

Improving access to safe blood products through local production and technology transfer in blood establishments



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Improving access to safe blood products through local production and technology transfer in blood establishments



**World Health
Organization**

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List of abbreviations

AIDS	acquired immune deficiency syndrome
API	active pharmaceutical ingredient
BRN	Blood Regulators Network
CAPA	corrective action preventive action
CJD	Creutzfeldt-Jakob disease
CMV	cytomegalovirus
EBV	Epstein Barr virus
EIS	electronic information system
ELISA	enzyme-linked immunosorbent assay
FFP	fresh frozen plasma
F IX	factor IX (nine)
F VIII	factor VIII (eight)
GAP	Global Alliance for Progress
GDP	gross domestic product
GMP	good manufacturing practice
HA	human albumin
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HEV	hepatitis E virus
HGV	hepatitis G virus
HIC	high-income countries
HIV	human immunodeficiency virus
HSA	human serum albumin
HTLV	human T-cell lymphotropic virus
IBTO	Iran Blood Transfusion Organization
ID	individual donation
IG	immunoglobulin
IM	intramuscular
IRC	Indonesian Red Cross
IT	information technology
ITP	immune thrombocytopenic purpura
IU	international unit

IV	intravenous
IVD	in vitro diagnostic devices or tests
IVIG	IV immunoglobulin
LMIC	low- and middle-income countries
MCC	Medicines Control Council
MIC	middle-income countries
MoH	ministry of health
MRB	Market Research Bureau
NAT	nucleic acid techniques
NBI	National BioProducts Institute
NRA	national regulatory authority
PCC	prothrombin complex concentrate
PDMP	plasma-derived medicinal products
PID	primary immune deficiency
QA	quality assurance
R&D	research and development
SAHF	South African Haemophilia Foundation
SANBS	South African National Blood Service
SOP	standard operating procedure
TT	transfusion transmitted
TTI	transfusion-transmitted infection
TSE	transmissible spongiform encephalopathy
USA	United States of America
vCJD	variant Creutzfeldt-Jakob disease
WHO	World Health Organization
WNV	West Nile virus

Glossary

The definitions given below apply to the terms used in this report. They may have different meanings in other contexts.

Albumin: A plasma-derived medicinal product used for patients needing protein or volume replacement.

Apheresis: The process by which one or more blood components are selectively obtained from a donor by withdrawing whole blood, separating it by centrifugation and/or filtration into its components, and returning those not required to the donor. The term 'plasmapheresis' is also used for a procedure dedicated to the collection of plasma.

Blood collection: A procedure whereby a single donation of blood is collected in a sterile receptacle containing anticoagulant and/or stabilizing solution, under conditions designed to minimize microbiological contamination, cellular damage and/or coagulation activation.

Blood component: A constituent of blood that can be prepared under such conditions that it can be used directly (or after further processing) for therapeutic applications. The main therapeutic blood components are red blood cell concentrates, platelet concentrates, plasma for transfusion, and cryoprecipitate.

Blood establishment: Any structure, facility or body that is responsible for any aspect of the collection, testing, processing, storage, release and/or distribution of human blood or blood components when intended for transfusion or further industrial manufacturing. It encompasses the terms 'blood bank', 'blood centre', 'blood service' and 'blood transfusion service'.

Blood product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma-derived medicinal products.

Closed system: A system developed for aseptic collection and separation of blood and blood components, manufactured under clean conditions, sealed to

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