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 phenylpropanolamine, the scientific conclusions are as follows:

In view of available data on palpitations from spontaneous reports, including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between phenylpropanolamine and palpitations is at least a reasonable possibility. Therefore, the PRAC concluded that the product information (PI) of products containing phenylpropanolamine 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 phenylpropanolamine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing phenylpropanolamine 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(s) should be added under the SOC Cardiac disorders with a frequency Not known:

Cardiac disorders

Not known: ***palpitations***

Package Leaflet

- Section 4

Not known: frequency cannot be estimated from the available data

a forceful heartbeat that may be rapid or irregular (palpitations)

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	16 March 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	15 May 2025