Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisation(s)

The marketing authorisation holders (MAHs) shall complete the condition(s) below, within the stated timeframe, and the Competent Authorities shall ensure that the following is fulfilled:

<u>Medicinal products containing finasteride 1 mg for oral use:</u> The MAHs of medicinal products containing finasteride 1 mg for oral use should operate a risk management system to be described in a risk management plan (RMP) which shall be submitted to the relevant competent authorities. The MAHs should update their RMP or implement a new one to reflect the agreed patient card as an additional risk minimisation measure to address the important identified risks of suicidal ideation and sexual dysfunction.	Within 6 months from the Commission Decision.