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 dorzolamide, the scientific conclusions are as follows:

A cumulative review of 60 ICSRs describing the adverse event "photophobia" found that events were mostly non-serious (n=59). The majority of reports originated from consumers (n=25), and mostly involved elderly patients (n=26). Among cases with available information, the outcome of the events of photophobia was recovered in 17 cases and causality was assessed as related or possibly related in 31 cases, using a conservative approach as causal relationship with dorzolamide could not be excluded. A positive dechallenge was reported in thirteen cases, and a positive rechallenge in two cases.

A possible mechanism of action is described by Sponsel et al. Indeed, dorzolamide's primary action of reducing aqueous humor could alter the refractive properties of the eye, leading to changes in light perception. Dorzolamide can have systemic effects despite its topical application, and may be absorbed into the systemic circulation to some extent. This systemic absorption could potentially affect other parts of the eye not directly related to intraocular pressure, possibly leading to light sensitivity. Moreover, the medication's potential to cause ocular discomfort or other superficial eye irritations, as noted in reported side effects like irritation and burning sensations, could contribute to a heightened sensitivity to light.

Furthermore, photophobia is a known adverse reaction to brinzolamide eye drops, another topical carbonic anhydrase inhibitor. A significant disproportionality signal with ROR (-) of 3,26 was identified in Eudravigilance. In addition, the event is listed in the USA prescribing information of the innovator product.

Based on this cumulative evidence, PRAC recommends to add photophobia as an adverse reaction to the product information of dorzolamide.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for dorzolamide the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing dorzolamide is unchanged subject to the proposed changes to the product information
The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

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 **Eye disorders** with a frequency Unknown:

Photophobia

<Package Leaflet>

- Section 4

Not known (frequency cannot be estimated from the available data):
Abnormal sensitivity of the eyes to light

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	30 November 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	29 January 2026