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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): polatuzumab vedotin

Procedure No. PSUSA/00010817/202506

Period covered by the PSUR:
1 year to 09 June 2025

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Scientific conclusions

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

In view of available data on risks from clinical trials, spontaneous reports, and the literature, including in 4 cases with a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between polatuzumab vedotin and adverse reaction `extravasation injury´ is at least a reasonable possibility. The PRAC concluded that the product information of products containing polatuzumab vedotin should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for polatuzumab vedotin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing polatuzumab 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.