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Synapse Labs Pvt. Ltd: EMA recommends suspension of medicines over flawed studies

EMA's human medicines committee (CHMP) has recommended the suspension of the marketing authorisations of a number of generic medicines tested by Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Pune, India.

The recommendation follows a good clinical practice (GCP) inspection which showed irregularities in study data and inadequacies in study documentation and in the computer systems and procedures to appropriately manage study data. This raised serious concerns about the validity and reliability of data from bioequivalence studies conducted at the CRO. Such studies are carried out to show that a generic medicine releases the same amount of active substance in the body as the reference medicine.

To reach its conclusion for the over 400 medicines tested by Synapse Labs on behalf of EU companies, the CHMP looked at all available information, including bioequivalence data potentially available from other sources. A list of the medicines concerned is available on the EMA website.

For around 35 of the medicines concerned, sufficient supporting data were available to demonstrate bioequivalence; this means that marketing authorisations for these medicines will be maintained and ongoing marketing applications can continue.

For all other medicines, supporting data were lacking or insufficient to show bioequivalence and the CHMP therefore recommended suspending their marketing authorisations. To lift the suspension, companies must provide alternative data demonstrating bioequivalence. Medicines for which ongoing marketing authorisation applications rely solely on data from Synapse Labs will not be granted authorisation in the EU.

Some of the medicines that have been recommended for suspension may be of critical importance (e.g., due to lack of available alternatives) in some EU Member States. National authorities will assess the situation and can postpone the suspension of these medicines for a maximum of 2 years in the interest of patients. Companies have to submit the required bioequivalence data for these medicines within 1 year.

EMA and national authorities will continue to work closely together to ensure that studies on EU medicines are carried out to the highest standards and that companies comply with all aspects of good clinical practice. If companies do not meet required standards, authorities will take necessary measures to ensure the integrity of data used to approve EU medicines.

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The CHMP's recommendation will now be sent to the European Commission which will issue a legally binding decision in due course.

Information for patients and healthcare professionals

- Several generic medicines have been suspended from the EU market because the company that tested them is considered unreliable.
- There is no evidence of harm or lack of effectiveness with any of the affected medicines. However, the medicines have been suspended until supporting data from more reliable sources are available.
- Patients taking the affected medicines can contact their doctor or pharmacist for information about alternatives.
- National authorities in the EU will consider how critical individual medicines are in their countries and make final decisions on whether to suspend or allow them to remain available while new data are generated.

More about the medicines

The review covered generic medicines authorised or being evaluated via national, decentralised or mutual recognition procedures on the basis of studies conducted by Synapse Labs Pvt. Ltd, located in Pune, India, on behalf of marketing authorisation holders in the EU. EMA's SPOC Working Party is following the impact of the referral outcome on the supply of critical medicines in EU Member States.

More about the procedure

The review was initiated at the request of the Spanish Agency of Medicines and Medical Devices (AEMPS) under Article 31 of Directive 2001/83/EC in relation to the Agency's findings of non-compliance with good clinical practice (GCP) at the Synapse Labs Ptv. Ltd. sites in Pune, India.

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

National authorities will decide if some of the medicines recommended for suspension are of critical importance in their countries.