EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: apixaban

Procedure No. EMEA/H/C/PSUSA/00000226/201505

Period covered by the PSUR: 18 May 2014 – 17 November 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

During the reporting period of the PSUR for apixaban, a number of pruritus cases (n=85) were reported and 20 were assessed as possibly related to the medication. In 15 of these a positive de-challenge or re-challenge was observed and no confounding factor (use of co-medication or co-morbidities such as the occurrence of hypersensitivity) was described. In light of the reported data, it is recommended that 'pruritus' should be specifically included in section 4.8 of the SmPC under the SOC 'Immune system disorders' with the frequency of "uncommon". The Package Leaflet is to be updated accordingly.

Therefore, in view of available data regarding pruritus, the PRAC considered that changes to the product information were warranted.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

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

The CHMP recommends that the terms of the Marketing Authorisation should be varied.