

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:

The Marketing Authorisation Holder (MAH) shall provide an educational pack covering the therapeutic indications RA and sJIA, targeting all physicians who are expected to prescribe/use RoActemra containing the following:

- Physician Information Pack
- Nurse Information Pack
- Patient Information Pack

The Member States shall discuss and agree the content and format of the educational material, together with a communication plan, with the national competent authority prior to distribution of the educational material.

The Physician Information Pack should contain the following key elements:

- The Summary of Product Characteristics
- Dose calculation (RA and sJIA patients), preparation of infusion and infusion rate
- Risk of serious infections
 - The product should not be given to patients with active or suspected infection
 - The product may lessen signs and symptoms of acute infection delaying the diagnosis
- Serious infusion reaction and their management
- Serious hypersensitivity reactions and their management
- Risk of gastrointestinal perforations especially in patients with history of diverticulitis or intestinal ulcerations
- Reporting of serious adverse drug reactions
- The Patient Information Packs (to be given to patients by healthcare professionals)
- Diagnosis of Macrophage Activation Syndrome in sJIA patients
- Recommendations for dose interruptions in sJIA patients

The Nurse Information Pack should contain the following key elements:

- Prevention of medical errors and infusion reactions
 - Preparation of infusion
 - Infusion rate
- Monitoring of the patient for infusion reactions
- Reporting of serious adverse drug reactions

The Patient Information Pack should contain the following key elements:

- Patient Information Leaflet
- Patient Alert Card
 - to address the risk of getting infections which can become serious if not treated. In addition, some previous infections may reappear.
 - to address the risk that patients using RoActemra may develop complications of diverticulitis which can become serious if not treated.