

**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 shall 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, at launch, all physicians who are expected to prescribe/use NovoSeven are provided with an Educational pack containing the following:

- Physician information pack
- Patient information pack

Both information packs are to be used as part of an educational plan provided to minimise risk of medication errors that may be associated with the change in concentration of the new NovoSeven formulation.

The physician information pack should contain the following:

- Summary leaflet of the product features and reconstitution guide, including highlighted changes that have been made for the new formulation of NovoSeven.
- Educational slide kit
- Dosing reference card
- Question & Answer booklet
- Patient information pack
- Letter to healthcare professionals

The physician information should contain the following key elements:

- Clear demarcation of the new formulation of NovoSeven from original NovoSeven, with clear descriptions of any differences in the vial sizes, colour codes and dosing and reconstitution instructions
- Clear information about their difference in concentration.
- Information about the potential safety risks of errors in dosing calculation resulting from the confusion between the two formulations and its possible clinical consequences (e.g. potential for thrombotic risk if overdose).
- Encouragement to report medications errors and their causes and consequences.

The patient information pack to be used by healthcare professionals in the education of the patients should contain the same above described key elements.

The Marketing Authorisation Holder must implement this educational plan nationally, prior to marketing, and as agreed with the competent authorities in the Member States.