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 methylphenidate, the scientific conclusions are as follows:

In view of available data on epistaxis from spontaneous reports, including close temporal relationship, positive de-challenge and re-challenge, and the mechanistic plausibility, PRAC considered a causal relationships between methylphenidate and epistaxis is at least a reasonable possibility. PRAC concluded that the product information of products containing methylphenidate should be amended accordingly.

The CMDh agrees with the scientific conclusions made by PRAC.

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

On the basis of the scientific conclusions for methylphenidate the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing methylphenidate 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 methylphenidate 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 4.8

The following adverse reaction should be added under the SOC '*Respiratory, thoracic and mediastinal disorders*' with a frequency of '***not known'***:

Epistaxis

Package Leaflet

- Section 4. Possible side effects

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

Not known (frequency cannot be estimated from the available data)

…

Nosebleed

…

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	7 August 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	6 October 2022