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 prazepam, the scientific conclusions are as follows:

In view of available data on the risk of falls in elderly patients from the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between prazepam and falls in elderly patients is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing prazepam 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 prazepam the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing prazepam 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 4.4

A warning should be added as follows:

<u>Elderly patients:</u>

<u>Prazepam should be used with caution in elderly due to the risk of sedation and/or musculoskeletal weakness that can increase the risk of falls. Elderly patients should be given a reduced dose (see section 4.2).</u>

Package Leaflet

- Section 2 – Warnings and precautions

<u>Elderly patients:</u>

Talk to your doctor or pharmacist before taking <PRODUCT NAME> if you:

<u>are over 65. Some elderly patients can feel dizzy, drowsy, or experience muscle weakness after taking <product name>, and may be in danger of falling.</u>

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	05 January 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 February 2026