ANNEX

CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY 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 should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

The Member States shall ensure that the Marketing Authorisation Holder (MAH) will provide all physicians who are expected to prescribe/use Aclasta in the authorised indications of treatment of osteoporosis in post-menopausal women and in men at increased risk of fracture, including those with a recent low-trauma hip fracture, and treatment of osteoporosis associated with long-term systemic glucocorticoid therapy in post-menopausal women and in men at increased risk of fracture with an updated physician information pack containing the following:

- Physician educational material
- Patient information pack

The physician educational material should contain the following key elements:

- The Summary of Product Characteristics
- Reminder card with the following key messages:
    - Need to measure serum creatinine before treatment with Aclasta
    - Contraindication in patients with creatinine clearance < 35 ml/min
    - Contraindication in pregnancy and in breast-feeding women due to potential teratogenicity
    - Need to ensure appropriate hydration of the patient
    - Need to infuse Aclasta slowly over a period of no less than 15 minutes
    - One-yearly dosing regime
    - Adequate calcium and vitamin D intake are recommended in association with Aclasta administration.
    - Need for appropriate physical activity, non-smoking and healthy diet
- Patient information pack

The patient information pack should be provided and contain the following key messages:

- Package leaflet
- Contraindication in patients with severe kidney problems
- Contraindication in pregnancy and in breast-feeding women
- Need for adequate calcium & vitamin D supplementation, appropriate physical activity, non-smoking and healthy diet
- Key signs and symptoms of serious adverse events
- When to seek attention from the health care provider