16 December 2021
EMA/201095/2022
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Procedure no.: EMEA/H/C/PSUSA/00000226/202105

Active substance(s): apixaban

Period covered by the PSUR: 17/05/2020 To: 17/05/2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data from the literature including cases with a positive dechallenge with time-to-onset (TTO) of 2 weeks or less, the PRAC considers a causal relationship between apixaban and cutaneous vasculitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing apixaban 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 apixaban the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing apixaban 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.