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 must ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented in their national territory:

- Prior to launch of the new indication of the product in the Member State, the national competent authority shall agree the content and format of the educational material with the Marketing Authorisation Holder

- The Marketing Authorisation Holder (MAH) should ensure that, at launch of the new indication, all Healthcare Professionals who are expected to use and/or prescribe INOmax as part of the treatment of peri- or post- operative pulmonary hypertension in adults and children in conjunction to heart surgery are provided with an Educational pack.

The educational pack should contain the following:

- Summary of Product Characteristics and Patient Information Leaflet for INOmax

- Educational material for Healthcare Professionals

The educational material should be a pocket size guide that includes information on the following key elements:

- The risk of rebound effect and the precautions to take when discontinuing the treatment
- The risk of abrupt discontinuation of Inomax therapy in the event of critical failure of the delivery system and how to prevent it
- The monitoring of Methaemoglobin level
- The monitoring of NO_2 formation
- The potential risk of bleeding and haemostasis disorders
- The potential risks if used in combination with other vasodilators which act on cGMP or cAMP