

ANNEX

**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 should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented.

The Member States shall agree the final educational material with the Marketing Authorisation Holder (MAH) prior to launch of the new indication in their territory.

The Member States shall ensure that the provision of educational material implemented for the authorised indication of treatment of adult patients with macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO), is extended to the potential prescribers concerned by the new indication: treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis. The educational material contains the following:

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

The physician information should contain the following key elements:

- The Summary of Product Characteristics
- Aseptic techniques to minimise the risk of infection
- Use of antibiotics
- Techniques for the intravitreal injection
- Patient monitoring after IVT injection
- Key signs and symptoms of IVT injection related adverse events including increased intraocular pressure, glaucoma, ocular hypertension, cataract, traumatic cataract related to injection technique, vitreous detachment, vitreous haemorrhage, endophthalmitis, retinal detachment, retinal tear, mechanical failure of device and implant misplacement
- Management of IVT injection related adverse events

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

- Patient information leaflet
- How to prepare for Ozurdex treatment
- What are the steps following treatment with Ozurdex
- Key signs and symptoms of serious adverse events including increased intraocular pressure and ocular hypertension
- When to seek urgent attention from their health care provider