



First regional meeting
of directors of blood transfusion services
in Europe

Copenhagen, Denmark
4-5 June 2007

ABSTRACT

During this first regional meeting of directors of blood transfusion services (WHO European Region) common challenges related to blood and patient safety in Member States were identified and proposals were made on the development of a regional plan of action to strengthen this area and prevent the transmission of HIV/AIDS and other blood-borne pathogens.

Forty-eight countries of the Region were represented. Participants agreed that increased political commitment to blood and patient safety, supported by a harmonized and collaborative approach to strengthening the quality and adequacy of blood supplies, capacity building and networking are key interventions. They emphasized the need for a common platform for discussion, information exchange and cooperation among Member States. A set of recommendations was developed.

Keywords

Blood transfusion services
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Introduction

A safe and adequate blood supply reflects on the health status of the general population through various entry points: healthy life style (safe donor selection criteria), health indicators' values (the prevalence of infectious agents and trends of disease), and quality of care and patient safety (the availability and appropriateness of transfusion therapy). A safe and adequate blood supply is a necessary prerequisite to enable health services to cope efficiently with the demand and contribute to improving the public health status. Therefore, blood and blood components in all Member States must comply with comparable quality and safety standards. Transfusion therapy should be available for and accessible to acute and chronically-ill patients and able to meet their needs.

The existing European legislation (European Union (EU) dedicated directives) and the World Health Organization (WHO) and Council of Europe (COE) recommendations and guides, all highlight the importance of efficient blood services to protect donors, recipients and ultimately the population at large.

Common challenges for the blood reserve have been identified in the WHO European Region. Examples of these are: increasing cross-border movement, the HIV/AIDS epidemic and disparities in terms of quality and safety standards in blood services/health services. The decreasing trends in blood donations in many countries and ageing populations raise additional concerns with regard to the availability of and access to transfusion therapy in both the short and longer terms.

Action is required to address shortfalls and imbalances in national blood supplies. Within the health systems framework, emphasis must be placed on the whole blood service configuration. Information exchange, cooperation and partnership (national and international) are considered to be essential mechanisms for progress in this field.

This first regional meeting of directors of blood transfusion services in the WHO European Region was convened on the basis of the above and in accordance with the recommendations of the Regional meeting of directors of blood services in central and eastern Europe and the newly independent states that took place in Ljubljana, Slovenia, 21-23 April 2005 (1).

The aim of the first regional meeting was to review existing information, share experiences and draw up region-specific strategic directions for strengthening the quality, safety and availability of the blood supply, with particular emphasis on quality and safety monitoring mechanisms.

The objectives of the event were:

1. to assist in the process of regional benchmarking and priority setting with a view to safer national blood supplies and to prevent the transmission of HIV and other blood-borne pathogens;
2. to provide a common platform for discussion, information exchange and cooperation between Member States, looking into sustainable future collaborative activities;

3. to develop region-specific strategic directions for strengthening the quality, safety and availability of the blood supply, and to facilitate setting milestones for action.

The meeting was attended by representatives of 48 Member States, the European Commission (EC), European Directorate for Quality of Medicines (EDQM), other international organizations and WHO Headquarters. It is important to note that two institutions dedicated to international education in the field were represented.

Opening address

In his opening address, Mr Gerard Schmets welcomed the participants, noting the high rate of participation and the interest of Member States in this event.

Blood safety is an important and longstanding issue on the WHO agenda. A number of resolutions dedicated to strengthening the quality, safety and adequacy of national blood supplies have been adopted by the World Health Assembly (WHA) starting in 1975 with Resolution WHA28.72 (2), which urged Member States to promote the development of nationally coordinated blood services based on voluntary non-remunerated blood donation. Since 1987 (WHA40.13/87) (3), additional resolutions have been adopted that focus on strengthening the safety and adequacy of cell, tissue and organ transplantation services.

The safety and availability of the blood supply have major implications on health in the European Region in the context of the HIV/AIDS epidemic, the enlargement of the EU and increasing cross-border movement and inequalities in terms of quality standards and safety requirements, as applied to health services. The WHO health system framework with its four functions (stewardship, resources, service delivery, financing) must be used in designing interventions for both efficiency and long-term sustainability. In the national context, the main challenge lies in the choice of intervention and in the degree to which it is prioritized in terms of value, resources and policies.

Emphasis needs to be placed on strengthening blood services through an integrated approach and on securing access to safe and available supplies for all Member States in the Region. WHO is focusing on country needs and tailor-made support interventions draw on longstanding collaboration with the COE, the EC, other international partners, and stakeholders.

Objective of the meeting

Following the introductory note, the meeting outline and objectives were presented. Along with similar input from the other WHO Regions, the regional strategic directions to emerge from the meeting would contribute to the global strategic planning exercise coordinated by WHO headquarters.

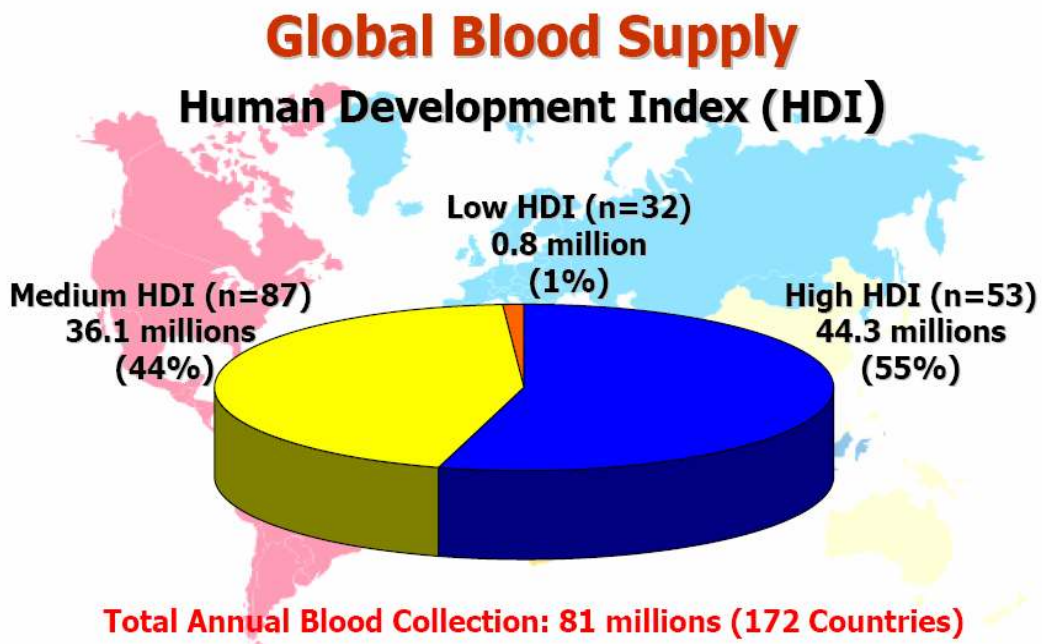
Election of officers

Dr Vasilij Mikhilchuk, Ukraine, was elected as Chair of the meeting and Professor Cees Th. Smit Sibinga, Academic Institute IDTM, Netherlands, as Rapporteur.

The global picture of blood safety

The WHO integrated strategy for a safe, adequate, available and accessible blood supply (WHA28.72) (2) requires sustained interventions worldwide, according to the huge variation in needs that exists among and within regions. The global database for blood safety was developed to monitor progress and regularly update the dedicated strategic agenda. The analyses of data collected at regular intervals are carried out in accordance with the Human Development Index (HDI) of Member States. The analysis of the 2004 data (responses from 172 countries, representing 95% global population) showed that, although progress had been made (Fig. 1), there were still major discrepancies between low, medium and high HDI countries (Fig. 2).

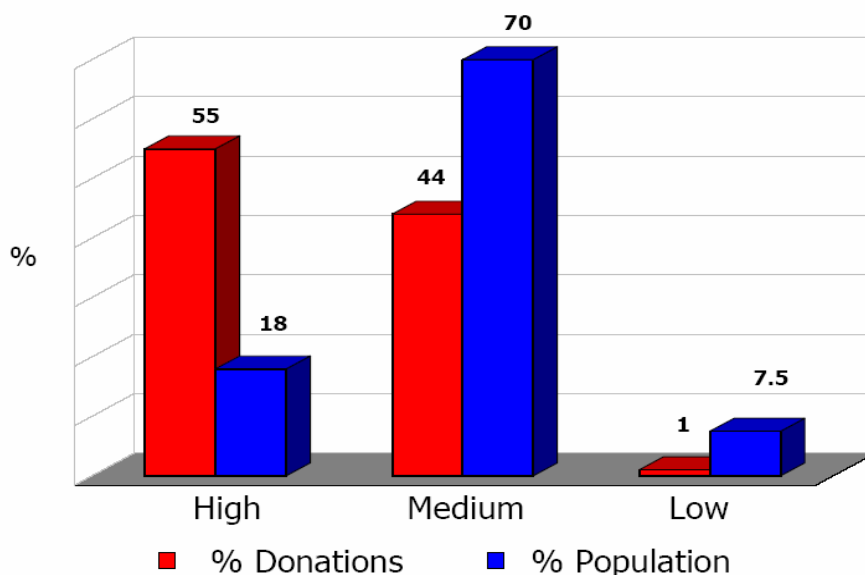
Fig. 1. Global blood supply



Source: WHO global database for blood safety, 2004.

Fig. 2. Global population and blood supply

Global Population and Blood Supply

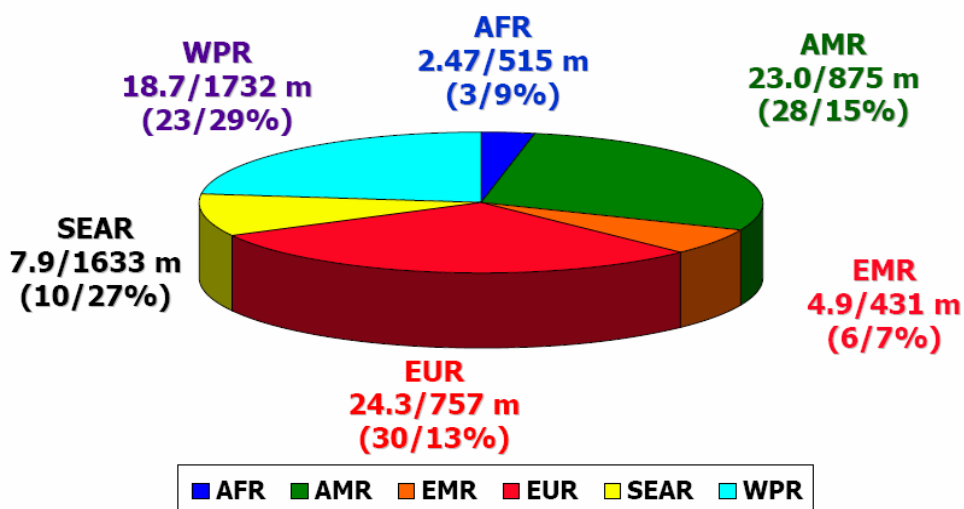


Source: WHO global database for blood safety, 2004.

Three aspects were considered in the presentation of data: needs, safety requirements and bedside transfusion. In terms of availability, there is still an important gap to be covered; in 77 out of 172 respondent countries donation rates are less than 1% (low HDI and partly medium HDI). The European Region appears to be the most advanced of the WHO regions. However, the aggregated figures do not reflect the wide variation of country profiles (Fig. 3).

Fig. 3. Regional blood supply versus population

Regional Blood Supply vs Population



Source: WHO global database for blood safety, 2004.

AFR: WHO African Region; AMR: WHO Region of the Americas; EMR: WHO Eastern Mediterranean Region
SEAR: WHO South-East Asia Region; WPR: WHO Western Pacific Region

The 2004 figures indicate a shift towards voluntary non-remunerated blood donors, with 47% of the global voluntary blood donations (VBD) coming to the global blood supply from low and medium HDI countries, compared to 27% in 2001. The need for continuous effort to increase and maintain VBD is highlighted by the decline in blood donations in 37 countries. An increase in testing completeness is also reported. However, the quality of processes is not always guaranteed. In 2004, 26 countries still reported that blood transfusion units were partly being issued without testing and that reagents and supplies were occasionally exhausted.

The use of haemovigilance as a safety monitoring tool is reported mostly by high HDI countries but this is not the case in most of those in the low HDI group. However the quantitative data do not give a true reflection of its implementation status or field function. The main challenges identified relate to making safe blood available: low donation rates, high discard rates, risks of transmission of infectious agents, limited traceability; fragmentation of services and approaches, and the underlined need for integration within health care services and sustainability. More information can be found at: www.who.int/bloodsafety and www.who.in/worldblooddonorday.

EU work in the field of blood safety

The EU regulations in the field of quality and safety standards for human substances were based on the following provisions of the Amsterdam Treaty (1997):

- Art 95 specifically regulating the internal market
 - Objective: free circulation → harmonization
 - e.g. Directive 2001/83/EC.

- Art 152 specifically directed to public health
 - Objective: health protection → minimum standards
 - e.g. Directive 2002/98/EC.

Current legislation focuses on substances of human origin, which comprise blood and blood components, cells, tissues and organs. EU Directive 2002/98/EC of the European Parliament and the Council of the European Union and its three EC directives – 2004/33, 2005/62 and 2005/62 – regulate the field of blood and blood components. EU Directive 2004/23/EC with two additional EC directives regulate the field of transplantation of tissues and cells. The results of the open consultation on policy options on organ donation and transplantations (2006) will be reported this year.

The transposition of these directives is in process in all 27 EU Member States. The paucity of guidelines, technical requirements, including traceability (haemovigilance), self-sufficiency and voluntary non-remunerated blood donors often results in local challenges. The EU supports the adaptation of the directives to local conditions with a certain degree of flexibility.

Work is carried out bearing in mind the interaction between pharmaceuticals and human substances. Collaborative work with international organizations, such as COE and WHO, is an important part of this process. The future trends might possibly lead to a 'human substances' legal framework.

The Technical Assistance and Information Exchange Institute (TAIEX) was set up to provide short-term technical assistance in applying and enforcing EU legislation in candidate and new EU Member States, as well as in countries included in the European Neighbourhood Policy <http://taiex.ec.europa.eu/>.

Within the EC Programme of community action in the field of public health 2003–2008, selected projects in the field of blood safety have been funded during the last three years (2005–2007). The priorities of the present Call for Proposals, which closed in May 2007, focus on the development of practical guides for risk assessment and validation methodologies, including the evaluation of different types of procedures and guideline production, as well as the promotion of voluntary non-remunerated blood donation. http://ec.europa.eu/phea/calls/call_for_proposals_en.html.

COE and EDQM contributions to the quality and safety of blood products

The COE has advocated the principles of public health protection and patient safety since 1956. These were subsequently developed and supported through international and inter-institutional partnerships.

The area of blood transfusion and transplantation services was transferred in 2007 to the EDQM and dedicated steering committees were created to continue the ongoing activities and their further development. Participation is open to all 37 Member States that are party to the European Pharmacopoeia Convention as well as to the Observer States. EDQM collaborates closely with EC DG SANCO and WHO in order to ensure complementarities of action and avoid duplication.

The programme of work aims to contribute to strengthening the blood safety agenda by promoting voluntary non-remunerated donations and implementing quality and safety standards for the collection of blood and blood components and their storage, distribution and use, and to propose ethical, safety and quality standards for professional practices. It is anticipated that training and networking will enhance the transfer of knowledge and that practices will be monitored for epidemiological risk assessment. The European Bank of Frozen Blood, which deals with rare blood groups, will continue to ensure the availability of rare blood products.

The regular publication and update of the COE *Guide to the preparation, use and quality assurance of blood components* will continue. This publication has become a technical reference used also outside the European Region (for example, in Australia, Canada, New Zealand, USA). The 14th edition is programmed for early 2008, while the 15th edition is expected to be fundamentally reorganized.

Within the EDQM, issues of blood derivatives are dealt with through the European Pharmacopoeia (special groups of experts on plasma derivatives developing the plasma derivatives monograph, standards for substances used in blood preparations, reference

substances of human origin, etc.), and the Official Medicines Control Laboratories (OMCL) network. They aim to promote the exchange of information, experiences and best practices, develop complementary synergistic strategies, and enhance communication and collaboration among the various stakeholders in order to avoid duplication and promote the better use of the available resources.

The overall goal is to enhance public health and patient safety by harmonizing the quality and safety standards for blood services through interaction with national and international partners (national health authorities, EC DG SANCO and WHO).

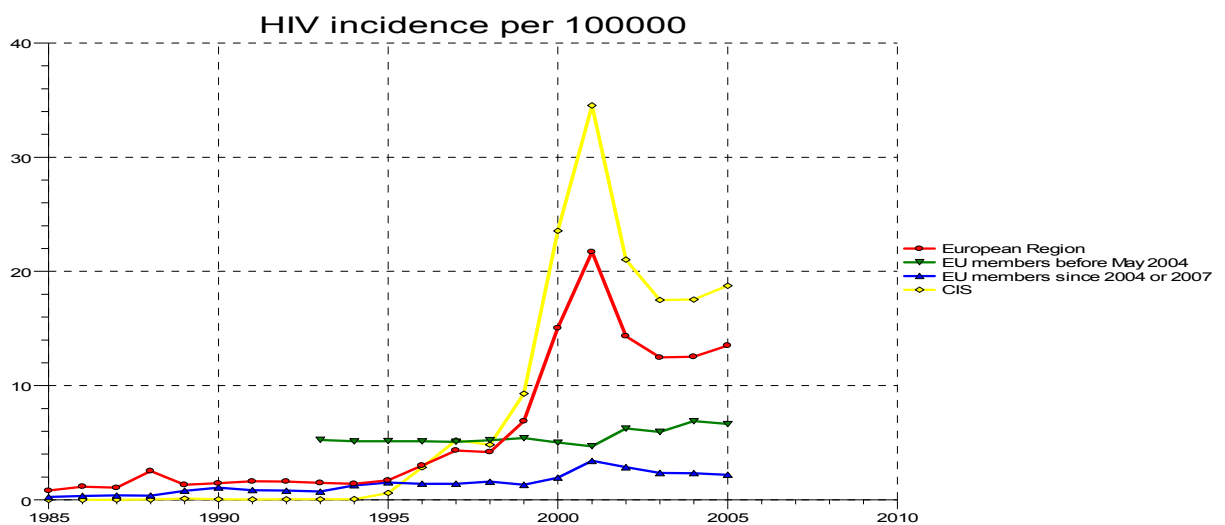
Blood safety in the WHO European region: current trends and emerging challenges

The WHO European Region comprises 53 Member States covering several time zones. The variations related to health system development and health care expenditure across the Region, as well as the underlying changes in the socio-political environment facilitating cross border movement, increase the challenges related to equitable access to and the quality of health care delivery.

The population of the WHO European Region remains steady in number but changes in structure, due to the low natural population growth rate (the lowest of the WHO Regions) and the overall increase in life expectancy.

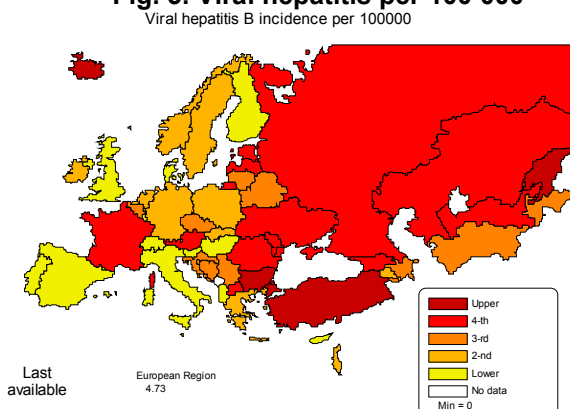
The HIV/AIDS epidemic continues to expand in the eastern part of the Region (Fig. 4) where high rates of viral hepatitis B and C and also recorded (Figs. 5 and 6).

Fig. 4. HIV incidence per 100 000



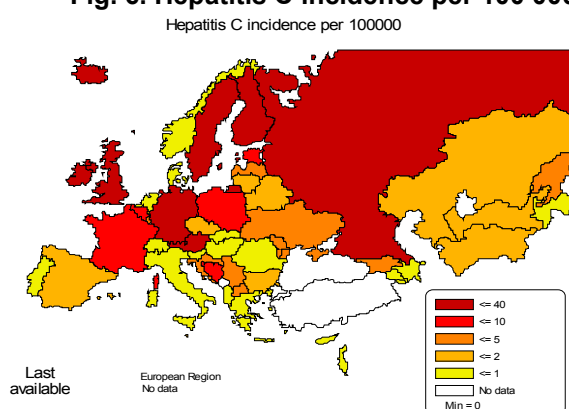
Source: HFA database 2007.

Fig. 5. Viral hepatitis per 100 000



Source: HFA database 2007.

Fig. 6. Hepatitis C incidence per 100 000



Source: HFA database 2007.

There are major discrepancies in the safety and adequacy of the blood supply with variations at regional, national or institutional levels. The status, organization and delivery capacity of the blood service are closely linked to the development of the national health system. Often, there is a lack of a consistent safety culture at individual and institutional levels due to limited communication between professionals, historically-based practices and weak pro-active risk assessment. Limited funds generate priority-setting challenges, mostly concerning the choice of technologies and interventions.

Donor availability varies considerably across the Region from <4 per 1000 to >40 per 1000 in the general population, as does the percentage of voluntary non-remunerated blood donations. The more the population is exposed to epidemiological threats, the greater the incidence of remunerated donations and the discard ratio of collected blood due to infectious diseases marker reactivity. The clinical use of blood is subject to the same variations in relation to the availability and choice of blood components and alternatives to transfusion.

The EC regulatory framework and the COE and WHO recommendations and technical documents promote sustainable, nationally-coordinated blood services that meet the health care demand equitably, when required, at minimum cost, with minimum wastage and with increased efficacy and strengthened patient safety. In further support of this work, both the first and second Global Patient Safety Challenges identified by the WHO World Alliance for Patient Safety include blood safety (*'Clean care is safer care'* – first challenge; *'Safe surgery saves lives'* – second challenge).

The need for enhanced cooperation and a coordinated strategy for action, the importance of cost-effectiveness in the provision of adequate safe blood supplies, and difficulties in developing and maintaining voluntary non-remunerated blood donations were already identified at the Regional meeting of directors of blood services in central and eastern Europe and the newly independent states in 2005.

The aging population, the epidemiological context and the constant advancement of medical technologies strongly impact the adequacy of and access to transfusion therapy.

To address issues identified at regional level, an integrated approach to strengthening blood services is proposed whereby interventions at various levels of prevention and care are interlinked. Three entry points are suggested: prevention, provision and evaluation, supported by regulation, research and education. This would encourage the formulation of strategic directions for action towards developing blood services according to national needs, using the health system perspective, and closely correlated to national morbidity profiles. At the same time, this would allow the promotion of regionally harmonized attitudes and practices based on shared information and scientific evidence.

Country presentations

A number of country representatives made presentations illustrating the current status of their national blood services and related developments in their countries.

Blood services reforms in Armenia, Georgia, Kyrgyzstan, Latvia, Russian Federation and Uzbekistan were outlined.

In connection with the promotion of safe blood donations, the first “Club 25” initiative in Europe (promotion of safe blood donation in young people) was successfully launched in Turkey.

Information was given on the progress made and the challenges met in implementing a national haemovigilance system in France, as well as on the recent merger between blood and transplantation services in the UNK.

Framework of the Social Cohesion Initiative: South-Eastern Europe (SEE) health development action – blood safety

The project, "Blood safety - increasing regional self-sufficiency in safer blood and blood components", was developed as a follow-up to the Dubrovnik Pledge (2005), which recognized blood safety as one of the seven health priority interventions required in the SEE Region. Romania took the lead in this project.

The long-term aim of the project is to contribute to regional self-sufficiency and to achieve mutual trust in the quality and safety of blood supplies in south-eastern Europe. It comprises two components:

Component one: Strengthening mutual trust and acceptability of the quality of blood in the SEE Region.

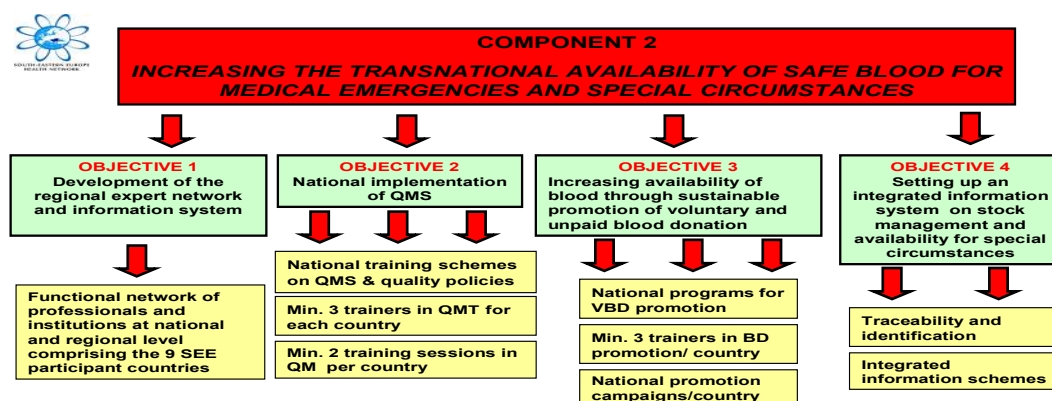
Component one has two objectives: 1) to develop national blood safety policies in line with the EU directives and international recommendations in the field; and 2) to increase the availability of blood and blood components through the sustainable promotion of voluntary non-remunerated blood donations. It was launched in June 2005 and closed in August 2006. The development of national blood policies in participating countries is considered one of its

main achievements. The team spirit and common operational tools developed during the implementation process contributed to setting up a professional network in the SEE Region to promote sharing of information and expertise. The identification of common ways of meeting comparable challenges and strengthening cooperation enhanced the confidence of the existing capacities and of their potential as driving forces for change.

Component two: Increasing the trans-national availability of safe blood for medical emergencies and special circumstances, as well as the availability of rare blood group donations.

The four objectives of this component are shown in Fig. 7 below. They focus on network development, the implementation of quality management systems (QMS), the sustained and sustainable promotion of voluntary non-remunerated blood donation and integrated information systems supporting improved traceability and stock management for special circumstances.

Fig. 7. Component 2: Increasing the trans-national availability of safe blood for medical emergencies and special circumstances



Source: SEE Health Network project on increasing regional self-sufficiency in blood and blood safety Component one, completion report, August 2006 (adapted).

QM: quality management; QMS: quality management systems; QMT: quality management training

The continuation of the SEE blood safety project through Component 2 is considered essential in order to consolidate existing achievements and maintain political recognition and professional commitment to this public health priority towards effective, reliable and sustainable blood services. Conversion of the SEE blood safety project into a continuous regional programme within the framework of the SEE Health Network could further enhance the functionality of its technical network.

Safety and security of supply of plasma and plasma products in the European Region

Plasma is a valuable resource and its collection and processing must strictly adhere to good manufacturing practices. Securing the supply of plasma products requires special strategies where the role of multi-stakeholders and partnership is essential. The availability and use of plasma derivatives varies in the European Region. The example of Factor VIII consumption (WHO essential medicines list) strictly relates to Gross National Product (GNP) (GNP>US\$ 10 000 use of 3.54 IU/capita; GNP US\$ 2000–US\$ 10 000 use of 0.82 IU/capita; GNP<US\$ 2000 use of 0.02 IU/capita) according to the World Federation of Haemophilia survey carried out in 2005.

General factors affecting source plasma and derivatives are the nature and availability of raw material, access to facilities and technologies, health hazards, precautionary measures and emergency situations and non-harmonized regulations. Out of 16 million litres of recovered plasma worldwide, 5.8 million litres are annually discarded. Reasons for this can be that the collected blood is not always separated into components, collection is often fragmented, the quality criteria of the plasma for fractionation are not fulfilled, local fractionation facilities are not available or obsolete, or there is no contract fractionation programme.

The quality and safety of plasma for fractionation is regulated in accordance with the EU blood directive, annex 14, the EU directive on good manufacturing practice (GMP), and the EMEA Plasma Master File Procedural Guidelines, as well as the recommendations of EDQM, the International Conference of Drug Regulation Authorities (ICDRA) and WHO in this area. The WHO recommendations on the production, control and regulation of human plasma for fractionation were issued in 2005 (<http://www.who.int/bloodproducts>). Several options can be chosen or combined, such as: purchase of plasma derivatives, external fractionation agreement of national plasma and local manufacture.

The practical impact of plasma collection for fractionation on the blood supply system must be carefully considered. This requires an increase in the percentage of voluntary regular donors, epidemiological follow up, the standardized collection of recovered plasma, the choice and range of test kits; the introduction of nucleic acid amplification technologies and the centralization of testing, adequate freezing and storage capacities, all supported by appropriate documentation, regular inspections and audits. Additionally, a sufficient volume of raw plasma must be available for the purpose with a view to cost-effectiveness and economies of scale.

The development and implementation of a comprehensive national blood supply system appropriately regulated and meeting basic international criteria for safety and quality are the prerequisites for action. Regional networks, partnership and stakeholders' consultations are essential tools for complementarity of action, as well as the advancement of the safety and availability of plasma and derivatives according to needs.

Major gaps and the need for action in the WHO European Region

In some Member States, cultural, socio-economic and historical circumstances have resulted in fragmented and uncoordinated blood services. Further impediments still encountered by many blood services include a lack of resources both in terms of financing and staffing, which now requires consolidation and stringent cost-efficiency measures, including appropriate infrastructure.

Participants were divided into three randomly selected groups (Annex 2) with a view to drafting regional strategic directions in the light of the issues and challenges identified during the country and regional presentations. The proposed integrated approach to strengthening blood services, using prevention, provision and evaluation as entry points, was submitted for discussion and brainstorming.

The main issues reported by the working groups are summarized below.

Working Group 1

In analyzing the various challenges encountered by those participating in the group, it was emphasized that a national **blood safety policy and a plan** comprise the first prerequisite for safe and sustainable blood services. The **key preventive activities** should focus on the appropriate use of blood, through various mechanisms, such as early diagnosis of underlying conditions, training of clinicians in the appropriate indications for transfusion therapy and blood salvage procedures.

Waste management, in particular biological waste, is an important preventative measure with respect to the protection of patients, health care workers and the environment (medical and non-medical).

In terms of the **appropriate provision** of safe blood and blood components, attention must be paid to ensuring the appropriate functioning of blood services on a national scale, through the centralization of specific activities and multi-stakeholder involvement. The importance of promotion strategies that enhance the quality and availability of safe blood donors – the primary source of blood – should be fully recognized.

A **general risk management process**, including appropriate communication strategies, was seen as an immediate practical step.

Working Group 2

Discussions focused on the major gaps and limitations encountered in various countries and the possibility of drawing a common line between the participating Member States. The following **main challenges** were identified as:

- the often weak coordinating mechanisms of the blood services on a local and national scale, or the absence of these;
- the low level or lack of compliance with various dedicated guidelines, particularly at the clinical site;

- the inadequate functioning of transfusion committees (resulting in their having a limited role in monitoring the use of blood and blood-related clinical performance).

In order to address the above, the **major needs** are:

- sharing of experience in using restructuring and reorganization mechanisms that are in line with European requirements;
- continuous education and training of health care professionals, as well as the enforcement of mechanisms for the implementation of dedicated guidelines;
- research in evidence-based interventions, trends in blood donation and blood substitutes.

It was emphasized that **sustained financing** is essential to support successful operational change and appropriate service delivery.

Working Group 3

The lack of adequate standardized procedures at various levels of the blood service, with particular emphasis on the clinical site, as well as the absence of mechanisms for enforcing their application, were identified as **major gaps and limitations** to be addressed.

The group stressed the **need for increased commitment to the issue of blood and patient safety**, which requires the following action: the appropriate sensitization of opinion leaders; harmonization of the supportive legal framework with the relevant international directives; increasing the attention given to logistics in the process of reform; and, last but not least, the education and training of the various levels of staff and stakeholders involved in the process.

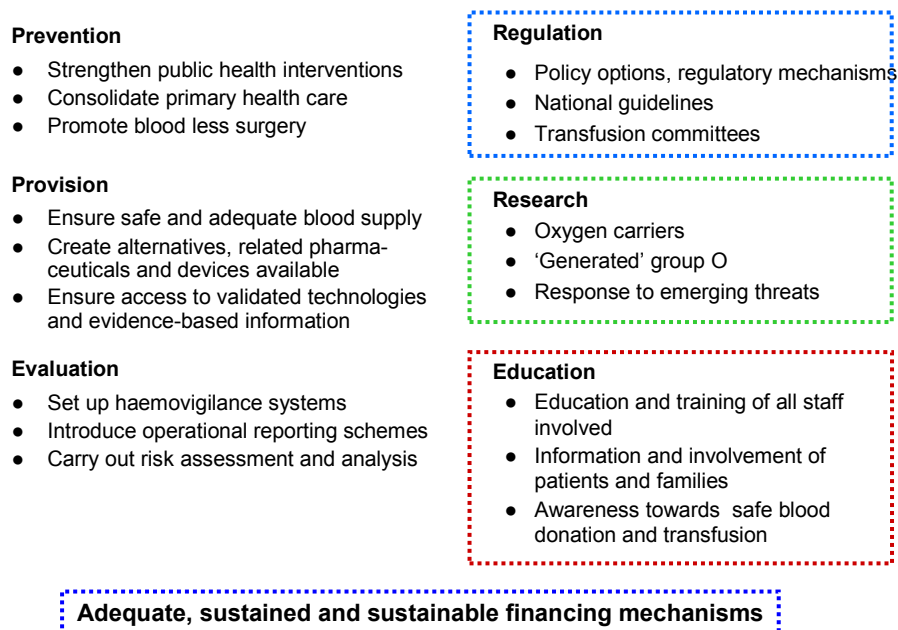
A **memorandum to Governments** was mentioned as a tool to increase awareness and promote recognition of the importance of strengthening the sustainability and safety of blood services through an integrated approach. The group recognized the role of the World Health Assembly resolutions on this issue, and that of the WHO Regional Committee in raising awareness of the importance of the quality, safety and availability of blood supplies.

Plenary discussions on the development of regional strategic directions for strengthening the quality, safety and availability of the blood supply through an integrated approach

The reports of the working groups were compiled using the following key words that emerged from the debate: consolidation, coordination, communication, cost-effectiveness, accountability. The plenary discussion was conducted according to a framework based on three integrated areas of action (Fig. 8):

1. prevention: links with public health programmes (primary and secondary levels of care);
2. provision: blood supply, pharmaceuticals (for example, alternatives to blood transfusion, iron supplements, EPO, etc.); devices, technologies and information;
3. evaluation of the system: haemovigilance systems, operational reporting schemes, risk assessment, risk analysis.

Fig. 8. Strengthening blood and patient safety



Political commitment was considered essential to the development and implementation of appropriate legal and regulatory measures and to securing adequate resources, including sustained financing, education and training (of decision makers, staff, patients, their families, and the population at large) and dedicated research.

Regional directions were developed under the following three main headings:

- Promoting and strengthening awareness on the importance of blood safety in health care;
- Capacity building;
- Monitoring and evaluation of the system.

Promoting and strengthening awareness of the importance of blood safety in health care

Policy level

- Promotion of the importance of political commitment and integrated sustainable strategies covering the blood chain and related interventions.
- Development/strengthening of dedicated blood policies and national blood programmes that provide a vision and action plan adapted to national circumstances.
- Protection of national resources through legislative and regulatory mechanisms.

Operational level

- Strengthening of primary health care and public health interventions.
- Addressing the community site.

- Addressing the clinical site: prevention of blood loss; use of blood (clinical indication, guidelines and enforcing mechanisms audits/ inspections); logistics of blood (handling of blood, optimization of stock management).
- Prevention of waste.
- Producing documentation and maintaining records (national databases).

Capacity building

Safe blood donors

- Relevant staff.
- Social marketing processes.

Education and training of staff (including decision-making levels)

- Training curricula.
- Availability and promotion of guidelines (ownership).

Provision of information

- Promotion of blood donation (public awareness).
- Purchasing community (tiered pricing).
- Documentation centre (web based); shared information through electronic portals.

Research

- Behavioural studies on donor motivation and retention.
- Clinical usage of blood (patterns and transfusion triggers).
- Alternatives to blood (for example, oxygen carriers, blood substitutes (e.g. Euro blood)).

Quality systems and related management systems

- Development and implementation based on recognized standards and requirements.

Partnership (national and international)

- Twinning programmes.
- Networking.
- International score cards.

Monitoring and evaluation of the system

Benchmarking

- Continuous SWOT (strengths, weaknesses, opportunities and threats) analysis of the system and comparison with national baselines and peers.

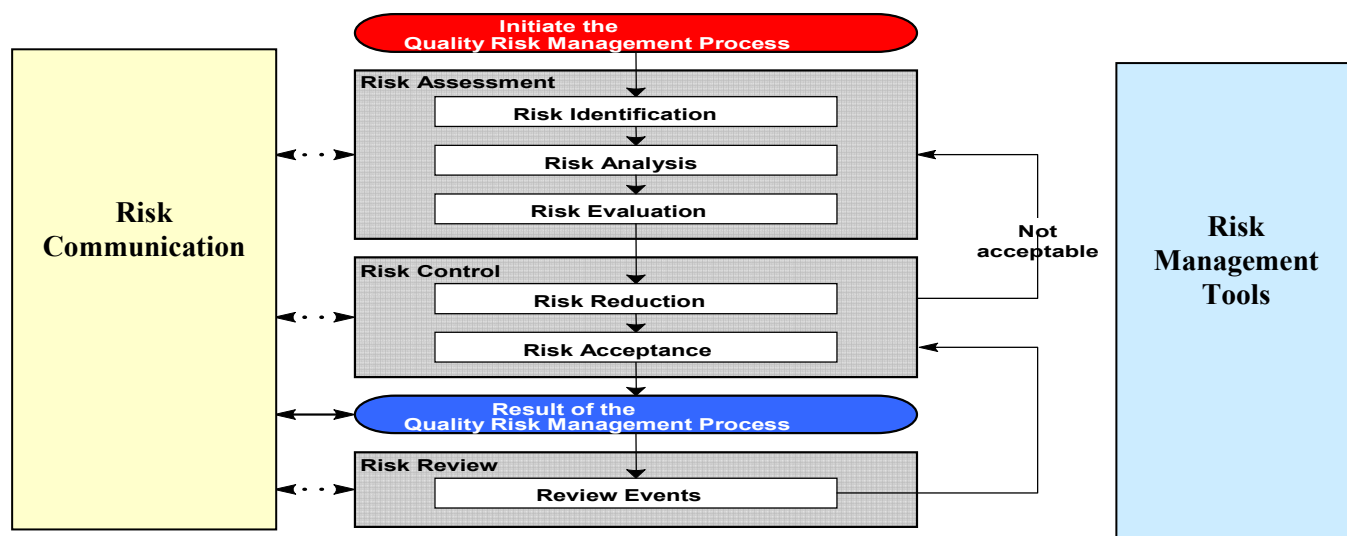
Harmonization of definitions and tools for data collection

- Strong logistic framework for a uniform reporting scheme.
- Compliance to standards through audits and inspections.

Haemovigilance

- Traceability, identification and notification of outcomes, including adverse events.
Risk analysis and risk management of the blood transfusion chain (based on an approach similar to Q9¹)
- Practical steps towards a general quality risk management process/team approach (Fig. 9).

Fig. 9. Quality risk management process



Continuous improvement

- Stepwise development of the system through management of change, using a stepwise approach including product, process, system and, ultimately, chain orientation:
 - a) Product orientation – the consistent outcome (quality control);
 - b) Process orientation – the number of procedures involved in producing the outcome (quality assurance);
 - c) System orientation – the various stakeholders involved in the process: suppliers, producers and customers;
 - d) Chain orientation – recognizing all stakeholders important for the total management of operations and output (total quality management).

Proposed immediate action:

- To formulate a memorandum to governments raising their awareness of the importance of addressing blood services through an integrated health system approach.
- To revise and bring the legal provisions in line with technological and managerial progress and support the promotion of action and sustainable development.

¹ Q9: quality risk management concept paper presented at the Sixth International Conference on Harmonization, Osaka, Japan, 12-15 November 2003.

- To strengthen networks, partnerships and information exchange through the development of twinning programmes, sharing success stories, and coordinating national and international stakeholders' action.

Concluding remarks

Blood safety contributes to the achievement of the UN millennium development goals 4, 5, 6 and 8². More than 20 years after the adoption of the first WHO dedicated resolution (WHA28.72) (2), important disparities remain unaddressed in the quality and efficiency of blood services and, subsequently, the availability and safety of blood supplies.

This is of particular concern in the context of the WHO European Region, considering its epidemiological background (HIV/AIDS, viral hepatitis B and C, tourism malaria, etc.), and the increasing differences between Member States with respect to access to and quality of health promotion and care, including blood services.

The extensive discussions held during the meeting, as well as various reports, have brought to light country-specific challenges connected with improving the safety and availability of blood supplies. However, a number of common issues also became evident in this respect, as well the need for an integrated approach to supporting blood service adequacy.

To ensure both the efficiency and the sustainability of required interventions, these must be seen in the larger context of the development of national health systems and in the light of national morbidity profiles and adjusted to the existing levels of development and health care structures in the countries. Strengthening primary health care interventions and addressing the clinical site (use and logistics of blood) at operational level are prevention measures with a direct impact on blood reserve management.

The current paucity of commitment to quality improvement at various levels of decision-making in some Member States calls for sustained advocacy to ensure that the appropriate level of support is given to blood services. Evidence-based information at the decision-making level and increasing public awareness are required in order to deal with the complexities and risks related to blood donation and transfusion.

The availability of blood supply is also challenged by the ageing population of the European Region and the high percentage of replacement donations on a regional scale. Concerted social marketing and promotion campaigns are needed to enhance access to reliable blood resources and to meet the demand.

Provision of updated information, relevant education and training schemes, as well as research programmes on, for example, behavioural studies, transfusion triggers, and blood

² The UN millennium development goals (MDGs) are eight goals to be achieved by 2015 that respond to the world's main development challenges, drawn from the actions and targets contained in the Millennium Declaration that was adopted by 189 nations and signed by 147 heads of state and governments during the UN Millennium Summit in September 2000. Blood safety contributes to MDGs: 4 – reduce child mortality; 5 – improve maternal health; 6 – combat HIV/AIDS, malaria and other diseases, 8 – global partnership for development

substitutes, are elements of the compulsory capacity-building process, which should be organized on a national level.

Monitoring and evaluation of the system are part of the continuous cycle of improvement. These urge for the harmonization of tools and definitions for data collection (including a uniform reporting scheme), proactive risk assessment, analysis and management of the blood transfusion chain.

Lastly, it is important to establish and strengthen networks of stakeholders with a view to information and knowledge sharing, which can translate into consistent advocacy, and improved practice.

Recommendations

To participants

- The information and knowledge gained during the meeting should be shared with Ministries of Health and other relevant institutions in the respective countries.
- Feedback should be provided to the WHO Regional Office on:
 1. the proposed regional strategic directions with respect to an integrated health system approach to strengthening blood safety and adequacy, in consultation with national stakeholders as appropriate;
 2. the status of quality policies, strategies and operational tools/indicators that are used at the national level for monitoring and evaluation of blood services.
- Further networking, information exchange and sharing of experiences in blood service delivery at international and national levels are encouraged.

To Member States

- Adequate priority should be given to the development of blood services using a nationally-coordinated approach that is integrated with the existing health care structures and interventions. Strengthened communication and appropriate resources (infrastructure, equipment and personnel) are seen as important cost-containment mechanisms.
- Support should be given to the development of national programmes for the promotion of voluntary, non-remunerated and regular blood donations and their connection with public health interventions (e.g. promotion of healthy lifestyle, addressing health determinants). World Blood Donor Day should be observed and supported as an opportunity to strengthen public awareness.
- Building on evidence-based practices and experiences is part of continuous professional development and, together with research in health sciences (e.g. novel technologies, blood substitutes), should be seen as an important prerequisite for strengthening the quality, safety and adequacy of the blood supply.

To WHO

- The importance of blood services and the need for an integrated approach within the overall structure and complexity of the national health system should be advocated at the highest level in Member States with a view to safe and adequate blood supplies

- Assistance in the development of dedicated training programmes and technical information, documents and tools in support of the capacity-building process should be provided for all levels of staff.
- Regional meetings for blood service directors should be organized on a regular basis to provide a forum for exchange of information and discussion, enable progress monitoring and evaluation, and enhance collaboration among national and international stakeholders and networking at regional level.

References

1. *Regional meeting of directors of blood services in central and eastern Europe and the newly independent states, Ljubljana, Slovenia, 21-23 April 2005. Report.* Copenhagen, WHO Regional Office for Europe, 2005.
2. Resolution WHA28.72. Utilization and supply of human blood and blood products. In: *Twenty-eighth World Health Assembly, Geneva, 13-30 May 1975. Handb. Res. Vol. I, 1.5.2.2; 8.2.4 Thirteenth plenary meeting, 29 May 1975 (Committee A, fourth report).* Geneva, World Health Organization, 1975 (<http://www.who.int/bloodsafety/en/WHA28.72.pdf>, accessed 20 August 2007).
3. Resolution WHA40.13. Development of guiding principles for human organ transplants. In: *Fortieth World Health Assembly, Geneva, 4-15 May 1987. Handb. Res. Vol. II (1985), 1.15.1 (Eleventh plenary meeting, 13 May 1987 – Committee B, first report).* Geneva, World Health Organization, 1987 (<http://www.who.int/transplantation/en/WHA40.13.pdf>, accessed 20 August 2007).

Annex 1

Programme

Monday 4 June 2007

- 08:30 – 09:00 Registration
- 09:00 – 09:20 Opening address
- 09:20 – 09:35 Objectives of the workshop
- 09:35 – 09:50 Election of Chair and Rapporteur
Introduction of participants
- 09:50 – 10:10 The global picture of blood safety (*Neelam Dhingra*)
- 10:10 – 10:30 Coffee break
- 10:30 – 10:50 EU work in the field of blood safety (*Thomas Brégeon*)
- 10:50 – 11:10 Council of Europe and EDQM contributions to quality and safety of blood products (*Jean Marc Spieser*)
- 11:10 – 11:30 Blood safety in the WHO European region: current trends and emerging challenges (*Valentina Hafner*)
- 11:30 – 12:00 Discussions
- 12:00 – 13:00 Lunch
- Presentations from participant countries
The allotted time includes 10 minutes for discussions after each presentation
- 13:00 – 13:25 Blood services in Kyrgyzstan (*Sagynbek Abazbekov*)
- 13:25 – 13:50 Blood services in Latvia (*Gita Nemceva*)
- 14:15 – 14:40 The experience of ‘Club 25’ in promoting safe blood donation in Turkey (*Yusuf Emre Ak*)
- 14:40 – 15:00 Blood services in the Russian Federation (*Natalya Markarian, Evgeniy Selivanov*)
- 15:00 – 15:30 Coffee break
- 15:30 – 16:00 Haemovigilance and traceability along the blood chain – the French experience (*Olivier Nasr*)
- 16:00 – 16:25 Blood services in Armenia (*Smbat Daghbashyan*)
- 16:25 – 16:50 The merger of blood and transplantation services in the UK (*Steve Morgan*)
- 16:50 – 17:20 Blood services in Georgia (*Rola Shavlakadze*)
- 17:20 – 17:40 Blood services in Uzbekistan (*Khamid Yakubovich Karimov*)
- 17:45 Conclusions and closure of day 1

Tuesday 5 June 2007

- 09:00 – 09:10 Summary of day 1
- 09:10 – 09:40 Framework of the Social Cohesion Initiative:
SEE health development action - blood safety (*Alina Mirella Dobrota*)
- 09:40 – 10:00 Safety and security of supply of plasma and plasma products in Europe
(*Theo Evers*)
- 10:00 – 10:30 Coffee break
- 10:30 – 12:00 Major gaps and need for action in the WHO European region – group work
- 12:00 – 13:00 Lunch
- 13:00 – 14:00 Identifying common priorities and levels of intervention: reports from
working groups
- 14:00 – 15:00 Strategic lines of action at regional level, embedded in health systems
framework – plenary discussion
- 15:00 – 15:30 Coffee break
- 15:30 – 16:30 Strategic lines of action at regional level, enhanced communication and
supportive mechanisms – plenary discussion
- 16:30 – 17:30 Conclusions and recommendations
- 17:30 Closure of the meeting

Annex 2

Composition of the working groups

GROUP 1	GROUP 2	GROUP 3
Facilitator: Albania Rapporteur: United Kingdom Interpreter: G. Pignasty	Facilitator: Netherlands Rapporteur: Slovakia	Facilitator: Russian Federation Rapporteur: Portugal Interpreter: V. Illyukhin
Armenia	Belarus	Azerbaijan
Austria	Croatia	Belgium
Bosnia and Herzegovina	Denmark	Bulgaria
Cyprus	Germany	Estonia
Finland	Greece	France
Georgia	Hungary	Kazakhstan
Ireland	Lithuania	Kyrgyzstan
Latvia	Luxembourg	Montenegro
Malta	Norway	Republic of Moldova
Poland	Romania	Slovenia
Tajikistan	Serbia	Sweden
Turkmenistan	Spain	Switzerland
Uzbekistan	The former Yugoslav Republic of Macedonia	Turkey
		Ukraine

Annex 3

Participants

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