

## **Annex IV**

### ***Condition of the marketing authorisations***

***Condition considered essential for the safe and effective use of the medicinal product including pharmacovigilance***

The National Competent Authorities coordinated by the Reference Member State, shall ensure that the following conditions are fulfilled by the MAH:

1. a prospective observational study aimed to evaluate the prescription recommendations of Mifepristone Linepharma for early pregnancy termination mentioned in the opinion should be performed. The submission of a revised protocol should take place within 10 days after the Commission Decision.