

**ANNEX**  
**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 ADDRESSED BY THE MEMBER STATES**

The Member States should ensure that the MAH provides an educational programme for Remicade to ensure that physicians who intend to prescribe Remicade to paediatric Crohn's disease patients are aware of:

- The risk of opportunistic infections and tuberculosis (TB) in patients treated with Remicade.
- The need to assess the risk of TB in patients prior to treating with Remicade.
- The risk of acute infusion related reactions and delayed hypersensitivity reactions.
- The risk of lymphoma and other malignancies.
- The patient alert card, which is to be given to patients using Remicade.
- That children may be at increased risk of developing infections and the need for immunisations to be up to date.