EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): fluticasone furoate

Procedure No. EMEA/H/C/PSUSA/00009154/202404

Period covered by the PSUR: 27 April 2021 to 26 April 2024

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## Scientific conclusions

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

In view of available data on dysphonia, aphonia, dysgeusia, ageusia and anosmia from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between fluticasone furoate and dysphonia, aphonia, dysgeusia, ageusia and anosmia is at least a reasonable possibility. The PRAC concluded that the product information of products containing fluticasone furoate 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 fluticasone furoate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fluticasone furoate 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.