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Start of a review concerning the conduct of studies at Synapse Labs Pvt. Ltd, India

The European Medicines Agency (EMA) has started a review of medicines for which studies have been conducted by Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Kharadi, India. This follows a good clinical practice (GCP) inspection carried out by the Spanish Agency of Medicines and Medical Devices (AEMPS) which raised serious concerns about the validity and reliability of study data generated at the CRO.

Having considered the findings of the GCP inspection, the Spanish medicines agency requested EMA's human medicines committee (CHMP) to assess the impact on the benefits and risks of medicines that were authorised on the basis of studies performed at Synapse Labs' facilities. EMA has also been requested to look at the impact on medicines currently being evaluated for authorisation that use study data generated at the CRO.

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 generic medicines authorised or currently being evaluated via national, decentralised or mutual recognition procedures on the basis of studies conducted by Synapse Labs Pvt. Ltd, India, on behalf of marketing authorisation holders and applicants.

More about the procedure

The review has been initiated at the request of the Spanish medicines regulatory agency 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.

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