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.

Based on positive de-challenge and re-challenge, the review of spontaneous reports cumulatively received by the MAHs, together with the analysis of published articles, revealed a causal association between “Dysphemia” and methylphenidate/dexmethylphenidate. Therefore, the ADR “Dysphemia” should be included in the product information, as observed from spontaneous reports and literature, with frequency *unknown*.

Furthermore, a footnote to the already labelled ADRs “Bruxism” (frequency: *common*) and “Trismus” (frequency: *not known*) should be included in the Summary of Product Characteristics to clarify how the frequency has been calculated.

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 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

For the following adverse reaction already labelled under the SOC “Psychiatric disorders” with a frequency “common” a footnote should be added:

“Bruxism*”

Wording for the footnote:

* Based on the frequency calculated in adult ADHD studies (no cases were reported in the paediatric studies

For the following adverse reaction already labelled under the SOC “Musculoskeletal and connective tissue disorders” with a frequency “not known” a footnote should be added:

“Trismus*”

Wording for the footnote:

* Based on the frequency calculated in adult ADHD studies (no cases were reported in the paediatric studies

The following adverse reaction should be added under the SOC “neurological disorder” with frequency unknown:
“Dysphemia”.

Package Leaflet

All MPH products:

- 4. Possible side effects

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

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	May 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	13 July 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 September 2020