ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

The MAH shall agree the details of a controlled distribution system with the National Competent Authorities and must implement such programme nationally to ensure that prior to prescribing all health care professionals who intend to prescribe and/or dispense Tracleer are provided with a Prescriber Kit containing the following:

- Information about Tracleer
- Patient Information Booklet/Patient Reminder Card

The Member States shall ensure that the MAH shall set up a surveillance programme/registry to collect information on the demographics, safety and outcome data from patients prescribed Tracleer to reduce the number of new digital ulcers in patients with systemic sclerosis and ongoing digital ulcer disease. The data to be collected shall be agreed with the CHMP. Details of the operation of the surveillance programme/registry shall be agreed with the National Competent Authorities in each Member State.

The patient information booklet for patients prescribed Tracleer should include the following key elements:

- That Tracleer is teratogenic in animals
- That pregnant women must not take Tracleer
- That women of child bearing potential must use effective contraception
- That hormonal contraceptives on their own are not effective
- The need for regular pregnancy tests
- That Tracleer causes a decrease in haemoglobin and the need for regular blood tests
- That Tracleer is hepatotoxic and the need for regular monitoring of liver function

The MAH shall agree with each National Competent Authority the content of a "Reminder Letter" to all known prescribers of Tracleer, reminding them of the safety concerns with Tracleer in relation to pregnancy.