



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 October 2018
EMA/798331/2018
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): ivabradine hydrochloride

Procedure No. EMEA/H/C/N/PSR/S/0019



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 results of this DUS study showed an increase in adherence to the SmPC guidelines in the post-RMM period compared to the pre-RMM period. This increase in adherence was measured for all the four criteria under study. Therefore, in view of available data regarding the PASS final study report, the PRAC considered that 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.