

Availability, safety and quality of blood products

The Sixty-third World Health Assembly,

Recalling resolution WHA58.13 on blood safety: proposal to establish World Blood Donor Day and preceding related resolutions since resolution WHA28.72 on utilization and supply of human blood and blood products, which urged Member States to promote the full implementation of well-organized, nationally coordinated and sustainable blood programmes with appropriate regulatory systems and to enact effective legislation governing the operation of blood services;

Recognizing that achieving self-sufficiency, unless special circumstances preclude it, in the supply of safe blood components based on voluntary, non-remunerated blood donation, and the security of that supply are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population;

Conscious that plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines¹ and of the need to facilitate access to these products by developing countries;

Concerned by the unequal access globally to blood products, particularly plasma-derived medicinal products, leaving many patients in need of transfusion and with severe congenital and acquired disorders without adequate treatment;

Aware that a major factor limiting the global availability of plasma-derived medicinal products is an inadequate supply of plasma meeting internationally recognized standards for fractionation;

Bearing in mind that treatment using labile blood components is gradually being included in medical practice in developing countries and that thereby increased quantities of recovered plasma should become available for fractionation into plasma-derived medicinal products to meet their needs;

Concerned that in developing countries, blood components separation technology and fractionation capacity are lacking, and that, because of insufficient regulatory controls and failure to implement appropriate practices in blood establishments, plasma from developing countries is often unacceptable for contract fractionation, with considerable wastage of plasma as a result;

¹ The WHO Model List of Essential Medicines identifies individual medicines that together could provide safe and effective treatment for most communicable and noncommunicable diseases. This List includes plasma-derived medicinal products, namely immunoglobulins and coagulation factors, which are needed to prevent and treat a variety of serious conditions that occur worldwide (<http://www.who.int/medicines/publications/essentialmedicines/en/index.html>).

Convinced that assuring the suitability of plasma for fractionation requires the establishment of a nationally coordinated and sustainable plasma programme within a properly organized, legally established and regulated national blood programme;

Recognizing that, as the capacity to collect plasma is limited and would not suffice to produce enough essential medicines to cover global needs, it is essential that all countries have local capacity to collect plasma of acceptable quality and safety from voluntary and unpaid donations in order to meet their needs;

Convinced that fractionation should be set up as close to the source as possible, and that, where national plasma fractionation capacities are lacking, there should be an option for supply of fractionation capacity in other countries, ensuring that the supply of plasma derived medicinal products can be made available to meet local needs in the country of the plasma supplier;

Recognizing that access to information about strategies to ensure supplies of blood products sufficient to meet demand, effective mechanisms of regulatory oversight, technologies to ensure the quality and safety of blood products, and guidelines on the appropriate clinical use of blood products and the risks of transfusion have become more and more necessary;

Bearing in mind that voluntary and non-remunerated blood donations can contribute to high safety standards for blood and blood components, and being aware that the safety of blood products depends on testing of all donated blood for transfusion-transmissible infections, and correct labelling, storage and transportation of blood products;

Bearing in mind that patient blood management means that before surgery every reasonable measure should be taken to optimize the patient's own blood volume, to minimize the patient's blood loss and to harness and optimize the patient-specific physiological tolerance of anaemia following WHO's guide for optimal clinical use (three pillars of patient blood management);

Recognizing that excessive and unnecessary use of transfusions and of plasma-derived medicinal products, unsafe transfusion practices, and errors (particularly at the patient's bedside) seriously compromise patient safety;

Concerned that unsafe and/or poor-quality blood products can render patients vulnerable to avoidable risk if the blood programmes are not subject to the level of control now exercised by experienced national or regional regulatory authorities;

Alarmed that patients in developing countries continue to be exposed to the risk of preventable transfusion-transmitted infections by bloodborne pathogens such as hepatitis B virus, hepatitis C virus and HIV;

Noting the increasing movement across boundaries of blood products and blood safety-related in vitro diagnostic devices, together with their rapid development and introduction into health-care systems of both developed and developing countries;

Recognizing the value of international biological reference materials (WHO International Standards) for the quality control of blood products and related in vitro diagnostic devices for detection of known and emerging bloodborne pathogens;

Convinced that traceability at all stages of the preparation of blood products, from the donor to the recipient and vice versa, is essential to identify risks, particularly the transmission of pathogens and transfusion reactions, and to monitor the efficacy of corrective measures aiming to minimize such risks;

Convinced that good practices need to be implemented for recruiting voluntary, non-remunerated healthy blood and plasma donors from low-risk donor populations and testing of all donated blood for transfusion-transmissible pathogens, and that the whole chain of processes in the production of blood products, i.e. correct processing, labelling, storage and transportation, needs to be covered by relevant, reliable quality-assurance systems;

Recognizing that stringent regulatory control is vital in assuring the quality and safety of blood products, as well as of related in vitro diagnostic devices, and that special effort is needed to strengthen globally the technical capacity of regulatory authorities to assure the appropriate control worldwide;

Recalling previous resolutions of the Health Assembly mentioning the vital need to strengthen blood establishments and ensure the quality, safety and efficacy of blood products,

1. URGES Member States:¹

- (1) to take all the necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency, unless special circumstances preclude it;
- (2) to take all the necessary steps to update their national regulations on donor assessment and deferral, the collection, testing, processing, storage, transportation and use of blood products, and operation of regulatory authorities in order to ensure that regulatory control in the area of quality and safety of blood products across the entire transfusion chain meets internationally recognized standards;
- (3) to establish quality systems, for the processing of whole blood and blood components, good manufacturing practices for the production of plasma-derived medicinal products and appropriate regulatory control, including the use of diagnostic devices to prevent transfusion-transmissible diseases with highest sensitivity and specificity;
- (4) to build human resource capacity through the provision of initial and continuing training of staff to ensure quality of blood services and blood products;
- (5) to enhance the quality of evaluation and regulatory actions in the area of blood products and associated medical devices, including in vitro diagnostic devices;
- (6) to establish or strengthen systems for the safe and rational use of blood products and to provide training for all staff involved in clinical transfusion, to implement potential solutions in order to minimize transfusion errors and promote patient safety, to promote the availability of transfusion alternatives including, where appropriate, autologous transfusion and patient blood management;

¹ And regional economic integration organizations, where applicable.

(7) to ensure the reliability of mechanisms for reporting serious or unexpected adverse reactions to blood and plasma donation and to the receipt of blood components and plasma-derived medicinal products, including transmissions of pathogens;

2. REQUESTS the Director-General:

(1) to guide Member States to meet internationally recognized standards in updating their legislation, national standards and regulations for effective control of the quality and safety of blood products and associated medical devices, including in vitro diagnostics;

(2) to advise and build capacity in Member States on leadership and management of blood supply systems in order to strengthen national coordinated and sustainable blood and plasma programmes by sharing best practices about the organizational structure of blood supply systems in order to increase efficiency and minimize error;

(3) to augment the support offered to Member States for developing and strengthening their national regulatory authorities and control laboratories so as to increase their competence in the control of blood products and associated medical devices, including in vitro diagnostic devices, and to foster the creation of regional collaborative and regulatory networks where necessary and appropriate;

(4) to ensure sustainable development and provision of international biological reference materials (WHO International Standards) for use in the quality control and regulation of blood products and related in vitro diagnostic devices;

(5) to improve access by developing countries to international biological reference materials and to the scientific information obtained in their validation in order to assure the appropriate use of these materials;

(6) to develop, provide and disseminate guidance and technical support to strengthen national coordinated blood and plasma programmes and introduction of blood component separation and plasma fractionation technology, to meet local needs, and promote effective regulatory oversight of blood services and implementation of good manufacturing practices in plasma-fractionation programmes, under the responsibility of regulatory authorities;

(7) to provide guidance, training and support to Member States on safe and rational use of blood products and to support the introduction of transfusion alternatives including, where

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