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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): pegfilgrastim

Procedure No. EMEA/H/C/PSUSA/00002326/201901

Period covered by the PSUR: 31 January 2016 to 31 January 2019

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Scientific conclusions

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

Three reported cases show a causal relationship between the adverse drug reaction (ADR) Stevens-Johnson syndrome and pegfilgrastim. The number of cases is small, but because of the seriousness of the ADR, the PRAC recommends that the Product Information should be updated accordingly.

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 pegfilgrastim the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pegfilgrastim 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.