12 October 2023
EMA/440258/2023
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): pregabalin

Procedure No. EMEA/H/C/PSUSA/00002511/202301

Period covered by the PSUR: 1 February 2021 To: 31 January 2023

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Scientific conclusions

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

In view of the available data on suicidal ideation following withdrawal of pregabalin from spontaneous case reports describing a close temporal relationship between the withdrawal of pregabalin and the onset of suicidal ideation either with or without other withdrawal symptoms, including one case with a pos. rechallenge, the PRAC considers a causal relationship between pregabalin and suicidal ideation after pregabalin withdrawal to be probable and concluded that the product information of products containing pregabalin 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 pregabalin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pregabalin 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.