ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

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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 agree the details of a controlled distribution system for the 20 ml vial of Revatio 0.8 mg/ml solution for injection with the National Competent Authorities and must implement such programme nationally to ensure that prior to prescribing all health care professionals who intend to prescribe and/or dispense Revatio 0.8 mg/ml solution for injection are provided the following:

- Information for Healthcare professionals
- Copy of the Summary of Product Characteristics (SPC)
- Data Capture Form (DCF) designed to facilitate reporting of events of hypotension and associated problems

The Information for Healthcare professionals should contain the following key elements:

- Information about the Pharmacovigilance Monitoring Programme regarding the potential risk of clinically relevant hypotension and related problems to be put into place with the use of the DCF.
- Information on the switch from the 50 ml vial to the 20 ml vial for Revatio 0.8 mg/ml solution

The Marketing Authorisation Holder shall agree the information for healthcare professionals, and the healthcare professionals to be targeted, with the national competent authority of each Member State prior to the launch of the 20 ml vial of Revatio 0.8 mg/ml solution for injection in that country.