The CMDh recommendation mentioned below is based on the WHO’s Medical Eligibility Criteria for Contraceptive use (MEC) editions 2004 and 2009. In this guidance document, the WHO concludes that there is “intermediate level” evidence that the contraceptive effectiveness of combined oral contraceptives (COC’s) is not affected by co-administration of most broad spectrum antibiotics. This conclusion is based on the WHO assessment report “Hormonal contraceptive use in women taking antibiotics”.

In procedure NL/H/xxxx/WS/063 the interaction COC’s and broad spectrum antibiotics has been deleted from section 4.5 of the SmPCs of the products involved in this variation. Although several other changes were also made to section 4.5 in this variation, the purpose of publication of this PAR is to focus on the deletion of the interaction between COC’s and broad spectrum antibiotics.

All marketing authorisation holders of products with an ATC code present in the Excel sheet attached to this cover note are recommended to adapt the product information accordingly, and to delete the interaction between COC’s and broad spectrum antibiotics from the product information.

The change should be implemented within 1 year following publication of the PAR, either in the course of another regulatory procedure, e.g. renewal or as part of a (grouped) variation application of type IB or type II of the “C” category of the Classification Guideline affecting the product information, or through a separate variation under C.I.z (Type IAIN if no further assessment needed, type IB if minor assessment needed).