Annex IV

Conditions to the marketing authorisations

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National Competent Authorities of Member States or Reference Member States, if applicable, shall ensure that the following conditions are fulfilled by the MAHs:

Conditions	**Date**
For chlormadinone-containing combined hormonal contraceptives The MAHs for chlormadinone containing CHCs should carry out a post-authorisation safety study to compare the risk of VTE with chlormadinone/ethinyestradiol versus levonorgestrel/ethinyestradiol. The protocol of this study should be submitted to the PRAC within 6 months after notification of the EC Decision. The final study report should be submitted by:	End of December 2018