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 tixocortol, chlorhexidine gluconate / tixocortol pivalate, the scientific conclusions are as follows:

Cumulatively, there were 18 non-serious medication errors. Respectively, three cases of incorrect route of drug administration were identified during the reporting period and 9 cases cumulatively, two of whom were paediatric patients. For these cases, parents administrated nasal drops of tixocortol, chlorhexidine gluconate / tixocortol pivalate to the wrong administration site (eyes or throat). Based on the information reviewed in this PSUR, PRAC considered that sections 1 and 3 of the patient leaflet should be amended to better reflect the correct administration route of tixocortol, chlorhexidine gluconate / tixocortol pivalate for intranasal use in the product information.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing tixocortol, chlorhexidine gluconate / tixocortol pivalate were warranted.

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 tixocortol, chlorhexidine gluconate / tixocortol pivalate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing tixocortol, chlorhexidine gluconate / tixocortol pivalate 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 tixocortol, chlorhexidine gluconate / tixocortol pivalate are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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 **<u>underlined and in bold</u>**, deleted text ~~strike-through~~)>

Package leaflet

- Section 1 "What [Name of the medicinal product] is and what it is used for":

"Therapeutic indications

This medicine is indicated **<u>for intranasal use only</u>** for the inflammatory and allergic manifestations of the nasopharynx: allergic rhinitis, seasonal rhinitis, acute and chronic congestive rhinitis, vasomotor rhinitis."

- Section 3 "How to use [Name of the medicinal product]":

"*Method of administration*

<u>For intranasal use only, do not spray in the eyes or mouth</u>.

Do not swallow. […]"

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	July 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	2 September 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	1 November 2017