25 January 2024
EMA/84642/2024
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): sunitinib

Procedure No. EMEA/H/C/PSUSA/00002833/202304

Period covered by the PSUR: 01/05/2020 To: 30/04/2023

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Scientific conclusions

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

In view of available data on risk of hyperammonaemic encephalopathy from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between sunitinib and hyperammonaemic encephalopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing sunitinib 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 sunitinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sunitinib 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.