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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): imatinib

Procedure No. EMEA/H/C/PSUSA/00001725/202105

Period covered by the PSUR: 11 May 2018 to 10 May 2021

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Scientific conclusions

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

In view of available data on panniculitis and based on a possible class effect, the PRAC considers a causal relationship between imatinib and panniculitis (including erythema nodosum) is established. The PRAC concluded that the product information of products containing imatinib should be amended 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 imatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing imatinib 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.