

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

Phase II



Intellectual
Property and Trade

R&D
Innovation

Technology
Transfer

Improving Access

Financing

Monitoring and
Reporting



World Health
Organization

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

Phase II



**World Health
Organization**

WHO Library Cataloguing-in-Publication Data

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

1.Blood – standards. 2.Blood Transfusion – methods. 3.Blood Banks. 4.National Health Programs. I.World Health Organization.

ISBN 978 92 4 156520 2 (NLM classification: WH 23)

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Printed by the WHO Document Production Services, Geneva, Switzerland
Editing and design by Inis Communication – www.iniscommunication.com
Photo: WHO

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Acknowledgements

Improving Access to Safe Blood Products through Local Production and Technology Transfer in Blood Establishments is a project developed by Dr Ana Padilla, Blood Products and Related Biologicals Programme, in the World Health Organization (WHO) Essential Medicines and Health Products Department. As project manager, Dr Padilla took responsibility for the organization and coordination of the project activities and prepared the reports of the activities carried out in phase I and phase II.

Grateful acknowledgement is made of the contribution of Dr Peter L Page (1946–2014) and Dr Thierry Burnouf, who from the very beginning of this project provided unfailing support and invaluable advice. Thanks are extended to all those who provided comments, advice and information during the preparation and consultation process for developing both the overall project and the reports. They are listed at the end of this report.

This project forms part of an overall framework, Improving Access to Medical Products through Local Production and Technology Transfer, coordinated by the WHO Department of Public Health Innovation and Intellectual Property, with funding from the European Commission. Special thanks are due to Dr Zafar Mirza, Dr Robert Thierry and Dr Lembit Rägo, who endorsed and supported the initial project concept in WHO.

This publication has been produced with the assistance of the European Commission. The contents of this publication are the sole responsibility of WHO and can in no way be taken to reflect views of the European Commission.

Thanks are also due to the Government of Indonesia and relevant key stakeholders for their collaboration, collegial contributions and enthusiasm in moving this project forward. Acknowledgement is made of the invaluable support and collaboration provided by the WHO country office in Indonesia during the development and implementation of the WHO workshops in Jakarta.

Glossary

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

Albumin A plasma derivative used for patients who need 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 the blood by centrifugation and/or filtration into its components, and returning unrequired components to the donor. The term “plasmapheresis” is used for the 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 banks, blood centres, blood transfusion units, blood services and blood transfusion services.

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

Cryoprecipitate A single-donor or small-pool therapeutic plasma fraction obtained by thawing frozen plasma at 2–4 °C and used to treat factor VIII, von Willebrand factor or fibrinogen deficiencies.

Donor A person in defined good health conditions who voluntarily donates blood or blood components, including plasma for fractionation.

Factor VIII Blood coagulation factor VIII, which is deficient in people with haemophilia A. Also called “antihaemophilic factor”.

Factor IX Blood coagulation factor IX, which is deficient in people with haemophilia B.

First-time (tested) donor A donor whose blood or plasma is tested for the first time for infectious disease markers in a blood establishment.

Fractionation A (large-scale) process by which plasma is separated into individual protein fractions, which are then purified further for medicinal use (variously referred to as “plasma derivatives”, “fractionated plasma products” or “plasma-derived medicinal products”). The term “fractionation” is usually used to describe a sequence of processes, including plasma protein separation steps (typically precipitation or chromatography),

purification steps (typically ion-exchange or affinity chromatography), and one or more steps for the inactivation or removal of bloodborne infectious agents (viruses and, possibly, prions).

Fractionator An organization that performs plasma fractionation to manufacture plasma-derived medicinal products.

Good manufacturing practice The part of quality assurance that ensures products are consistently produced and controlled to the quality standards appropriate to their intended use, and as required by the marketing authorization or product specification. Good manufacturing practice is concerned with both production and quality control.

Hepatitis A virus A non-enveloped, single-stranded RNA virus; the causative agent of hepatitis A.

Hepatitis B virus An enveloped, double-stranded DNA virus; the causative agent of hepatitis B.

Hepatitis C virus An enveloped, single-stranded RNA virus; the causative agent of hepatitis C.

Human immunodeficiency virus (HIV) An enveloped, single-stranded RNA virus; the causative agent of acquired immunodeficiency syndrome.

Immunoglobulin Also known as “immune globulin” and “gamma globulin”. Used in the treatment of primary immunodeficiency and a number of other conditions. Polyvalent immunoglobulin is prepared from a large number of donors. Hyperimmune or specific immunoglobulins are prepared from plasma containing high levels of antibody to a certain infectious agent or antigen, such as rabies, tetanus, hepatitis B and Rhesus factor.

Incidence The rate of newly acquired infection identified over a specified time period in a defined population.

Know-how A set of information in the form of unpatented inventions, formulae, designs, drawings, procedures and methods, together with accumulated skills and experience in the hands of a licensor firm’s professional personnel, which could assist a transferee or licensee of the object product in its manufacture and use and bring to it a competitive advantage. Know-how can be supported further with privately maintained expert knowledge on the

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