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 lidocaine hydrochloride / phenylephrine hydrochloride / tropicamide, the scientific conclusions are as follows:

In view of available data from cases reporting iridocele and cases reporting floppy iris syndrome, the PRAC considers a causal relationship is at least a reasonable possibility. In most cases, known risk factors, concomitant disease or other factors explaining the event were reported. However, a pattern in these risk factors was identified; they appear to be related to the use in patients with shallow anterior chamber and use in patients with insufficient pupil dilation. The PRAC concluded that the product information of products containing lidocaine / phenylephrine / tropicamide should be amended 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 lidocaine hydrochloride / phenylephrine hydrochloride / tropicamide the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing lidocaine hydrochloride / phenylephrine hydrochloride / tropicamide 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 lidocaine hydrochloride / phenylephrine hydrochloride / tropicamide 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~~)

Summary of Product Characteristics

Section 4.4

A warning should be added as follows:

X is not recommended in subjects with a shallow anterior chamber or a history of acute narrow angle glaucoma.
Use of <product name> in patients with shallow anterior chamber, a history of acute narrow angle glaucoma and/or insufficient pupil dilation can increase the risk of both iridocele and floppy iris syndrome.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11 April 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 June 2021