9 November 2023
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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): pramipexole

Procedure No. EMEA/H/C/PSUSA/00002491/202304

Period covered by the PSUR: 06 April 2022 to 06 April 2023

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Scientific conclusions

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

In view of available data on augmentation in Restless Legs Syndrome from the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pramipexole and augmentation in Restless Legs Syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing pramipexole with the indication' Restless Legs Syndrome' 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 pramipexole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pramipexole 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.