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 benzydamine, the scientific conclusions are as follows:

In view of available data on risks of use in pregnancy from the literature, spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between benzydamine and risks of use in pregnancy is at least a reasonable possibility. The PRAC concluded that the product information of products containing benzydamine should be amended accordingly to include the latest conclusions.

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 benzydamine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing benzydamine 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 4.6

[New information with regards to the risk(s) of the product when used during pregnancy should be added as follows]

Pregnancy

There are no clinical data from the use of <product name> during pregnancy.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed.

It is not known if the systemic [product name] exposure reached after topical administration can be harmful to an embryo/fetus.

Therefore, <product name> should not be used during pregnancy unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

Package Leaflet

Section 2. What you need to know before you <take/use> [product name]

Pregnancy, breast-feeding and fertility

[…]

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use [product name] during pregnancy unless clearly necessary and advised by your doctor. If you need treatment the lowest dose for the shortest time possible should be used.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	3 August 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	2 October 2025