ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES

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:

The Member States shall agree to the final healthcare educational pack with the Marketing Authorization Holder (MAH) prior to launch of the product in their territory.

The Member States shall ensure that the MAH provides to all physicians who are expected to prescribe or use INCIVO a healthcare professional educational pack containing the following:

- The Summary of Product Characteristics
- The Patient Information Leaflet
- The Physician Leaflet

The Physician Leaflet should contain the following key elements:

- Rash and Severe Cutaneous Adverse Reactions safety data from Phases 2 and 3
- Incidence of rash and severe cutaneous reactions
- Grading and management of rash and severe cutaneous reactions, particularly with respect to criteria for the continuation or discontinuation of telaprevir and the other treatment components.
- Pictures of rash according to different grades