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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): pirfenidone

Procedure No. EMEA/H/C/PSUSA/00002435/202102

Period covered by the PSUR: 27/02/2020 To: 27/02/2021

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Scientific conclusions

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

In view of the available data on from post-marketing reports the PRAC considers a causal relationship between Stevens Johnson syndrome and Toxic Epidermal Necrolysis and pirfenidone is considered at least a reasonable possibility. The PRAC concluded that the product information of products containing pirfenidone 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 pirfenidone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pirfenidone 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.