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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): trabectedin

Procedure No. PSUSA/00003001/202509

Period covered by the PSUR: 18 September 2022 to 17 September 2025

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Scientific conclusions

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

In view of available data on acute kidney injury from clinical trial(s), spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between trabectedin and acute kidney injury is at least a reasonable possibility. The PRAC concluded that the product information of products containing trabectedin 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 trabectedin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing trabectedin 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.