27 February 2020
EMA/316519/2020
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): pegaspargase (centrally authorised product)

Procedure No. EMEA/H/C/PSUSA/00010457/201907

Period covered by the PSUR: 14 July 2018 – 14 July 2019

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 pegaspargase (centrally authorised product), the scientific conclusions of CHMP are as follows:

In view of available data on anaphylactic shock from clinical trials, the literature and spontaneous reports, the PRAC concluded that the product information of products containing pegaspargase (centrally authorised product) should be amended to include anaphylactic shock in the list of adverse drug reactions. In addition, the PRAC recommended that the opportunity is taken to reclassify 'Toxic epidermal necrolysis' from the SOC Immune system disorders to the SOC Skin and subcutaneous system disorders.

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