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 THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

➢ The Member States must ensure that the education plans for physicians, health care providers, and patients contain the measures a) to m) as detailed below, and are suitable for the purpose of minimising adverse events associated with the intravitreal injection procedure (e.g. endophthalmitis) prior to marketing.

- An educational plan for physicians and health care providers which is aimed at risk minimisation and to support safe and effective use for the product. This plan shall consist of measures aiming to minimise adverse events associated with the intravitreal injection procedure (e.g. endophthalmitis) through adequate education about:

a) The intravitreal procedure as it was performed in the pivotal clinical studies
b) Sterile techniques to minimize risk of infection
c) Use of antibiotics
d) Use of povidone iodine
e) Performing lid scrubs
f) Use of anesthetic to ensure patient comfort
g) Techniques for the intravitreal injection
h) Management of intraocular pressure (IOP)
i) Management of endophthalmitis
j) Understanding the risk factors involved in developing endophthalmitis
k) Reporting of serious adverse events

- An educational plan for patients which is aimed at risk minimisation and to support safe and effective use for the product. This plan shall consist of measures to provide adequate education on:

l) Key signs and symptoms of serious adverse events associated with the intravitreal injection procedure
m) When to seek urgent attention from the health care provider