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 allergen for therapy: Ambrosia Artemisiifolia (302) (sublingual use, products authorised via decentralised procedure), the scientific conclusions are as follows:

In view of available data on the risk of 'Oral mucosal discolouration' from the literature, spontaneous reports including in 9 cases a positive de-challenge and in 3 cases a positive re-challenge, the PRAC considers a causal relationship between allergen extract of Ambrosia Artemisiifolia (sublingual use) and 'Oral mucosal discolouration' is at least a reasonable possibility. The PRAC concluded that the product information of products containing the active substance allergen extract of Ambrosia Artemisiifolia 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 allergen for therapy: Ambrosia Artemisiifolia (302) (sublingual use, products authorised via decentralised procedure) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing allergen for therapy: Ambrosia Artemisiifolia (302) (sublingual use, products authorised via decentralised procedure) 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 **<u>underlined and in bold</u>**, deleted text ~~strike through~~)

Summary of Product Characteristics

- Section 4.8

The following adverse reaction should be added under the SOC name '*Gastrointestinal disorders*' with a frequency *not known*:

<u>Oral mucosal discolouration</u>

Package Leaflet

Section 4. Possible side effects

Subsection *Possible other side effects*:

<u>Not known (frequency cannot be estimated from the available data)</u>

- **<u>Changes in the colour of the lining of the mouth</u>**

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	December 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	26 January 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 March 2025