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Synapse Labs Pvt. Ltd: re-examination confirms suspension of medicines over flawed studies

On 21 March 2024, EMA's human medicines committee (CHMP) confirmed its recommendation to suspend or not grant the marketing authorisations of a number of generic medicines tested by Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Pune, India. This confirmation concludes the re-examination requested by the applicants and marketing authorisation holders for some of the medicines concerned.

The CHMP adopted [its initial recommendation](#) in December 2023, after 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 manage study data. This raised serious concerns about the 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.

For the majority of the medicines tested by Synapse Labs on behalf of EU companies, the CHMP concluded that supporting data were lacking or insufficient to show bioequivalence and therefore recommended suspending the marketing authorisations of these medicines. For a small number of the medicines, sufficient supporting data were available to demonstrate bioequivalence; marketing authorisations for these medicines were maintained and ongoing marketing authorisation applications could continue.

During the re-examination, the CHMP considered that for one additional medicine¹ sufficient data were available to show bioequivalence; the marketing authorisation for this product can therefore also be maintained.

As a result of the CHMP's initial opinion and re-examination, the recommendation to suspend medicines for which adequate bioequivalence data are lacking is confirmed. 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. An [updated list](#) of the medicines affected by the procedure is available on EMA's website.

Some of the medicines that have been recommended for suspension may be of critical importance (e.g., due to a lack of available alternatives) in some EU Member States. National authorities will

¹ Nibufar. The product has been removed from the list of medicines recommended for suspension.



assess the situation and can postpone the suspension of these medicines for a maximum of two years in the interest of patients. Companies have to submit the required bioequivalence data for these medicines within one 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.

The CHMP's recommendation was sent to the European Commission which issued a legally binding decision on 24 May 2024.

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 their use 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 in July 2023 at the request of the Spanish Agency of Medicines and Medical Devices (AEMPS) under [Article 31 of Directive 2001/83/EC](#).

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted an opinion on 15 December 2023. Following a request from applicants and marketing authorisation holders for some of the medicines concerned, the CHMP re-examined its December 2023 opinion. On 21 March 2024, the CHMP adopted its final opinion. This was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 24 May 2024.

National authorities will decide if any of the medicines recommended for suspension are of critical importance in their countries and make final decisions on whether to suspend their use or allow them to remain available while new data are generated.