ANNEX

FOR USE OF THE MEMBER STATES

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

- The Member States must ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product as described below are implemented:

- To agree the details of an educational brochure with the MAH.

The Member States shall ensure that the MAH provides all doctors who are expected to prescribe MabCampath with a healthcare professional information pack containing the following:

- Educational brochure
- Summary of Product Characteristics (SPC) and Package Leaflet and Labelling

Key elements to be included in the educational brochure

- The risk of opportunistic infections, in particular CMV viraemia
- Recommendation to avoid vaccination with live vaccines for at least 12 months following MabCampath therapy
- The risk of infusion reactions
    - Need for premedication
    - That treatment for hypersensitivity reactions, including measures for resuscitation should be available during administration
    - That the risk of infusion reactions is highest in first week of therapy
    - That if the reaction is moderate or severe dosing should continue at the same level (ie no dose escalation) until each dose is well tolerated
    - That if therapy is withheld for more than 7 days then MabCampath should be reinstituted with gradual dose escalation