EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
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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): pegvaliase

Procedure No. EMEA/H/C/PSUSA/00010761/202011

Period covered by the PSUR: 22 May 2020 to 22 November 2020

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 dyspnoea from clinical trials and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pegvaliase and dyspnoea is at least a reasonable possibility. 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.