ANNEX

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

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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 ensure that prior to launch of the prefilled syringe form of Stelara, all healthcare professionals who are expected to prescribe/use Stelara are provided with educational materials containing the following:

Healthcare Professional educational pack

- Patient information pack

The key messages and components included in the Healthcare Professional educational pack are defined as follows:

- Summary of Product Characteristics
- Local Guidance for tuberculosis screening;
- Risk of serious infections, including salmonella, tuberculosis, and other mycobacterial infections;
- Risk of hypersensitivity reactions, including latex allergy warning and contraindication;
- Risk of malignancies.

The key messages in the patient information pack are defined as follows:

- Patient Information Leaflet
- Risk of reactivation of latent tuberculosis and information about the screening for tuberculosis according to the local guidance;
- Risk of serious infections, including salmonella, tuberculosis, and other mycobacterial infections;
- Risk of hypersensitivity reactions, including latex allergy warning and contraindication;
- Potential risk of malignancies;
- Appropriate techniques for self administration of Stelara, including use of the prefilled syringes.