Annex related to the Art. 127a

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 the 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:

1. The Member State shall agree the details of the Prescriber kit and a controlled distribution system with the Marketing Authorisation Holder (MAH) and must implement such programme nationally prior to launch to ensure that:

- Prior to prescribing (where appropriate, and in agreement with the National Competent Authority, dispensing) all healthcare professionals who intend to prescribe (and dispense) are provided with a prescriber kit containing the following:
    - Educational Health Care Professional's kit
    - Educational brochures for Patients
    - Patient cards
    - Summary of Product Characteristics (SmPC) and Package Leaflet and Labelling.