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 carbidopa / levodopa, the scientific conclusions are as follows:

Due to the high number of reports, several literature publications in the reporting interval and cumulatively, which suggest that patients under levodopa/carbidopa intestinal gel (LCIG) should be monitored during LCIG treatment in order to detect early a possible neuropathy, section 4.4 of the SmPC should be updated to add a warning on polyneuropathy, which is already listed as an adverse drug reaction in section 4.8. The Package leaflet should be updated 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 carbidopa / levodopa the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing carbidopa / levodopa 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 carbidopa / levodopa 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 4.4

A warning should be added as follows:

Polyneuropathy has been reported in patients treated with levodopa/carbidopa intestinal gel. Before starting therapy evaluate patients for history or signs of polyneuropathy and known risk factors, and periodically thereafter.

Package Leaflet

- 2. What you need to know before you use Duodopa

Warnings and precautions

Progressive weakness, pain, numbness or loss of sensation in the fingers or feet (polyneuropathy) have been reported in patients treated with levodopa/carbidopa intestinal gel. Your doctor will check for the signs and symptoms of neuropathy before you start levodopa/carbidopa intestinal gel and periodically thereafter. Tell your doctor if you already have neuropathy or medical condition that is associated with neuropathy.

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