ANNEX 127a

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 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 i.e. the details of a prescription checklist are implemented:

- Mycamine is contra-indicated if the patient has a history of hypersensitivity to micafungin, other echinocandins or excipients.
- Mycamine should not be used during pregnancy unless clearly necessary.
- Caution must be demonstrated if the patient:
  - has severe liver function impairment
  - has chronic liver diseases known to represent preneoplastic conditions (e.g. advanced liver fibrosis, cirrhosis, viral hepatitis, neonatal liver disease or congenital enzyme defects)
  - is receiving a concomitant therapy including hepatotoxic and/or genotoxic properties
  - is receiving concomitant therapy with amphotericin B desoxycholate
  - has history of haemolysis, haemolytic anaemia or renal impairment.
- Patients receiving sirolimus, nifedipine or itraconazole in combination with Mycamine should be monitored for sirolimus, nifedipine or itraconazole toxicity and the sirolimus, nifedipine or itraconazole dosage should be reduced if necessary.
- Patients should be carefully monitored for liver damage and for worsening of renal function.
- To minimise the risk of adaptive regeneration and potentially subsequent liver tumour formation, early discontinuation in the presence of significant and persistent elevation of ALT/AST is recommended.