EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2024
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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): Aclidinium and Aclidinium / Formoterol fumarate dihydrate

Procedure No. EMEA/H/C/PSR/0047

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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 results of the study show that aclidinium increases the risk of any cardiac arrhythmia and atrial fibrillation compared to LABAs and other LAMAs. In addition, the results also show that aclidinium/formoterol FDC increases the risk of any cardiac arrhythmia and atrial fibrillation compared to LABAs and other LAMA/LABA combinations. Therefore, in view of available data regarding the PASS final study report, the PRAC considered that changes to the product information are 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.