

**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 ropinirole, the scientific conclusions are as follows:

In view of available data reporting cases of aggressive behaviour and violent behaviour (towards humans and animals) and in order to better inform healthcare professionals and patients about the various possible manifestations of impulse control disorders (ICDs), the PRAC recommends that aggressive behaviours, which are already listed as “aggression” in section 4.8 of the summary of product characteristics, should be reflected in the warning on ICDs in ropinirole’s product information. Furthermore, for section 4.8 “aggression” should be included in the list of possible ICDs manifestations, although aggression has also been associated with psychotic reactions.

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 ropinirole the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ropinirole 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 amended as follows:

#### Impulse control disorders

Patients should be regularly monitored for the development of impulse control disorders. Patients and carers should be made aware that behavioural symptoms of impulse control disorders including pathological gambling, increased libido, hypersexuality, **aggressive behaviours**, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists including ropinirole. Dose reduction/tapered discontinuation should be considered if such symptoms develop.

- Section 4.8

An adverse reaction should be amended as follows, under the SOC *Psychiatric disorders*:

Impulse control disorders: pathological gambling, increased libido, hypersexuality, **aggression**, compulsive spending or buying, binge eating and compulsive eating can occur in patients treated with dopamine agonists including ropinirole (see section 4.4.).

### Package Leaflet

- Section 2

A warning should be amended as follows:

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings, **or aggressive behaviours**. Your doctor may need to adjust or stop your dose.

**Annex III**

**Timetable for the implementation of this position**

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Adoption of CMDh position:	February 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 April 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	11 June 2026