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

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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:

1. The Member State shall agree the details of a controlled distribution system with the Marketing Authorisation Holder (MAH) and must implement such programme nationally to ensure that:
   - Prior to launch, all doctors who intend to prescribe pomalidomide and all pharmacists who may dispense pomalidomide receive a Direct Healthcare Professional Communication as described below.
   - Prior to prescribing (where appropriate, and in agreement with the National Competent Authority, dispensing) all healthcare professionals who intend to prescribe (and dispense) pomalidomide are provided with a physician information pack 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.

2. The Member State shall ensure that the MAH shall implement a pregnancy prevention programme (PPP) within their territory. Details of the PPP **including the set-up of national measures to assess the effectiveness of and compliance with the PPP** should be agreed with the National Competent Authorities in each Member State and put in place prior to the marketing of the product.