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 xylometazoline, the scientific conclusions are as follows:

In view of available data on risk from spontaneous reports including cases of close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the Lead Member State considers a causal relationship between xylometazoline and epistaxis is at least a reasonable possibility.

Update of section 4.8 of the SmPC to add the adverse reaction “Epistaxis” with a frequency “Uncommon”. The Package leaflet is 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 xylometazoline the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing xylometazoline 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 xylometazoline 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 **underlined and in bold**, deleted text ~~strike through~~)

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 "Uncommon":

Epistaxis

Package Leaflet

4. Possible side effects

"Uncommon"

Nosebleeds

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	28.01.2021
Transmission to National Competent Authorities of the translations of the annexes to the position :	14.03.2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	13.05.2021