Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Based on the review of the medically confirmed case reports of meningioma during the reporting period, the PRAC considers that sections 4.3, 4.4 and 4.8 of the summary of product characteristics should be updated. The package leaflet is updated accordingly.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for nomegestrol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing nomegestrol 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 nomegestrol 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 4.3

The sentence should be added as follows:

presence or history of meningiomas

- **Section 4.4**

A warning should be added as follows:

Meningioma

The occurrence of meningioma (single and multiple) have been reported with prolonged use (several years) of nomegestrol tablet at doses of 3.75 or 5 mg daily and higher. If a meningioma is diagnosed in a patient treated with nomegestrol, treatment should be stopped (see section 4.3).

Section 4.8

The following adverse reaction: **meningioma** should be added under the SOC Neoplasms benign, malignant and unspecified with a frequency **very rare.**

Package Leaflet

Section 2:

A wording should be added as follows:

Do not take nomegestrol

- in case of presence or history of meningioma (generally benign tumour of the tissue located between the brain and the skull). In case of doubt contact your doctor.

Meningiomas

Cases of meningioma (generally benign tumours of the brain) have been reported with nomegestrol (see section 4 "Possible side effects"). If a meningioma is diagnosed, treatment with nomegestrol should be stopped.

Section 4

Cases of meningioma have been reported with prolonged use (several years) of nomegestrol at doses of 3.75 or 5 mg daily and higher (see section Do not take nomegestrol).

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	October, 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	1 December 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30 January 2019