EMA urgently reviewing multiple sclerosis medicine Zinbryta following cases of inflammatory brain disorders

02/03/2018

Medicine to be voluntarily withdrawn from the market by the company

The European Medicines Agency (EMA) has started an urgent review of the multiple sclerosis medicine Zinbryta (daclizumab) following 7 cases of serious inflammatory brain disorders in Germany, including encephalitis and meningoencephalitis, and one case in Spain.

In parallel to the start of the review, the company that markets Zinbryta (Biogen Idec Ltd) has informed EMA of its intention to voluntarily withdraw the medicine's marketing authorisations.

Doctors in the EU will be contacted directly in the coming days with further information. Until then EMA advises that:

- doctors should not start new patients on Zinbryta;
- doctors should review patients currently treated with Zinbryta and initiate alternative therapy, as soon as possible;
- patients must not stop their medication without discussing with their doctor;
- patients who have any questions should talk to their doctor.

The company has also informed EMA of its decision to stop ongoing clinical studies with Zinbryta in the EU. Patients in clinical studies who have any question should contact the doctor treating them in their study.

EMA will communicate further as necessary.

More about the medicine

Zinbryta is authorised for treating relapsing forms of multiple sclerosis. Following a 2017 review of the medicine's effects on the liver, the use of the medicine was restricted to patients who have tried at least two other disease-modifying treatments and cannot be treated with any other multiple sclerosis treatments.

To date over 8,000 patients have been treated with Zinbryta worldwide. The majority of EU patients have been treated in Germany.

More information is available on the medicine's dedicated webpage.

More about the procedure

The review of Zinbryta was initiated following a request from the European

Commission on 26 February 2018, under Article 20 of Regulation (EC) No 726/2004.

The initial review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations.