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 selegiline, the scientific conclusions are as follows:

In view of available published data on the risk associated with drug-drug interaction with serotonin agonists from literature and in view of a plausible mechanism of action, the PRAC considers a causal relationship is at least a reasonable possibility. The PRAC concluded that the product information of products containing selegiline should be amended accordingly.

In view of available data on impulse control disorders and compulsions from the literature including in some cases a close temporal relationship and a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between selegiline and impulse control disorders and compulsions is at least a reasonable possibility. The PRAC concluded that the product information of products containing selegiline 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 selegiline the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing selegiline 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 4.5

The following drug-drug interaction should be added:

Serotonin agonists

Selegiline should not be used in combination with serotonin agonists (e.g. sumatriptan, naratriptan, zolmitriptan, rizatriptan, lasmiditan) due to the risk of severe interactions (potentially leading to serotonin syndrome).

- Section 4.8

The following adverse reaction(s) should be added resp. deleted under the SOC Psychiatric disorders with a frequency not known:

Impulse control disorders and compulsions*

Delete:

~~Hypersexuality~~

To be added under the table of adverse reactions:

***Impulse control disorders and compulsions: pathological gambling, hypersexuality, compulsive spending or buying, binge eating and compulsive eating.**

Package Leaflet

- Section 2

Tell your doctor or pharmacist if you are taking, have recently taken or might take use any other medicines

medicines used to treat migraine attacks (e.g. sumatriptan, naratriptan, zolmitriptan, rizatriptan, lasmiditan)

- Section 4

Frequency not known:

Problems controlling impulses and compulsive behaviours (such as compulsive shopping, gambling, eating, or sexual behaviour)

Delete:

Frequency not known:

~~Hypersexuality~~

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2025 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	05 January 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 February 2026