Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

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

Based on the review of data considered during the assessment of this PSUSA procedure, the PRAC is of the view that a causal relationship between the use of fluticasone propionate and the occurrence of nasal ulcers when taken in intranasal formulation could not be excluded and therefore requests the update of section 4.8 of the Summaries of Product Characteristics (SmPCs) of this formulation, in order to reflect this adverse drug reaction with the frequency 'not known'. The package leaflet should be updated accordingly.

The CMDh 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 fluticasone propionate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing fluticasone propionate is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing fluticasone propionate are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike through~~)

Intranasal formulations

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the SOC Respiratory, thoracic and mediastinal disorders with a frequency not known:

Nasal ulcers

Package Leaflet

- Section 4. Possible side effects

Frequency not known:

Sores in the nose

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	23 December 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	21 February 2018