27 January 2022
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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)

Procedure no.: EMEA/H/C/PSUSA/00010761/202011

Active substance(s): pegvaliase

Period covered by the PSUR: 24/11/2020 To: 23/05/2021

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Scientific conclusions

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

In view of available data on dizziness from clinical trial(s) and spontaneous reports including in some cases a close temporal relationship and one case with four positive re-challenges, the PRAC considers a causal relationship between pegvaliase and dizziness is at least a reasonable possibility. However, as it is evident that dizziness can also be a symptom of a hypersensitivity reaction to Palynziq, the PRAC recommended that dizziness be added to the list of hypersensitivity reaction terms in the product information rather than as a new separate adverse reaction. The PRAC concluded that the product information of products containing pegvaliase should be amended accordingly.

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 pegvaliase the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pegvaliase 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.