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 cabergoline the scientific conclusions are as follows:

A cumulative search of the MAH's safety database for all cabergoline cases with indication of lactation identified cases of cardiac disorders, vascular disorders, posterior reversible encephalopathy syndrome and central nervous system vascular disorder.
Furthermore, a literature review identified case series of psychiatric disorders. In a few cases, psychotic symptoms occurred following administration of cabergoline for lactation suppression.
Therefore, PRAC considered that a causal relationship between cardiovascular, neurologic and psychiatric disorders in post-partum women treated with cabergoline for the inhibition of lactation and cabergoline cannot be excluded and recommends the addition of a warning in section 4.4 of the SmPC.
In addition, PRAC made a recommendation to evaluate promptly the patient if hypertension, suggestive chest pain, severe, progressive, or unremitting headache (with or without visual disturbance) or evidence of central nervous system toxicity develops. The patient leaflet is 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 cabergoline the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing cabergoline 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 cabergoline 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 Special warnings and precautions for use:

Serious adverse events including hypertension, myocardial infarction, seizures, stroke or psychiatric disorders have been reported in postpartum women treated with cabergoline for inhibition of lactation. In some patients the development of seizures or stroke was preceded by severe headache and/or transient visual disturbances. Blood pressure should be carefully monitored during the treatment. If hypertension, suggestive chest pain, severe, progressive, or unremitting headache (with or without visual disturbances), or evidence of central nervous system toxicity develop, cabergoline should be discontinued and the patient evaluated promptly.

Package Leaflet

Warnings and precautions
Tell your doctor immediately if you notice or someone notices in you:

If you have just given birth you may be more at risk of certain conditions. These may include high blood pressure, heart attack, convulsion, stroke or mental health problems. Therefore, your doctor will need to check your blood pressure regularly during the treatment. Speak immediately to your doctor if you experience high blood pressure, chest pain or unusually severe or persistent headache (with or without vision problems).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October 2019 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	01/12/2019
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30/01/2020