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 Naphazoline, naphazoline / zinc sulphate, the scientific conclusions are as follows:

In view of available data on severe cardiovascular and/or cerebrovascular adverse reactions from the literature, including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between naphazoline, naphazoline/zinc sulphate and severe cardiovascular and/or cerebrovascular events is at least a reasonable possibility when naphazoline is used excessively. The PRAC concluded that the product information of products containing naphazoline, naphazoline/zinc sulphate should be amended accordingly.

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 Naphazoline, naphazoline / zinc sulphate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing Naphazoline, naphazoline / zinc sulphate 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 4.9

The signs and symptoms of overdose should be added as follows:

Post marketing data has shown that excessive systemic exposure, for example due to intentional or accidental overdose of naphazoline (including inadvertent oral ingestion), may lead to severe cardiovascular and/or cerebrovascular adverse reactions.

Package Leaflet

3. How to use [Product name]

[…]

If you use more [Product name] than you should

Using substantially more of [Product name] than the recommended dose, for example if [Product name] is accidentally swallowed, may lead to severe side effects affecting the heart and blood circulation. Symptoms may include: decreased heart rate (bradycardia), severe headache, nausea, vomiting, problems with breathing, increased heart rate (tachycardia), and chest pain.

The following statement should be included in the same section, if it, or an equivalent statement, is not already present in the PIL:

If you experience side effects, or in case of accidental intake/ingestion of an overdose of [Product name], seek immediate medical attention.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	11/05/2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10/07/2025