EMA/266340/2022 Rev.1

Update as of 24 June 2022:

A group of companies involved in this procedure has requested a re-examination of EMA's May 2022 opinion. Upon receipt of the grounds of the request, the Agency will re-examine its opinion and issue a final recommendation.

20 May 2022

Synchron Research Service: suspension of medicines over flawed studies

EMA's human medicines committee (CHMP) has recommended the suspension of the marketing authorisations of several generic medicines tested by Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, India.

The recommendation comes after irregularities were found in how the CRO carried out bioequivalence studies, which raised serious concerns about the company's quality management system and the reliability of data from that site. Bioequivalence studies are conducted to show that a generic medicine releases the same amount of active substance in the body as the reference medicine.

The CHMP looked at all medicines tested by Synchron Research Services on behalf of EU companies and found that for the majority (around 100 medicines) no adequate bioequivalence data were available from other sources. The Committee recommended that these medicines be suspended. To lift the suspension, companies relying on data from Synchron Research Services must provide alternative data demonstrating bioequivalence. For a small number of authorised generic medicines (around 20), adequate bioequivalence data were available from other sources, and these medicines are allowed to remain on the EU market.

With just a couple of exceptions for which data from other sources are available, the majority of medicines that were being evaluated for authorisation on the basis of data from Synchron Research Services will not be granted authorisation in the EU.

The list of concerned medicines can be found here.

Some of the medicines that have been recommended for suspension may be of critical importance (e.g. due to lack of available alternatives) in a given EU Member State. Therefore national authorities can temporarily postpone the suspension in the interest of patients. Member States should also decide whether recalls of the affected medicines are needed in their territories.

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EMA and national authorities will continue working 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 (GCP). If companies do not meet required standards, authorities will take whatever measures necessary to ensure the integrity of data used to approve EU medicines.

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.
- Several alternative medicines are available. Patients taking the affected medicines can contact their doctor or pharmacist for more information.
- 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 procedures on the basis of studies conducted by Synchron Research Services, located in Ahmedabad, India on behalf of marketing authorisation holders. The medicines were authorised or being evaluated for approval in several EU Member States.

See details of the concerned medicines.

More about the procedure

The review was initiated at the request of national medicines regulatory authorities in several EU countries (Belgium, Denmark, Finland, the Netherlands and Sweden), under Article 31 of Directive 2001/83/EC.

The review has been carried out by the 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.