

**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 States shall agree the details of a controlled access programme with the Marketing Authorisation Holder (MAH) and must implement such programme nationally to ensure that:
  - Prior to launch, all doctors who intend to prescribe Revlimid and all pharmacists who may dispense Revlimid receive a Direct Healthcare Professional Communication.
  - Prior to prescribing (where appropriate, and as agreed with the MAH, dispensing) all healthcare professionals who intend to prescribe (and dispense) Revlimid are provided with an Educational Healthcare Professional's Kit containing the following:
    - Educational Healthcare Professional brochure
    - Educational brochures for patients
    - Patient card
    - Risk awareness forms
    - Information on where to find latest Summary of Product Characteristics (SmPC)
2. The Member States shall ensure that the MAH implements a pregnancy prevention programme (PPP) within their territory. Details of the PPP should be agreed with the MAH and put in place prior to the launch of the medicinal product.
3. The Member States should agree on the local implementation of the controlled access programme.
4. The Member States should also agree with the MAH prior to the launch of the product:
  - The feasibility of collecting detailed data relating to the indication in order to monitor the off-label use within the national territory.