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 cetalkonium / choline salicylate, the scientific conclusions are as follows:

In view of available data on medicines of the same therapeutic class, and considering a plausible mechanism of action, it is considered that a warning for cetalkonium / choline salicylate for risk of use in pregnancy, should be implemented. In addition, based on the available data from a literature article, it is considered that a warning regarding use in patients currently suffering from or with a history of peptic ulceration, should be implemented. Also, considering the data available for the therapeutic class of salicylates and the risk of salicylates poisoning, a warning regarding concomitant salicylates intake is also considered as relevant. It is concluded that the product information of products containing cetalkonium / choline salicylate 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 cetalkonium / choline salicylate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cetalkonium / choline salicylate 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 4.4

[…]

This product contains salicylate and should not be used with aspirin or other salicylates except under the direction of a physician or dentist.

This product should be used with caution in patients with an active or recurring peptic ulceration.

[…]

- Section 4.6

[…] **Pregnancy**

There are no clinical data from the use of [product name] during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic [product name] exposure reached after buccal administration can be harmful to an embryo/fetus.

During the first and second trimester of pregnancy, [product name] should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including [product name] 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. Therefore, [product name] should not be used during the last trimester of pregnancy.

[…]

Package Leaflet

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

Warning and precautions

[…]

This product contains salicylates. Talk to your doctor, dentist or pharmacist before taking this product with aspirin or other salicylates.

Talk to your doctor or dentist if you have an active or recurring stomach ulcer.

[…]

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.

Oral forms (e.g. tablets) of similar medicines can cause adverse effects in your unborn baby. It is not known if the same risk applies to [product name].

You should not use [product name] if you are in the last 3 months of pregnancy. You should not use [product name] during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, 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:	March 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 May 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 July 2026