EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): niraparib

Procedure No. EMEA/H/C/PSUSA/00010655/202009

Period covered by the PSUR: 27 March 2020 To: 26 September 2020

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Scientific conclusions

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

In view of available data on cognitive impairment from spontaneous reports, clinical trials and post marketing surveillance including in nine cases a close temporal relationship and in two cases a positive de-challenge, the PRAC considers a causal relationship between niraparib and cognitive impairment is at least a reasonable possibility. The PRAC concluded that the product information of products containing niraparib should be amended 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 niraparib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing niraparib 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.