ANNEX I

INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY FOR THE PURPOSES OF DESIGNATION, AUTHORISATION, ACCREDITATION OR LICENSING IN ACCORDANCE WITH ARTICLE 5(2)

Part A:

General information:

— identification of the blood establishment
— name, qualification and contact details of responsible persons
— a list of hospital blood banks which it supplies.

Part B:

A description of the quality system, to include:

— documentation, such as an organisation chart, including responsibilities of responsible persons and reporting relationships
— documentation such as site master file or quality manual describing the quality system in accordance with Article 11(1)
— number and qualifications of personnel
— hygiene provisions
— premises and equipment
— list of standard operating procedures for recruitment, retention and assessment of donors, for processing and testing, distribution and recall of blood and blood components and for the reporting and recording of serious adverse reactions and events.

ANNEX II

REPORT OF THE BLOOD ESTABLISHMENT'S PRECEDING YEAR'S ACTIVITY

This annual report will include:

— total number of donors who give blood and blood components
— total number of donations
— an updated list of the hospital blood banks which it supplies
— total number of whole donations not used
— number of each component produced and distributed
— incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components
— number of product recalls
— number of serious adverse events and reactions reported.

ANNEX III

LABELLING REQUIREMENTS

The label on the component must contain the following information:

— the official name of the component
— the volume or weight or number of cells in the component (as appropriate)
— the unique numeric or alphanumeric donation identification
— the name of producing blood establishment
— the ABO Group (not required for plasma intended only for fractionation)
— the Rh D Group, either Rh D positive or Rh D negative (not required for plasma intended only for fractionation)
— the date or time of expiry (as appropriate)
— the temperature of storage
— the name, composition and volume of anticoagulant and/or additive solution (if any).

ANNEX IV

BASIC TESTING REQUIREMENTS FOR WHOLE BLOOD AND PLASMA DONATIONS

The following tests must be performed for whole blood and apheresis donations, including autologous predeposit donations:

— ABO Group (not required for plasma intended only for fractionation)
— Rh D Group (not required for plasma intended only for fractionation)
— testing for the following infections in the donors:
  — Hepatitis B (HBs-Ag)
  — Hepatitis C (Anti-HCV)
  — HIV 1/2 (Anti-HIV 1/2)

Additional tests may be required for specific components or donors or epidemiological situations.