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 clotiazepam, the scientific conclusions are as follows:

In view of available data on the risk of fall in elderly from the literature and a plausible mechanism of action, the PRAC considers that a causal relationship between clotiazepam and fall in elderly is at least a reasonable possibility. Therefore, the PRAC concluded that the product information of products containing clotiazepam should be amended accordingly, in section 4.4 of the SmPC to add a warning on the risk of fall in elderly. The Package leaflet should also be updated accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for clotiazepam the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing clotiazepam is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing clotiazepam are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

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

A warning should be added as follows:

Elderly patients:

Clotiazepam should be used with caution in elderly due to the risk of sedation and/or musculoskeletal weakness that can increase the risk of falls, with serious consequences in this population. Elderly patients should be given a reduced dose (see section 4.2).

Package Leaflet

- Section 2

Warnings and precautions

Elderly patients:

Talk to your doctor or pharmacist before taking >PRODUCT NAME< if you:
are over 65. This is due to the increased sensitivity to adverse reactions in the elderly such as drowsiness, dizziness and muscle weakness. There is also an increased risk of falling that may result in serious injury.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	January 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	14 March 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	13 May 2021