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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): imiquimod

Procedure No. EMEA/H/C/PSUSA/00001729/202001

Period covered by the PSUR: 26 January 2017 to 26 January 2020

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Scientific conclusions

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

Regarding the risk of exacerbation of autoimmune conditions, the PRAC considers that since this is reflected in Section 4.8 of the SmPC and relevant warnings are included in section 4.4, the Package Leaflet should reflect this information.

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