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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): pegaspargase (centrally authorised product)

Procedure No. EMEA/H/C/PSUSA/00010457/201807

Period covered by the PSUR: 15 January 2018 – 14 July 2018

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## 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:

Cumulatively there were 62 reports of gamma-glutamyl transferase increased. Of the 62 events, 54 cases were considered related (of which 21 were from clinical trials) and 8 were considered not related. Based on the presented data and given the known liver toxicity associated with Oncaspar, the adverse event 'increased Gamma-glutamyl transferase' should be added to the product information.

Section 4.4 of the SmPC already states that "*It is strongly recommended that every time Oncaspar is administered to a patient, the name and lot number of the product are recorded in order to link the patient and the lot of the product".* This information should also be included in the Package Leaflet.

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.