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 National Competent Authorities shall agree the details of an education programme for surgeons with the MAH, who must implement such programme nationally to ensure that:

Prior to use of the product, surgeons should be provided with educational material containing:

- a copy of the SPC
- a detailed description of:
  - the recommended methods for reconstitution of the product prior to implantation
  - the preparation of the selected paraspinal site where the intended implantation will occur
  - the recommended manner of placement of the material together with some comments on the importance of local haemostasis
  - the methods for soft tissue closure around the implant. These descriptive texts are included in the product information.
- Information about:
  - Hypersensitivity and antibody formation
  - Embryo-foetotoxicity and the need for women with childbearing potential to use effective contraception for 2 years following implant
  - the risks of ectopic bone formation
  - interaction with bone void fillers
  - that the product should only be used once
- details of the post marketing surveillance studies including information on how to enroll patients

In addition, prior to use, surgeons intending to use Opgenra should receive a Training DVD containing animated images of an operation on a patient and including the following information:

- Product description
- Placement in sterile field
- Wound opening (soft and hard tissues)
- Reconstitution of product
- Implant field preparation (haemostasis)
- Administration (implantation)
- Containment of implanted materials (soft tissues)
- Instrumentation
- Wound closure (drainage)
- Follow-up measures