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 latanoprost (except for products with paediatric indication), the scientific conclusions are as follows:

In view of available data on nausea and vomiting from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between latanoprost (except for products with paediatric indication) and nausea and vomiting is at least a reasonable possibility. The PRAC concluded that the product information of products containing latanoprost (except for products with paediatric indication) 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 latanoprost (except for products with paediatric indication) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing latanoprost (except for products with paediatric indication) 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 latanoprost (except for products with paediatric indication) 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 4.8

The following adverse reactions should be added under the SOC Gastrointestinal disorders with a frequency uncommon

[…]

SOC Gastrointestinal disorders

Frequency 'uncommon': Nausea

Frequency 'uncommon': Vomiting

Package Leaflet

- Section 4 Possible side effects

[…]

Uncommon: **Nausea**

Uncommon: **Vomiting**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	30 January 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	31 March 2022