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 levonorgestrel, the scientific conclusions are as follows:

Levonorgestrel tablets for emergency contraception:

During the reporting period, out of 880 cases (with n=844 valid cases) with n=2052 adverse events (AEs) related to medication errors (Postinor) from one marketing authorisation holder (MAH), n=646 medication error related AEs describe an "inappropriate schedule of drug administration". It is agreed with the MAH that the reported AEs are in line with the known safety profile of levonorgestrel used as emergency contraception (LNG-EC), and the most frequently reported AEs are listed in the product information. In addition, the PRAC noted that other medicinal products indicated for emergency contraception authorised in the EU (and OTC/pharmacy-only in several countries) have a longer time frame of usage of 120 hours after unprotected sexual intercourse.

In view of the above and in order to minimise the risk of any confusion regarding the schedule of administration of levonorgestrel as emergency contraceptive, the PRAC recommends that further emphasis is given in the package leaflet on the appropriate schedule of drug administration, with the implementation of a black box including the warning that this medicinal product needs to be used within a short time frame of 72 hours after unprotected sexual intercourse.

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 levonorgestrel the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing levonorgestrel 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 levonorgestrel 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~~)

Package Leaflet

Levonorgestrel tablets for emergency contraception:

Section 3 How to take <Product Name>

Take the tablet as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected sex. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex. It can only prevent you becoming pregnant, if you take it within 72 hours of unprotected sex.

Annex III

Timetable for the implementation of this position

Timetable for the implementation of this position

Adoption of CMDh position:	September 2018 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	03 November 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	02 January 2019