15 September 2016
EMA/805571/2016
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/00002511/201601

Period covered by the PSUR: 1 February 2015 to 31 January 2016

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Scientific conclusions

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

Some studies and a few individual case reports suggested that seizures may occur rarely as serious symptom of pregabalin overdose. Based on the data submitted in this PSUR regarding overdose cases without a reported history of seizure and confounders, the PRAC concluded that reported cases of seizures should be added in the overdose section of the Product Information (Section 4.9).

Therefore, in view of the data presented in the reviewed PSURs, the PRAC considered that changes to the product information of medicinal products containing pregabalin were warranted.

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 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.

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