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Synchron Research Service: re-examination confirms suspension of medicines over flawed studies

On 15 September 2022, EMA's human medicines committee (CHMP) confirmed its recommendation to suspend the marketing authorisations of several generic medicines tested by Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, India. This concludes the re-examination requested by the marketing authorisation holders for some of the medicines concerned.

The CHMP adopted its initial recommendation in May 2022, 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 concluded that for the majority of the medicines investigated no adequate bioequivalence data were available from other sources and therefore recommended that they be suspended. For a small number of authorised generic medicines, adequate bioequivalence data were available from other sources, and these medicines were allowed to remain on the EU market.

During the re-examination, the CHMP identified that adequate bioequivalence data are available from an alternative study for eight medicines. The marketing authorisations for these medicines can therefore be maintained.[1]

As a result of the CHMP's initial opinion and re-examination, the recommendation to suspend around 100 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 Synchron Research Services will not be granted authorisation in the EU. An updated list of the medicines concerned by the procedure is available on the EMA website.

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 and national authorities can therefore 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.

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

[1] Diuver, Torasemide Teva, Torasemid AL, Torasemid-ratiopharm, Torasemid STADA, Torasemide and Torasemide Teva Italia. These products have been removed from the list of medicines recommended for suspension.

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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.

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 in January 2022 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 was carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which adopted an initial opinion on 19 May 2022. Following a request from marketing authorisation holders for some of the medicines concerned, the CHMP re-examined its May 2022 opinion. On 15 September 2022, 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 28 November 2022.