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, all physicians who are expected to prescribe/use ARCALYST are provided with a physician information pack containing the following:

- The Summary of Product Characteristics
- Physician information
- Patient Alert Card

The physician information should contain the following key messages:

- The risk of serious infections, including opportunistic bacterial, viral and fungal infections in patients treated with ARCALYST;
- The risk of acute injection-related reactions;
- The need to instruct patients on proper techniques for self-administration when the patient is willing and capable to do so, and guidance for Health Care Professionals on how to report administration errors;
- The identified or potential risk of immunogenicity that might lead to immune-mediated symptoms;
- The need for Health Care Professionals to perform an annual clinical assessment of patients regarding a potential increased risk for the development of malignancies;
- The need to measure neutrophil counts prior to initiating treatment, after 1 to 2 months and periodically thereafter while receiving ARCALYST as treatment with ARCALYST should not be initiated in patients with neutropenia;
- The need to monitor patients for changes in their lipid profiles;
- The unknown safety of ARCALYST in pregnant and lactating women, thus the need for physicians to discuss this risk with patients if they become or plan to become pregnant;
- The proper patient management as regards the interaction with vaccination;
- The possibility to include patients in the registry study to facilitate the collection of long term efficacy and safety data;
- The role and use of patient alert card.