15 October 2020
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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/PSUSA/00010039/202002

Period covered by the PSUR: 17 February 2019 to 17 February 2020

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Scientific conclusions

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

Regarding the risk of extravasation, 29 post-marketing cases were identified, of which the majority had a time-to-onset of the event occurring on the same day of infusion. In 10 cases, reasons for extravasation were reported, of which some concern administration errors and others following correct administration as per the SmPC. Based on the information provided by the MAH, it is agreed that extravasation resulting in local reactions can occur following administration of brentuximab vedotin and that it is important for HCPs to be aware of this. The MAH added the term 'infusion site extravasation' to the SmPC section 4.8 and to section 4 of 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 brentuximab vedotin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing brentuximab vedotin 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.