**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 Marketing Authorisation Holder (MAH) shall ensure that the medicinal product will be distributed only to Healthcare Establishments that meet criteria described in the Risk Management Plan.

The Marketing Authorisation Holder (MAH) shall ensure, prior to the distribution of the product to a particular Healthcare Establishment, that all surgeons and other healthcare professionals involved in the handling and administration of ChondroCelect or its components, as well as those involved in follow-up of patients treated with ChondroCelect in the Healthcare Establishment, receive training as per the educational programme described in the Risk Management Plan.

The educational programme for healthcare professionals contains the following components:

- Training material for Surgeons
- Training material for other Healthcare Professionals
- Informed consent for the patients to be signed prior to the treatment with ChondroCelect

The training materials for Surgeons shall include the following key messages and components:

- Summary of Product Characteristics
- The biopsy harvest procedure
- The surgical checklist to be completed at the operating theatre immediately prior to the first incision confirming the right patient, the right product, the right side of the implantation, and the type of biological membrane and fibrin sealant to be used in the procedure.
- The implantation procedure by knee-joint arthrotomy
- The follow-up protocol

The training material for other Healthcare Professionals shall include the following key messages and components:

- Summary of Product Characteristics
- The need for screening of donors using patient questionnaire and laboratory tests for hepatitis C, hepatitis B, HIV, and Syphilis
- The handling of the biopsy harvest
- The handling of ChondroCelect and its preparation for the implantation
- The schedule of follow-up of patients
- The recommended physiotherapy