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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): rivaroxaban

Procedure No. EMEA/H/C/PSR/S/0027

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Scientific conclusions

Taking into account the PRAC Assessment Report for the non-interventional imposed PASS final study report for the medicinal product(s) mentioned above, the scientific conclusions of CHMP are as follows:

The PRAC considered it appropriate to summarise the key results from this imposed PASS program, which had been conducted in 3 EU countries and the UK, and which comprised more than 40,000 patients in the VTE-T indication and 162,000 patients in the NVAF indication, and reflect those in the SmPC, section 5.1 Pharmacodynamic properties of the product information.

Furthermore, by finalisation of this category 1 study program, removal of the additional monitoring statement and the black triangle from the product information is warranted. Annex II of the product information should also be updated to remove this condition.

Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes to the product information and changes to the conditions of the marketing authorisation were warranted.

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 the results of the study for the medicinal product(s) mentioned above, the CHMP is of the opinion that the benefit-risk balance of these medicinal product(s) is unchanged, subject to the proposed changes to the product information.

The CHMP is of the opinion that the terms of the marketing authorisation(s) of the medicinal product(s) mentioned above should be varied.