Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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RE: EMA recommendation on provisional measures for daclizumab (Zinbryta) to protect patient health

Dear Professor Coles

Please see attached the European Medicines Agency (EMA) communications about the outcome of the EMA's Pharmacovigilance and Risk Assessment Committee (PRAC) discussions this week on provisional measures to protect patient health for Zinbryta (daclizumab), whilst the more comprehensive review of the benefits and hepatic risks is ongoing.

The review was initiated because whilst the risk of liver injury was already known at the time of its approval in the European Union in July 2016 and several measures were taken to manage this risk, a case has recently occurred of fatal fulminant liver failure in a patient treated with Zinbryta despite compliance with the recommended liver monitoring and test results that were in the normal range. . This is in the context of other reports of serious hepatic injury in the clinical trials and after being licensed, and a fatal case of autoimmune hepatitis during the trials.

A further letter to relevant UK healthcare professionals will be distributed shortly, but the key messages are in the attachment and also at the following location:
http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Zinbryta_20/Under_evaluation/WC500230924.pdf and here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Zinbryta/human_referral_prac_000067.jsp&mid=WC0b01ac05805c516f

The new advice currently applies to the UK and all other EU member states. There are important changes to the indications, contraindications, potential drug interactions, special warnings/precautions for use and the liver monitoring requirements that may be relevant to existing patients taking Zinbryta and in those whom treatment is being considered. Therefore, we advise that healthcare professionals promptly review all patients or potential patients to determine whether Zinbryta is still the most appropriate MS therapy.

The EMA is best placed to respond to any questions about the information or recommendations in these communications at www.ema.europa.eu/contact or +44 (0)20 3660 6000.

The MHRA is providing feedback on the PRAC discussions to the UK's Commission on Human Medicines (CHM) next week, along with feedback on the CHM's Pharmacovigilance Expert Advisory Group's (PEAG's) discussions last week on this issue. If the CHM have any further national recommendations, then these will be communicated as soon as possible. Otherwise, the EMA recommendations for provisional measures attached can be considered final.

We would be very grateful if you could assist us in distributing this letter and the EMA communications through the ABN network?

Yours sincerely,

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