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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): peginterferon beta-1A

Procedure No. EMEA/H/C/PSUSA/00010275/201701

Period covered by the PSUR: 19 Jul 2016 to 18 Jan 2017

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for peginterferon beta-1a, the scientific conclusions of CHMP are as follows:

457 cases of alopecia, including 15 cases with a positive de-challenge, were reported in the post-marketing setting. This is supportive of a causal relationship between the use of peginterferon beta-1a and alopecia. Furthermore, alopecia is listed in the Product Information of all interferon-beta 1a products and is therefore considered to constitute a pharmacological class effect. Based on the occurrence of alopecia in the pivotal clinical trial (2% in the treatment arm vs 1% in the placebo arm), this adverse drug reaction has been assigned the frequency “common”.

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 peginterferon beta-1a the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing peginterferon beta-1a 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.