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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): deferasirox

Procedure No. EMEA/H/C/PSUSA/00000939/201610

Period covered by the PSUR: 01 Nov 2015 to 31 Oct 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for deferasirox, the scientific conclusions of CHMP are as follows:

Following the reporting of one new case of drug reaction with eosinophilia and systemic syndrome (DRESS) after the data lock point of this PSUR, the MAH was requested to provide a comprehensive review as part of this PSUR procedure. A total of 3 cases were retrieved (2 from clinical trials and one from the literature), all with positive dechallenge and one with positive rechallenge. One case had a RegiSCAR score of 3-4 with liver damage, cervical lymph nodes and hypereosinophilia and a time to onset of 23 days of the symptoms (fever and maculopapular rash). Another case had a RegiSCAR score of 5 with multiple organs (liver, kidney and cardio respiratory tract) involved and a time to onset of 13 days of the symptoms (diffuse maculopapular rash with purpuric aspect on lower limbs and fever >39.7°C, face oedema at eyelids, lips and tongue). Taking into account the available evidence and the probable causal relationship with deferasirox treatment, the PRAC concluded that the current warning on skin reactions in section 4.4 of the SmPC should be updated to include DRESS and that DRESS should also be added as new adverse drug reaction in section 4.8 of the SmPC with a 'rare' frequency.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing deferasirox were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for deferasirox the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing deferasirox is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.