspection which raised concerns about the study data used to support marketing authorisation applications of some medicines in the EU. The inspection was carried out jointly by Austrian and German authorities in October 2019 in the context of the evaluation of an application for marketing authorisation of a medicine.

Having considered the inspection findings, the German medicines agency (BfArM) requested EMA to assess the impact of these findings on the benefits and risks of medicines that have been authorised in the EU on the basis of studies performed by Panexcell Clinical Laboratories Priv. Ltd at its site in Mumbai. EMA has also been requested to look at the impact of the findings on medicines currently being evaluated for authorisation.

EMA will now review the available data to determine if any action is necessary to protect public health.

More about the medicines

The review covers medicines authorised or currently being evaluated via national procedures on the basis of studies conducted by Panexcell Clinical Laboratories Priv. Ltd, India.

More about the procedure

This review has been initiated at the request of Germany, under [Article 31 of Directive 2001/83/EC](#).

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

