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): brivaracetam

Procedure No. EMEA/H/C/PSUSA/00010447/202401

Period covered by the PSUR:
15/01/2021 To: 14/01/2024

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Scientific conclusions

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

In view of available data on Stevens-Johnson syndrome from spontaneous reports, including in 4 cases with close temporal relationship and positive dechallenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between brivaracetam and Stevens-Johnson syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing brivaracetam 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 brivaracetam the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing brivaracetam 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.