ANNEX

Conditions or restrictions with regard to the safe and effective use of 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 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 should be agreed with the National Competent Authorities in each Member State and put in place prior to the marketing of the product.