ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY 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 shall ensure that the Marketing Authorisation Holder (MAH) implement, prior to the launch, an educational programme for physicians aiming to ensure proper injection placement to minimize occurrence of injection-related adverse events and to inform on expected and potential risks associated with the treatment

The physician educational programme should contain the following key elements:

- Injection technique and dosing interval.
- Proper amount of volumes for both reconstitution and injection differences in the metocarpophalangeal (MP) and proximal interphalangeal (PIP) joints.
- Recognition and treatment of severe immune-mediated reaction, including anaphylaxis.
- Information on bleeding risk in patients with coagulation disorders including those on concurrent anti-coagulation therapy.
- Information on the potential risk of matrix metalloproteinases (MMP) cross reactivity including the development of musculoskeletal syndrome and exacerbation/initiation of autoimmune disorders.
- Reminder of the need to report adverse events, including medication errors.
- The need to inform the patient about the signs and symptoms associated with the treatment and when to seek attention from the health care provider.
- The summary of product characteristics and the patient information leaflet