ANNEX

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

The EU Member States shall ensure that:

The Marketing Authorisation Holder (MAH) shall ensure that updated physician information packs are provided to all ophthalmology clinics where Lucentis is expected to be used. The physician information pack should contain the following:

- Physician information
- Intravitreal injection procedure video
- Intravitreal injection procedure pictogram
- Patient information packs

The physician information should contain the following key elements:

- The Summary of Product Characteristics
- Sterile techniques, including periocular and ocular disinfection, to minimise risk of infection
- Use of antibiotics
- Use of povidone iodine or equivalent
- Techniques for the intravitreal injection
- Key signs and symptoms of IVT injection related adverse events
- Management of IVT injection related adverse events

The patient information pack should be provided in the form of both patient information booklets and audio-CD that contain following key elements:

- Patient information leaflet
- How to prepare for Lucentis treatment
- What are the steps following treatment with Lucentis
- Key signs and symptoms of serious adverse events
- When to seek urgent attention from the health care provider