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 lisdexamfetamine, the scientific conclusions are as follows:

In view of available data on syncope from clinical trials and 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 lisdexamfetamine and syncope is at least a reasonable possibility. The PRAC concluded that the product information of products containing lisdexamfetamine should be amended accordingly. This applies for all approved products containing lisdexamfetamine, and across age ranges.

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 lisdexamfetamine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing lisdexamfetamine 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 lisdexamfetamine 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 **<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 *Nervous system disorders* with a frequency uncommon

<u>Syncope</u>

Package Leaflet

The following side effect should be added under section 4. Possible side effects with a frequency uncommon:

<u>Fainting</u>

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	10/2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	29/11/2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	20/01/2021