30 January
EMA/130522/2025
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): apixaban

Procedure No. EMEA/H/C/PSUSA/00000226/202405

Period covered by the PSUR:
18/05/2021 To: 17/05/2024

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Scientific conclusions

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

Anticoagulant-related nephropathy (ARN): In view of available data including 6 relevant, biopsy-confirmed cases of ARN indicating a possible association with apixaban, a pharmacological class effect (ARN is already listed for other DOACs rivaroxaban and edoxaban), and pathophysiological plausibility, the PRAC considers a causal relationship between apixaban and ARN is at least a reasonable possibility. The PRAC concludes that the product information of products containing apixaban should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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(s) 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.