ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

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The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The MAH shall ensure that all eye surgeons in the EU Countries in which silodosin will be marketed are provided with the following information:

- the Direct Healthcare Professional Communication (DHPC) on the association of Silodosin with Intraoperative Floppy Iris Syndrome and the two literature references mentioned in the text of the communication (at launch);
- a flow-chart describing the management of patients for which cataract surgery is scheduled (at launch and after launch);
- an educational program on the prevention and management of IFIS (at launch and after launch); covering the following topics:

    1. clinically relevant literature references on the prevention and management of IFIS;
    2. pre-operative assessment: eye surgeons and ophthalmic teams should establish whether patients scheduled for cataract surgery are being or have been treated with silodosin in order to ensure that appropriate measures are in place to manage IFIS during surgery.
    3. recommendation to surgeons and ophthalmic teams: discontinuing treatment with α1-adrenoceptor antagonists 2 weeks prior to cataract surgery has been recommended, but the benefit and duration of stopping therapy prior to cataract surgery has not yet been established.