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Report on financial and administrative implications for the Secretariat of resolutions proposed for adoption by the Executive Board or Health Assembly

1. Resolution Availability, safety and quality of blood products

2. Linkage to programme budget

Strategic objective:	Organization-wide expected result:
2. To combat HIV/AIDS, tuberculosis and malaria.	2.3 Global guidance and technical support provided on policies and programmes in order to promote equitable access to essential medicines, diagnostic tools and health technologies of assured quality for the prevention and treatment of HIV/AIDS, tuberculosis and malaria, and their rational use by prescribers and consumers, and, in order to ensure uninterrupted supplies of diagnostics, safe blood and blood products, injections and other essential health technologies and commodities.
4. To reduce morbidity and mortality and improve health during key stages of life, including pregnancy, childbirth, the neonatal period, childhood and adolescence, and improve sexual and reproductive health and promote active and healthy ageing for all individuals.	4.1 Support provided to Member States to formulate a comprehensive policy, plan and strategy for scaling up towards universal access to effective interventions in collaboration with other programmes, paying attention to reducing gender inequality and health inequities, providing a continuum of care throughout the life course, integrating service delivery across different levels of the health system and strengthening coordination with civil society and the private sector.
10. To improve health services through better governance, financing, staffing and management, informed by reliable and accessible evidence and research.	10.13 Evidence-based norms, standards and measurement tools developed to support Member States to quantify and decrease the level of unsafe health care provided.
11. To ensure improved access, quality and use of medical products and technologies.	11.1 Formulation and monitoring of comprehensive national policies on access, quality and use of essential medical products and technologies advocated and supported.

11.2 International norms, standards and guidelines for the quality, safety, efficacy and cost-effective use of medical products and technologies developed and their national and/or regional implementation advocated and supported.

11.3 Evidence-based policy guidance on promoting scientifically sound and cost-effective use of medical products and technologies by health workers and consumers developed and supported within the Secretariat and regional and national programmes.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

This resolution focuses on ensuring equitable access in Member States to blood products (blood, blood components and plasma-derived medicinal products) that are of assured quality, safety and efficacy, and on their sound, cost-effective and safe use. The resolution is linked to the above-mentioned Organization-wide expected results and their associated indicators, including number of policies, strategies, global norms, guidelines, tools, regulatory mechanisms and systems, quality standards and reference preparations for blood and blood products, strengthening policies and strengthening functionality of the national regulatory authorities and of national/regional programmes for sound and cost-effective use of blood products. In addition, the resolution is linked to prevention of transmission of HIV through contaminated blood products and the associated indicators, including number of Member States implementing quality-assured screening of all donated blood for HIV. It is also linked to the strengthening of health systems and improved patient safety through the establishment or improvement of national blood and plasma programmes, voluntary, non-remunerated donation programmes, quality systems, good manufacturing practices, appropriate legislative frameworks, and better clinical practice.

3. Budgetary implications

(a) Total estimated cost for implementation over the life-cycle of the Secretariat's activities requested in the resolution (estimated to the nearest US$ 10 000, including staff and activities).

US$ 20 million (US$ 12 million for activities and US$ 8 million for staff) for the period 2010–2013, covering: the application of WHO's existing norms and standards, including WHO guidelines and reference preparations to strengthen the technical capacity of regulatory authorities and blood transfusion services in Member States in updating legislation, national standards and regulations for national blood and plasma programme; the building of capacity in managing blood supply systems, in component separation technology, in quality systems, in regulatory oversight for the production and control of blood products and in safe and rational use of blood and blood products; and the promotion of collaboration, partnership and networking in technology transfer and research for safe and rational use of blood products and their alternatives.

(b) Estimated cost for the biennium 2010–2011 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant).

US$ 10 million (of which at least 50% of both activities and staff cost will be at regional and country levels).

(c) Is the estimated cost noted in (b), included within the existing approved Programme budget for the biennium 2010–2011?

No; US$ 1.2 million can be subsumed under the existing approved budget.

4. Financial implications

How will the estimated cost noted in 3(b) be financed (indicate potential sources of funds)?

Additional funding is expected through active mobilization of resources.

5. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant).

Headquarters, regional offices, WHO country offices, relevant WHO collaborating centres, nongovernmental organizations in official relations with WHO, and other key partners. Normative technical work on policies, strategies, legislation, quality systems, rational use of blood, haemovigilance, regulatory systems and quality assurance of blood products, including plasma for fractionation, will be coordinated by headquarters while implementation will be done at regional and country levels with, overall, at least 50% of the financial and human resources allocated to priority regions and countries.

(b) Can the resolution be implemented by existing staff? If not, please specify in (c) below.

No.

(c) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile).

At headquarters, two additional full-time professional staff will be required: one with specific expertise in research on evidence-based transfusion medicine and rational use of blood products and haemovigilance, and the other with specific expertise in quality assurance regulation and standardization of blood products, including quality and safety of plasma for fractionation. Two general service staff members will also be needed. For the work in priority regional and country offices four focal points will need to be appointed at professional level, two with proven experience in managing blood supply systems, quality systems and component preparation and two with field experience in good manufacturing practices, quality control and evaluation for quality and safety of blood products, including plasma for fractionation.

(d) Time frames (indicate broad time frames for implementation of activities).

During the biennium 2010–2011, working groups on rational use of blood products, quality systems and good manufacturing practices, haemovigilance and regulation will be established with clearly defined terms of reference, with representatives from regional offices and members of WHO expert panels.

A report on progress in implementing the resolution will be submitted to the Health Assembly in 2014 through the Executive Board, followed by biennial reporting and a final report in 2020.

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