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 promestriene (cream and vaginal capsules), the scientific conclusions are as follows:

There were respectively 5 cases of 'haemorrhage and injury' during the reporting period and 77 cases cumulatively. Based on the information presented in this PSUR, the PRAC considered that section 4.8 of the summary of product characteristics of promestriene (cream and vaginal capsules) should be amended to add vaginal bleeding. The Package 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 promestriene (cream and vaginal capsules) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing promestriene (cream and vaginal capsules) 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 promestriene (cream and vaginal capsules) 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 4.8

The following adverse reaction should be added under the System Organ Class (SOC) Reproductive system and breast disorders with a frequency “not known”:

Vaginal bleeding

Patient leaflet

- Section 4

Vaginal bleeding

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	November 2017 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	23 December 2017
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	21 February 2018