28 May 2020
EMA/CHMP/273774/2020
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/00000939/201910

Period covered by the PSUR: 1 November 2018 to 31 October 2019

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Annex IV

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

Scientific conclusions

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

The MAH provided a cumulative analysis across all populations of cases of Hepatic failure (serious and non-serious) with reported medical history. The quantitative analysis highlights the role of hepatic comorbidities and multi-organ failure in the occurrence of hepatic failure. Cases of hepatic failure were reported with all marketed formulations of deferasirox. An update of the EU SmPC is therefore recommended.

The MAH reported also 5 noteworthy cases of GI hemorrhage/gastric ulcer. Keeping in mind that gastrointestinal hemorrhage is associated with a high rate of mortality despite progress in diagnosis and treatment, an update of the EU SmPC treatment recommendations is therefore 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.

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