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 ethinylestradiol / etonogestrel, the scientific conclusions are as follows:

In view of the available data from clinical trials and considering the established causal relationship between ethinylestradiol/etonogestrel and urticaria, the PRAC considers that the current frequency "not known" should be amended to "uncommon". The PRAC concluded that the product information of products containing ethinylestradiol/etonogestrel 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 ethinylestradiol / etonogestrel the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ethinylestradiol / etonogestrel 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 ethinylestradiol / etonogestrel 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 frequency of the adverse reaction urticaria should be changed to:

~~Not known~~ **Uncommon**: Urticaria

Package Leaflet

Section 4: possible side effects

The following adverse reaction should be added:

Uncommon: Hives

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	February 2021 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	12 April 2021
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	10 June 2021