# APPLICATION FORM
# REQUESTING THE *AIFA* TO ACT AS REFERENCE MEMBER STATE

**(Proposed) name of the product:**

**MA number (if applicable):**

**Active substance:**

**Pharmaceutical form:**
**Strengths:**

**ATC Code:**

**Concerned Member States:**

**Legal basis:**

**Reference product in the CMS (if applicable):**
**First approval of the originator in the EEA:**

**(Proposed) therapeutic indications:**

**ACTIVE SUBSTANCE:**
**1) Sites(s) of Manufacture of the active substance:**
**2) Certifications available for each site:**
**3) Ph.Eur. Certificate of Suitability issued for the active substance(s):**
**4) Active Substance Master File (ASFM) to be used for:**

**MEDICINAL PRODUCT:**
**1)Sites(s) of Manufacture of the Medicinal Product:**
**2) Certifications available for each site:**
**3)last inspection by one MS:**

**BIOEQUIVALENCE:**
**1)Site used for Clinical Trial(s) on Bioavailability or Bioequivalence:**
**2) Certifications available for the site used:**
**3) bioequivalence test product, formula and strenght:**

**Planned submission date:**

**Name of Applicant/proposed Marketing Authorisation Holder Contact Person :**

**Other information:**

**Future Applicant in Italy: Name/Position:**
I herewith declare that only Italy is and will be requested to act as reference member State for the above mentioned procedure(s)
**Date:** **Signature**: