Annex IV

Conditions to the marketing authorisations

The marketing authorisation holders shall complete the below conditions, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

Conditions	**Date**
<u>Low dose nomegestrol acetate (2.5 mg)- or low dose chlormadinone acetate (1-2 mg)-containing products</u> For low dose NOMAC or CMA-containing products each MAH should implement a targeted follow-up questionnaires (if not yet established) containing the agreed key elements to further characterise the important potential risk of meningioma.	From the date of notification of the Commission Decision
<u>All nomegestrol acetate- or chlormadinone acetate-containing products</u> Each MAH should operate a risk management system to be described in a risk management plan (RMP) (if an RMP is already in place) which shall be submitted to the relevant National Competent Authorities for assessment. The RMP should reflect the agreed additional risk minimisation measures to address the important identified/potential risk of meningioma.	Within 6 months after Commission Decision