25 April 2014
Committee for Medicinal Products for Human Use (CHMP)

Yondelis

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

International non-proprietary name: trabectedin

Procedure No. EMEA/H/C/000773/PSUV/0038

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Scientific conclusions

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

Following the EU-RMP Version 7.0 update, drug-drug interactions was added as missing information. Additionally, based on the results of the 2 drug-drug interaction studies involving potent CYP3A4 inhibitors/inducers (ET743-OVC-1003 and ET743-OVC-1002), the CCDS was updated and the MAH proposed to reflect these results in the product information accordingly. Cases involving drug-drug interactions will continue to be monitored in future PBRERs/PSURs, especially those involving CYP3A4 and P-gp inhibition. Action taken with respect to drug-interactions is endorsed by the PRAC.

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 Yondelis, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance TRABECTEDIN is favourable subject to the proposed changes to the product information.

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