EMA/455238/2020
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/00010534/202004

Period covered by the PSUR: 22 October 2019 to 22 April 2020

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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 CHMP are as follows:

In view of available data on the drug-drug interaction between irinotecan and an UGT1A1 inhibitor, regorafenib, the PRAC concluded that the product information of products containing irinotecan (liposomal formulations) should be amended accordingly.

Update of section 4.5 of the SmPC to add regorafenib to the list of examples of UGT1A1 inhibitors. The Package leaflet is updated accordingly. The MAH also took the occasion to align the PI to QRD version 10.1.

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.