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 Thalidomide BMS and all pharmacists who may dispense Thalidomide BMS 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) Thalidomide BMS 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 ensure that the MAH provides the educational materials to the national patients' organisations for review or if such an organisation does not exist or cannot be involved, to a relevant patients' group. Patients involved should be preferably naïve to the history of thalidomide. Results of the user testing will have to be provided to the national competent authority and final materials validated at a national level.

5. The Member State should agree with the MAH prior to the launch of the product:
    - The most appropriate strategies to monitor the off-label use within national territory
    - The collection of detailed data to understand demographics of target population, indication and number of women of childbearing potential in order to monitor the off-label use within national territory