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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

Active substance: fondaparinux

Procedure No. EMEA/H/C/PSUSA/00001467/201512

Period covered by the PSUR: 7 December 2014 – 6 December 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for fondaparinux, the scientific conclusions of CHMP are as follows:

Allergic reactions (including very rare reports of angioedema, anaphylactoid/anaphylactic reaction) are mentioned for two indications (major orthopaedic surgery of lower limbs and/or abdominal surgery and treatment of Venous Thromboembolic Events) in the product information, but not for medically ill patients. Following a cumulative review of immune/allergic reaction data (which was conducted in 2012), the CCDS was updated to include the events of angioedema, anaphylactoid reaction and anaphylaxis. As these events were added to the CCDS in the post-marketing setting from a review of all reports, they are applicable to all indications, including medically ill patients.

Therefore, in view of available data regarding allergic reaction with the use of fondaparinux, the PRAC considered that changes to the product information of medicinal product containing fondaparinux were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for fondaparinux the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing fondaparinux is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.