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 from clinical trial(s), the literature, spontaneous reports, 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 methylphenidate and obsessive-compulsive disorder (including trichotillomania and dermatillomania) is at least a reasonable possibility. The PRAC concluded that the product information of products containing methylphenidate should be amended accordingly.

In view of available data from clinical trial(s), the literature, spontaneous reports, a close temporal relationship and a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action at least for increased intraocular pressure (IOP), the PRAC considers a causal relationship between methylphenidate and increased intraocular pressure and glaucoma is at least a reasonable possibility. The PRAC concluded that the product information of products containing methylphenidate should be amended accordingly.

In view of available data on dry eye from clinical trial(s), the literature, spontaneous reports, a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between methylphenidate and 'dry eye' is at least a reasonable possibility. The PRAC concluded that the product information of products containing methylphenidate should be amended accordingly

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

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 recommends that the terms of the marketing authorisation(s) should be varied.

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:
Increased intraocular pressure and glaucoma

There have been reports of increased intraocular pressure (IOP) and glaucoma (including open angle glaucoma and angle closure glaucoma) associated with methylphenidate treatment (see section 4.8). Patients should be advised to contact their doctor in case of experiencing symptoms suggestive of increased IOP and glaucoma. An ophthalmologist should be consulted and discontinuation of methylphenidate be considered if IOP increases (see section 4.3). Ophthalmologic monitoring of patients with a history of increased IOP is recommended.

- Section 4.8

The following adverse reaction(s) should be added under the SOC 'Eye disorders' with a frequency **not known'**:

- **Increased intraocular pressure,**
- **Glaucoma**

The following adverse reaction(s) should be added under the SOC 'Eye disorders' with a frequency '**uncommon**' along with the corresponding footnote "**Frequency derived from adult clinical trials and not on data from trials in children and adolescents; may also be relevant for children and adolescents**":

Dry eye

- Section 4.8

The following adverse reaction(s) should be added under the SOC Psychiatric disorders with a frequency **rare,** and previous below ADRs deleted**:**

Obsessive-compulsive disorder (including trichotillomania and dermatillomania)

Delete:

~~**Repetitive behaviours, Over focussing (very rare)**~~

Package Leaflet

- Section 2

Warnings and precautions under "Check with your doctor or pharmacist before taking <Tradename> if you or your child:"

- **If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of <product name>.**

Section 4

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

Frequency not known:

- **increased pressure in the eye**
- **eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)**

Frequency uncommon:

- **Dry eye**

- Section 4

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

Frequency rare:

Obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

Delete:

Frequency very rare:

abnormal thinking, lack of feeling or emotion~~, **doing things over and over again, being obsessed with one thing**~~

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	June 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	3 August 2025
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	2 October 2025