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:

Based on evidence from the scientific literature, the PRAC considers that further characterization of dopamine agonist withdrawal syndrome (DAWS) by inclusion of information regarding its' risk factors is deemed necessary. The PRAC concluded that the product information of products containing ropinirole should be amended accordingly.

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 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 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 ropiniroleare 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 4.4

~~Dopamine agonist withdrawal syndrome~~

~~To discontinue treatment in patients with Parkinson's disease, ropinirole should be tapered off (see section 4.2). Non-motor adverse effects may occur when tapering or discontinuing dopamine agonists including ropinirole. Symptoms include apathy, anxiety, depression, fatigue, sweating and pain which may be severe. Patients should be informed about this before tapering the dopamine agonist, and monitored regularly thereafter. In case of persistent symptoms, it may be necessary to increase the ropinirole dose temporarily (see section 4.8).~~

Dopamine agonist withdrawal syndrome (DAWS)

DAWS has been reported with dopamine agonists, including ropinirole (see section 4.8). To discontinue treatment in patients with Parkinson's disease, ropinirole should be tapered off (see section 4.2). Limited data suggests that patients with impulse control disorders and those receiving high daily dose and/or high cumulative doses of dopamine agonists may be at higher risk for developing DAWS. Withdrawal symptoms may include apathy, anxiety, depression, fatigue, sweating and pain and do not respond to levodopa. Prior to tapering off and discontinuing ropinirole, patients should be informed about potential withdrawal symptoms. Patients should be closely monitored during tapering and discontinuation. In case of severe and/or persistent withdrawal symptoms, temporary re-administration of ropinirole at the lowest effective dose may be considered.

Package Leaflet

Section 2 - What you need to know before you take [TRADENAME]

Warnings and precautions

Tell your doctor if you experience symptoms such as depression, apathy, anxiety, fatigue, sweating or pain after stopping or reducing your ropinirole treatment **(called dopamine agonist withdrawal syndrome or DAWS)**. If the problems persist more than a few weeks, your doctor may need to adjust your treatment.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	March 2020 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	10 May 2020
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	9 July 2020