24 September 2020
EMA/547814/2020

Panexcell Clinical Laboratories: suspension of medicines over flawed studies

On 24 July 2020, EMA's human medicines committee (CHMP) recommended the suspension of the marketing authorisations of generic medicines tested by Panexcell Clinical Laboratories Priv. Ltd at its site in Mumbai, India.

The recommendation came after Austrian and German inspectors found irregularities in how the company carried out bioequivalence studies. These are studies used to show that a generic medicine produces the same amount of active substance in the body as the reference medicine.

The inspectors found samples from different patients that were exceptionally similar and an instance of personnel documenting the wrong room temperature for the area where samples were being processed. These findings raise serious concerns about the company's quality management system and the reliability of data from that site.

The CHMP looked at all medicines tested by Panexcell on behalf of EU companies and found none for which adequate data were available from other sources.

The Committee therefore recommended that all medicines authorised in the EU on the basis of bioequivalence studies conducted by Panexcell be suspended from the market. To lift the suspension, companies in the EU relying on data from Panexcell must provide alternative data demonstrating bioequivalence.

Medicines that were being evaluated for authorisation on the basis of data from Panexcell will not be granted authorisation in the EU.

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 was sent to the European Commission for a legally binding decision.

Information for patients and healthcare professionals

- Some generic medicines have been suspended from the EU market because the company that tested them may be unreliable.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- 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.

More about the medicine

The review covers generic medicines authorised or currently being evaluated via national procedures on the basis of studies conducted by Panexcell Clinical Laboratories Priv. Ltd, India on behalf of marketing authorisation holders. The medicines were authorised or being evaluated for approval in Denmark, Finland, France, Germany, Malta, the Netherlands, Spain, Sweden and the United Kingdom.[1] See details of the concerned medicines.

More about the procedure

The review was initiated at the request of Germany under Article 31 of Directive 2001/83/EC. The review was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted the Agency's opinion. The CHMP opinion was forwarded to the European Commission, which issued a final legally binding decision applicable in all EU Member States on 24 September 2020.

[1] As of 1.2.2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period.