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Studies from Alkem Laboratories Ltd cannot be used to support medicines approval in the EU

EMA recommends suspension of one medicine

The European Medicines Agency (EMA) has recommended the suspension of a medicine (Riluzole Alkem), for which studies were conducted at the Alkem Laboratories Ltd site in Taloja, India, and has required companies to provide new data for another medicine before it can be authorised in the EU.

The recommendations follow a joint routine inspection by German and Dutch authorities in March 2015, which revealed misrepresentation of data during the conduct of two different trials performed in 2013 and 2014 at the Taloja site. The findings cast doubts on the quality management system in place at the site, and thus on the reliability of the data of bioequivalence studies conducted between March 2013 and March 2015.

EMA's Committee for Medicinal Products for Human Use (CHMP) noted that, although there is no evidence of harm or lack of effectiveness linked to the conduct of studies by Alkem Laboratories Ltd, the studies cannot be accepted in marketing authorisation applications in the EU. Therefore, the Committee recommended that medicines authorised or being evaluated on the basis of these studies should be suspended or refused authorisation, unless alternative data are available from other sources.

The specific recommendations of the CHMP are as follows:

- Riluzole Alkem, a medicine for amyotrophic lateral sclerosis (ALS) which has yet to be marketed in the EU, should now be suspended.
- Ibuprofen Orion, a painkiller currently under evaluation by national authorities, cannot be authorised on the basis of studies carried out at Alkem Laboratories Ltd. So far no alternative studies from other sources have been provided.
- Cefuroxime Ingen Pharma, currently under evaluation by national authorities, can still be considered for authorisation, as studies from other sources have been provided.
- Cefuroxime Alkem and Cefuroxime Krka (antibiotics) can remain on the market in the EU, as alternative studies have been provided that support a positive benefit-risk balance.

The CHMP's recommendation concerning these medicines will now be sent to the European Commission for a legally binding decision valid throughout the EU.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

EMA will continue to work closely with national authorities and international partners to ensure that studies underpinning marketing authorisations in the EU are carried out to the highest standards and that companies continue to comply fully with all aspects of Good Clinical Practice (GCP).

Information for patients and for healthcare professionals

- Some studies carried out at the Alkem Laboratories Ltd site have been found to be flawed. As a result, a medicine is being suspended. Medicines under evaluation cannot be granted authorisation on the basis of these studies; further data would have to be provided to support authorisation.
- The medicine being suspended, Riluzole Alkem, contains riluzole and is not yet on the market in the EU. Its suspension is therefore not expected to have any impact on patients in the EU. Other riluzole-containing medicines remain available.
- There is no evidence of harm or lack of effectiveness with any of the medicines linked to studies conducted by Alkem Laboratories Ltd.
- Patients should continue to take their medicines as prescribed.

More about the medicines

The review covered medicines authorised via national procedures in individual EU Member States, whose marketing authorisation applications included data from studies conducted by Alkem Laboratories Ltd, Department of Bioequivalence, C-17/7, MIDC Industrial Estate, Taloja, Dist. Raigad – 410208 India. It also included ongoing marketing authorisation applications for medicines which use study data from the site.

More about the procedure

The review of Alkem was initiated on 1 April 2016 at the request of the German medicines authority (BfArM), 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.

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu