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 phenylephrine (ophthalmic formulations), the scientific conclusions are as follows:

In view of available data on paediatric population from the literature and spontaneous reports, the PRAC considers that 10% phenylephrine (ophthalmic formulation) is not recommended for use in children aged 12 to 18 years and that the age specification of the contraindication for use in children should be further clarified. The PRAC concluded that the product information of products containing 10% phenylephrine (ophthalmic formulation) should be amended accordingly.

Update of section 4.2 and 4.4 of the SmPC to add a non-recommendation for use in children aged 12 to 18 years. The Package leaflet is updated accordingly.
Update of section 4.2, 4.3 and 4.4 of the SmPC to clarify the age specification of the contraindication for use in children. 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 phenylephrine (ophthalmic formulations) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing phenylephrine (ophthalmic formulations) 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 phenylephrine (ophthalmic formulations) 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~~)

10% phenylephrine (ophthalmic formulation)

Summary of Product Characteristics

Section 4.2

Paediatric population

<X> is contraindicated in children aged below 12 years (see section 4.3).

There are no data in children aged 12 to 18 years. <X> is not recommended in these patients.

Section 4.3

Children aged below 12 years (see section 4.4).

Section 4.4

Paediatric population

Use in children aged below 12 years is contraindicated, since serious systemic adverse reactions have been reported with ophthalmic products containing phenylephrine.

Use in children aged 12 to 18 years is not recommended as adequate clinical experience is missing.

Package Leaflet

Section 2 - What you need to know before you <take> <use> <X>

Do not use <X>:

In children below the age of 12 years.

Warnings and precautions:

<X> should not be used in children below the age of 12 years as children appear more sensitive to the risk of serious side effects.

<X> is not recommended to be used in children aged 12 to 18 years as adequate clinical experience is missing.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	1/11/2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	31/12/2020