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 etonogestrel, the scientific conclusions are as follows:

In view of available data from spontaneous reports including in some cases a close temporal relationship, the PRAC considers a causal relationship between insertion of etonogestrel implant and vasovagal reactions is at least a reasonable possibility. The PRAC concluded that the product information of etonogestrel-containing implants should be amended accordingly.

Update of section 4.8 of the SmPC to add the adverse reaction vasovagal reactions with implant insertion. 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 etonogestrel the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing 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 etonogestrel are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that 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

4.8 Undesirable effects

During post marketing surveillance, a clinically relevant rise in blood pressure has been observed in rare cases. Seborrhoea has also been reported. Anaphylactic reactions, urticaria, angioedema, aggravation of angioedema and/or aggravation of hereditary angioedema may occur.

The following undesirable effects have been reported in connection with the insertion or removal procedure of the implant:

Insertion or removal of the implant may cause bruising, including haematoma in some cases, slight local irritation, pain or itching.

Insertion of the implant may cause vasovagal reactions (such as hypotension, dizziness, or syncope).

Package Leaflet

4. Possible side effects [...]

During the insertion or removal of Implanon NXT, bruising (severe in some cases), pain, swelling, or itching may occur and, in rare cases, infection. A scar may be formed, or an abscess may develop at the implantation site.

Due to insertion of the implant you might feel faint.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	April 2022 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	06 June 2022
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	05 August 2022