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Availability, safety and quality of blood products

Revision of draft resolution considered by the Executive Board at its 125th session[1] reflecting comments and proposals made by Bangladesh, Brazil, Chile, China, India, Japan, New Zealand, Nigeria, Paraguay, Republic of Moldova, and United Kingdom of Great Britain and Northern Ireland

The Executive Board recommends to the World Health Assembly the adoption of the following resolution,

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 sufficiency in the supply of safe blood components and the security of that supply based on voluntary, non-remunerated blood donation, are important national goals to prevent blood shortages and meet the transfusion requirements of the patient population; [based on comments by Bangladesh, Japan, Nigeria, New Zealand and Republic of Moldova[1]]

Conscious that plasma-derived medicinal products for the treatment of haemophilia and immune diseases are included in the WHO Model List of Essential Medicines[2] and of the need to facilitate access to these products by developing countries;

[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

[2] 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).

Concerned by the unequal access globally to blood products, including 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;

Concerned that in developing countries, blood components separation technology and fractionation capacity are lacking, and 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;

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 access to information about strategies to ensure supplies of blood products sufficient to meet demand, effective mechanisms of regulatory oversight, and technologies to ensure the quality and safety of blood products, 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 and 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 the WHO's guide for optimal clinical use (three pillars of patient blood management);

Recognizing that excessive and unnecessary use of transfusions, unsafe transfusion practices and errors (particularly at the patient's bedside) seriously compromise patient safety; [based on comments by Bangladesh, Chile, Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

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;

[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

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

~~Concerned~~ **Observing [Nigeria[1]]** that the increasing mobility of populations is contributing to increased risk of transmission of infectious diseases worldwide; **[deletion proposed by Brazil and Paraguay[1]]**

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 blood-borne pathogens;

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

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:[2]

(1) to take all the necessary steps to establish, implement and support nationally coordinated, efficiently managed and sustainable blood and plasma programmes;

(2) to take all the necessary steps to update their national legislation on the collection, testing, processing, storage, transportation and use of blood products and operation of regulatory authorities to ensure that regulatory control in the area of quality and safety of blood products meets internationally recognized standards;

[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

[2] And regional economic integration organizations, where applicable.

(3) to establish quality systems, good manufacturing practices and appropriate regulatory control for the production of blood components and plasma derived medicinal products.

(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; [based on comments by India and Republic of Moldova[1]]

(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, and to promote the use of autologous transfusion; [based on comments by Bangladesh, China, Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

(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 [based on comments by Chile and New Zealand[1]]** 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; [based on comments by Chile and New Zealand[1]]

(3) to extend 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 fostering 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;

[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.

(6) to develop, provide and disseminate guidance and technical support to strengthen national blood and plasma programmes and **introduction of blood component separation technology, [based on comments by Bangladesh[1]]** 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 autologous transfusion and safe transfusion practices; [based on comments by Bangladesh, China, Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

(8) to encourage research into new technologies for producing safe and effective blood substitutes; [based on comments by Republic of Moldova and United Kingdom of Great Britain and Northern Ireland[1]]

(9) to inform regularly, at least every four years, the Health Assembly, through the Executive Board, on actions taken by Member States and other partners.

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[1] See document EB125/2009/REC/1, summary record of the first meeting, section 5.