EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: trabectedin

Procedure No. EMEA/H/C/PSUSA/00003001/201409

Period covered by the PSUR: 18 September 2013 – 17 September 2014

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Scientific conclusions

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

As infusion site reactions and tissue necrosis are known events, the PRAC considered that it is important to highlight more clearly to health care professionals that the use of central venous access is strongly recommended, which is further explained in section 4.4 of the SmPC. Hence, the SmPC wording in section 4.2 should also include a reference to section 4.4 and not only to section 6.6.

Therefore, in view of available data regarding infusion site reactions and tissue necrosis the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for trabectedin the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing trabectedin is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisations should be varied.