Amsterdam, 19 September 2019
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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/00002435/201902

Period covered by the PSUR: 27 February 2018 – 27 February 2019

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Annex IV

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

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As requested the MAH provided a review of reported anaphylactic reactions. Two clinical trial cases presented alternative causes. There were 18 post-marketing cases reviewed by the MAH. Based on the clinical details, the severity of the reactions and the need for treatment with adrenaline and ICU admission it is concluded that a small number of cases (n=6) represented severe hypersensitivity reactions, requiring immediate assessment and treatment. The cases represent a range of manifestations of anaphylaxis, including angioedema, respiratory symptoms (4 cases), cutaneous symptoms (2 reports), hypotension (3 reports), collapse and tachycardia. All required hospitalisation and treatment with adrenaline (excluding one case where treatment was not specified). Angioedema is listed as an uncommon adverse reaction of pirfenidone in the current product information. It is recommended following assessment that the product information is updated with anaphylaxis.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for pirfenidone (for centrally authorised product) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pirfenidone (for centrally authorised product) 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.