Annex G
Glossary

Albumin The major protein in plasma, which is important in maintaining blood volume via osmotic pressure.

Antibody A protein, an immunoglobulin, produced by the immune system and found in the blood in response to the presence of antigens.

Antigen A substance, often a foreign protein, that stimulates the immune system to form an antibody.

Anti-(Rh)D antibody Antibody against the Rhesus blood group D-antigen.

Apheresis A procedure in which whole blood is temporarily withdrawn from a donor, one or more of its components are selectively removed, and the remainder of the blood is then reinfused into the donor.

Autologous donation Blood donation for the donor's own use.

Biologicals Medicines or medical devices derived from human or animal tissues.

Blood components Therapeutic components that have been manufactured from blood; these include red cells, white cells, platelets and plasma for transfusion.

Blood group Complex chemical substances, found on or in the surface of red cells, distinguish each blood group. The two more important blood group systems in transfusion work are the ABO (blood types A, B, O and AB) and the Rh(D) systems.

Bovine spongiform encephalopathy (BSE) An infection of the nervous system in cows. Also known as 'mad cow disease'.

Chromatography Process by which plasma is separated into its components, based on size, charge or other chemical properties, via interaction with a 'gel', which provides the basis for the separation.

Coagulation factors Proteins that when activated function as enzymes, leading to the production of thrombin and then fibrin, which together with platelets form a thrombus or clot that prevents loss of blood after vessel injury.

Code of Good Manufacturing Practice (GMP) A set of standards that provide assurance that a manufacturer has a quality system in place that meets the requirements for the product being made.

Cold-ethanol fractionation Often referred to as Cohn fractionation, this process involves the addition of varying concentrations of ethanol to cooled plasma in order to precipitate fractions, which are further purified into individual plasma products.

Creutzfeldt-Jakob disease (CJD) A central nervous system disease that causes presenile dementia, neurological degeneration and distinctive electroencephalographic changes, caused by an abnormal prion.

Cross-match A term used when testing the patient's serum against the donor's red cells to ensure compatibility prior to blood transfusion.

Cryoprecipitate A clotting factor preparation derived from plasma. It includes Factor VIII and fibrinogen and may be used in the treatment of massive bleeding and, occasionally, for the treatment of haemophilia A and von Willebrand's disease.

Directed donation Donations of blood from relatives or friends of a recipient that are specifically requested to be given to that recipient.

Factor VIII A clotting factor that, as a concentrate, is used to treat haemophilia A (classic haemophilia).

Factor IX A clotting factor that, as a concentrate, is used to treat haemophilia B (also known as Christmas disease).

Fibrinogen A soluble protein in blood plasma that is involved in the clotting mechanism and that when activated by thrombin becomes fibrin.

Fractionation The separation of a substance into its basic constituents.

Haemolysis The breakdown of red cells with the release of haemoglobin. Normally occurs at the end of the life span of a red cell. Haemolysis may occur in red cell antigen/antibody reactions.

Haemolytic Disease of the Newborn (HDN) A disease that can arise when there is incompatibility between the red cells of a foetus and those of the mother.

Haemophilia A hereditary deficiency of clotting factors in blood (usually referred to as haemophilia A or haemophilia B).

Haemovigilance Monitoring of untoward transfusion events and outcomes in hospitals.

Hepatitis B Viral inflammatory disease of the liver caused by the hepatitis B virus.

Hepatitis C Viral inflammatory disease of the liver caused by the hepatitis C virus. Now the most commonly reported notifiable disease in Australia.

Homologous blood Blood donation given for transfusion to an unknown recipient.

Hyperimmune immunoglobulins Immunoglobulin products prepared from the plasma of donors with high concentrations of specific antibodies.

Immunoglobulins Plasma proteins that combat infection.

Inhibitors Acquired antibodies that recognise as foreign clotting factors that have been administered as replacement therapy. Inhibitors attack and neutralise the Factor VIII or Factor IX that has been introduced into the body or even the patient's own Factor VIII or Factor IX.

Intramuscular immunoglobulin (IMIg) An immunoglobulin preparation designed for intramuscular rather than intravenous use.

Intravenous immunoglobulin (IVIg) An immunoglobulin designed for intravenous use.

Leucodepletion Removal of white cells from blood.

Licensing (or certification) audit Initial audit conducted by the Therapeutic Goods Administration to confirm that a manufacturer has complied with mandated requirements.

Memorandum of Understanding (MOU) A legal document that establishes a bilateral agreement between parties but is not a binding agreement and is not enforceable at law.

Mutual Recognition Agreement (MRA) An international agreement by which two (or more) countries agree to recognise and accept the findings of each other's conformity assessment bodies (e.g. regulatory agencies for medicinal products).

Nanofiltration A filtration process, used in the manufacture of plasma products, that can remove small particles such as a virus.

Pathogen Disease-causing agent.

Pharmaceutical Inspection Convention (PIC) PIC is a formal treaty between countries. PIC members are legally bound to recognise the manufacturer inspections of PIC members. Australia joined the convention in 1993.

PIC Scheme An informal cooperative arrangement between national health authorities, having no legal status. Its purpose is to facilitate the networking between participating authorities and the maintenance of mutual confidence, the exchange of information and experience in the field of GMP and related areas, and the mutual training of auditors.

Plasma Liquid portion of blood that contains proteins and electrolytes.

Plasmapheresis Automated procedure for removing whole blood from the donor, separating and collecting the plasma, and returning the remaining components to the donor.

Plasma starting pool Pool of numerous units of donated plasma used to manufacture a batch of plasma derived products.

Platelet One of the cellular components of blood that contribute to haemostasis and blood clotting.

Prion Protein that occurs normally in many organs and tissues, including the brain, spinal cord and eye of healthy humans and animals.

Recombinant product Recombinant products are produced by inserting a human gene into a cell line, which then synthesises the required human protein (e.g. Factor VIII or Factor IX). This product is then harvested from the supernatant for clinical use.

Recovered plasma Plasma obtained, after centrifugation, from whole blood donations.

Source plasma Plasma obtained through plasmapheresis.

Special Access Scheme Arrangements that provide for the import and/or supply of an unapproved therapeutic good for a single patient on a case-by-case basis.

Sponsor (product sponsor) Australian importer, exporter and/or supplier of a therapeutic good. The sponsor is required to be a resident of Australia, or registered as a business in Australia.

Therapeutic donation Where individuals with specific haematological conditions reduce their blood volume through controlled venesection.

Tolerisation The procedure of administering high doses of clotting factors to swamp inhibitors or other antibodies. Tolerisation may be used in a general immunological sense for failure of a person to respond to a foreign antigen.

Toll fractionation Exporting of plasma for fractionation, whereby plasma collected in one country is processed in another on a fee-for-service basis.

Transmissible spongiform encephalopathies (TSEs) A group of transmissible infections of the nervous system caused by an abnormal prion; TSEs including Creutzfeldt-Jakob disease and bovine spongiform encephalopathy.

Variant CJD A form of Creutzfeldt-Jakob disease, thought to be caused by eating beef infected with bovine spongiform encephalopathy ('mad cow disease').