15 November 2018
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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): irinotecan (liposomal formulations)

Procedure No. EMEA/H/C/PSUSA/00010534/201804

Period covered by the PSUR: 23 October 2017 – 22 April 2018

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Scientific conclusions

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

Based on review of data submitted in the PSUR procedure, including markedly increased reporting frequency of serious thromboembolic events, the PRAC considers that a relevant warning on this identified risk should be included in section 4.4 of the Summary of Product Characteristics for products containing liposomal irinotecan. The package leaflet should be updated accordingly.

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 irinotecan (liposomal formulations) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing irinotecan (liposomal formulations) 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.