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 lorazepam, the scientific conclusions are as follows:

Based on the published scientific literature an association between lorazepam and fall in elderly cannot be excluded. Drowsiness, fatigue, dizziness and muscular weakness are well-known side effect of lorazepam treatment according to the current SmPCs (section 4.8.) and thereby support the potential mechanism that may explain the increased risk of fall in elderly. In addition, in elderly patients a dose reduction is already recommended in section 4.2 and therefore in some cases may be possible that a too high dosing of lorazepam was involved.

Based on the above the PRAC considers relevant to amend the product information by adding a warning in section 4.4 on the increased risk of falls in elderly with a cross reference to dose reduction already included in section 4.2.

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 lorazepam the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing lorazepam 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 lorazepam 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 products

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 4.2

The following text should be included in section 4.2:

[Elderly and debilitated patients

For elderly and debilitated patients reduce the initial dose by approximately 50% and adjust the dosage as needed and tolerated.] **(see section 4.4 Special warnings and precautions for use)**

- Section 4.4

The following text should be included in section 4.4:

Elderly patients

Lorazepam 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 Posology).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	1 December 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30 January 2019