**ANNEX**

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

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

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 agree the details of an educational programme with the National Competent Authorities and must implement such programme nationally to ensure that, prior to prescribing, all physicians are provided with a healthcare professional information pack containing the following:

- Educational material
- Summary of Product Characteristics (SPC) and Package Leaflet and Labelling

**Key elements to be included in the educational material**

- Posology
- Instructions for administration
- Information on gel depot formation and possible injections site reactions
- Information on the identified and potential risks.