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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): brentuximab vedotin

Procedure No. EMEA/H/C/PSR/S/0022

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Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

Currently, the following is described regarding the safety profile in elderly treated with brentuximab vedotin monotherapy in SmPC section 4.8: "The safety profile in elderly patients was consistent with that of adult patients". Based on the information provided by the MAH, this statement is not considered adequate. The incidences of pneumonia, febrile neutropenia and neutropenia were shown to be considerable different for patients ≥65 years as compared to patients <65 years. Furthermore, as also mentioned by the MAH older age is an important risk factor for, among others, the occurrence of neutropenia and febrile neutropenia.

Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes to the product information were 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 the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of this/these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.