

2008 Report

# The Collection, Testing and Use of Blood and Blood Components in Europe

European Committee (Partial Agreement)  
on Blood Transfusion (CD-P-TS)

Give  
blood





# **The Collection, Testing and Use of Blood and Blood Components in Europe**

## **2008 Report**

C.L. van der Poel, MD, PhD<sup>1</sup>, M.P. Janssen, PhD<sup>1</sup> and M.-E. Behr-Gross, PhD<sup>2</sup>

1. Julius Center for Health Sciences and Primary Care, University Utrecht, Utrecht, The Netherlands

2. European Directorate for the Quality of Medicines and HealthCare, Council of Europe, Strasbourg, France

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*For further information concerning the work of the Council of Europe / EDQM in the area of blood transfusion please contact:*

Dr Marie-Emmanuelle Behr-Gross  
Department of Biological Standardisation, OMCL Network & HealthCare  
European Directorate for the Quality of Medicines and HealthCare (EDQM)  
Council of Europe  
7 allée Kastner, CS 30026  
F - 67081 STRASBOURG  
FRANCE  
tel: +33 (0)3 90 21 41 08  
fax: +33 (0)3 88 41 27 71  
E-mail: [marie-emmanuelle.behr-gross@edqm.eu](mailto:marie-emmanuelle.behr-gross@edqm.eu)

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# SUMMARY

This report provides data on the donors, collection, testing, use and quality aspects of blood and blood components in Member States (MS) of the Council of Europe (CoE). Data were supplied by MS in response to a questionnaire requesting detailed information on donors, collections, testing, distribution and quality aspects of blood and blood components for the year 2008. In its present form it follows a series of similar reports that have assessed such data in 1989, 1991, 1993, 1995, 1997 and, in its present revised form, as of the 2001 survey.

A Qualitative Evaluation Report on the questionnaire with recommendations for improvement of the process was performed and was reported in November 2004, including experience with data presentation from the 3 previous years. The format of the questionnaire was reviewed and re-designed by the authors and the CoE experts of the Committee of Experts on Quality Assurance in Blood Transfusion Services (SP-GS) and the Committee of Experts on Blood Transfusion (SP-HM) bureau in 2004.

Also, in 2008 as for former years, not all relevant data was obtained from each MS. Due to difficulties in implementation of data retrieval from automated blood banking systems, and the collation of data from many blood establishments (BE) on a national level within the MS, the process is designed so that annual repetition will lead to improvements.

In contrast to surveys for the years 2003 and earlier, the proportion of donations by voluntary non-remunerated and replacement donors was requested as of the 2004 questionnaire. The European Commission (EC) has acknowledged its importance of this information in its *Directive 2002/98/EC*.

In MS and in BE, data may be administered in different formats, and different definitions may have been operational. This could result in discrepancies if data is reported in different formats. In addition, some data may not be available from all respondents. It is anticipated that consistency and persistence with these CoE survey methods, in collaboration with the EC, will result in adaptation of the BE and MS towards uniform data collecting, and thereby the generation of better data and higher response rates among MS, when the questionnaires are used annually. In order to facilitate uniformity, definitions of the EC Directives and CoE Guidelines are used as far as possible (*Council Recommendation 98/463/EC, Directive 2002/98/EC, Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components, 9<sup>th</sup> edition, 2003*). In addition, it is to be welcomed that the European Medicines Agency (EMA) employs the same definitions, especially on infectious disease epidemiology in donor populations (*Guideline on Epidemiological data on Blood Transmissible Infections for inclusion in the Guideline on the Scientific Data Requirements for a Plasma Master File EMEA/CPMP/BWP/3794/03*). Uniformity of such definitions is of importance to the field, and circumvents unnecessary and costly repetitions in collating data.

In total, 33 questionnaires were received in 2008; the response rate (72%) is lower than previous years, despite the fact that an easier (web-based) system for data entry has been established. For the 2001 to 2007 surveys the response rates were 84%, 60%, 67%, 73%, 72%, 80% and 76%, respectively.

The average number of donors in relation to the general population is 29 (range 9-63) per 1000 inhabitants. On average 19% of the donor base consists of first time donors.

The number of whole blood (WB) collections is, on average, 39 per 1000 inhabitants, the average use of red blood cells (RBC) is 41 per 1000 inhabitants.

On average 2.6 litres (L) of plasmapheresis plasma per 1000 inhabitants are collected.

Blood use is either expressed in units issued by the BE (77% of the reporting MS), or reported as transfused units (23% of the reporting MS). The use of RBC varies considerably (range 9 - 60) and averages 41 total RBC Units (U) per 1000 inhabitants. In three of the reporting MS, less than 20 U per 1000 inhabitants are used, most likely reflecting an insufficient supply. In the reporting MS, on average 38% of the total platelet volume is supplied by (random) single donor platelets by apheresis; in 10 countries this volume amounts to more than 50%.

The amount of plasma delivered for fractionation into medicinal products differs greatly (range 0-31) among MS; an average yield of 8.2 L of plasma for fractionation per 1000 inhabitants is found. However, 17% of reporting MS deliver 15 L or more per 1000 inhabitants. In Europe, on average, 51% of the plasma for fractionation is from recovered plasma.

In 45% of the MS, 100% leucocyte depletion of RBC is carried out. Platelet concentrates and Fresh Frozen Plasma (FFP) are 100% leucocyte depleted in 55% and 33% of reporting MS, respectively. In 38% of the reporting MS all FFP is additionally safeguarded by either quarantine or pathogen reduction methods.

In all reporting MS, each donation is tested for anti-HIV-1/2, HBsAg and anti-HCV. In 91% of the reporting MS, all donations are tested for syphilis. Anti-HTLV-I/II testing is performed on all donations in 20% of reporting MS, and on first time donors in 7%. Anti-HBc is performed on all donations in 21% of the MS, and only on first time donors in another 14%. Prevalence and incidence of infectious diseases vary greatly among MS, and it is noted that in Europe a North-South gradient exists for the frequencies of hepatitis B (HBV) and C virus (HCV). The median prevalence amongst 'first time tested donors' is 6.9, 115 and 63 per 100 000 donors for HIV-1/2, HBV and HCV respectively. The median incidence amongst 'repeat donors' is 0.6, 1.7 and 2.0 per 100 000 donor years for HIV-1/2, HBV and HCV respectively.

Nucleic Acid Amplification Techniques (NAT) testing for HCV is performed on each donation in 57% of reporting MS, whereas HIV NAT and HBV NAT is performed on each donation in 59% and 36% of the MS, respectively.

Bacterial screening on platelet concentrates is performed in 73% of the MS. Screening of 80% or more of the platelet concentrates is performed in 21% of the MS. Haemovigilance data have repeatedly demonstrated the importance of bacterial safety for platelet concentrates.

All MS report that legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components are in place. In 76% of the reporting MS a National Council or Expert Committee to advise the Ministry of Health on transfusion-related policy issues exists. In 80% of the MS, a national blood policy on the quality and safety of blood and blood components is in place.

In 91 % of the reporting MS, a Quality System (QS) is established and maintained in BE. All donations are covered by ISBT, GMP or other procedures in 83% (25/30) of reporting MS. All donations are covered by Good Manufacturing Practices (GMP) in 20/24 MS reporting to have GMP. In 94% of the reporting MS, inspections are performed by the national authority at least every 2 years.

Labelling according to International Society for Blood Transfusion (ISBT)-128 or other procedures for donation tracking is performed by 87% of reporting MS. Labelling of all components by either ISBT 128 or another system is done by 86% of reporting MS.

Haemovigilance reporting in this survey began in 2004. The format for data acquisition on haemovigilance for the 2004 CoE questionnaire, in its basic form, was developed in collaboration with the CoE, experts and EC and adapted into *Directive 2005/61/EC*. In this report only those serious adverse reactions are presented that are probably or certainly (imputability grade 2 to 3) ascribable to transfusion of blood products, and data on some conditions that are not caused by these products themselves, such as TACO (Transfusion Associated Circulatory Overload), are

also reported. A national haemovigilance reporting system is present in 88% of the MS. Taking into account the possibility of under-reporting and the differences in national reporting systems, an overall incidence of approximately 6.9 serious adverse reactions per 100 000 distributed blood components is estimated. This estimate is based on data provided by 23 MS. Haemolysis, anaphylaxis, Transfusion Related Acute Lung Injury (TRALI) and TACO and transfusion associated HCV infections appear to be the most frequent serious adverse reactions.

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# LIST OF ABBREVIATIONS

|                      |                                                                                                     |
|----------------------|-----------------------------------------------------------------------------------------------------|
| <b>Ag</b>            | Antigen                                                                                             |
| <b>ALT</b>           | Alteplase testing                                                                                   |
| <b>BE</b>            | Blood Establishments                                                                                |
| <b>CD-P-TS</b>       | European Committee (Partial Agreement) on Blood Transfusion                                         |
| <b>CI</b>            | Confidence Intervals                                                                                |
| <b>CP</b>            | Cryoprecipitate                                                                                     |
| <b>CSP</b>           | Cryosupernatant Plasma                                                                              |
| <b>CMV</b>           | Cytomegalovirus                                                                                     |
| <b>CoE</b>           | Council of Europe                                                                                   |
| <b>EC</b>            | European Commission                                                                                 |
| <b>EDQM</b>          | European Directorate for the Quality of Medicines and HealthCare                                    |
| <b>ELISA</b>         | Enzyme-Linked Immunosorbent Assay                                                                   |
| <b>EMA</b>           | European Medicines Agency                                                                           |
| <b>EU</b>            | European Union                                                                                      |
| <b>FFP</b>           | Fresh Frozen Plasma                                                                                 |
| <b>FTA</b>           | Fluorescent Treponemal Antibody                                                                     |
| <b>FVIII</b>         | Factor VIII                                                                                         |
| <b>FYR Macedonia</b> | The former Yugoslav Republic of Macedonia                                                           |
| <b>GMP</b>           | Good Manufacturing Practice                                                                         |
| <b>GTS</b>           | Ad hoc working group on the guide to the preparation, use and quality assurance of blood components |
| <b>GVHD</b>          | Graft-Versus Host Disease                                                                           |
| <b>HBc</b>           | Hepatitis B core antigen                                                                            |
| <b>HBsAg</b>         | Hepatitis B surface Antigen                                                                         |
| <b>HBV</b>           | Hepatitis B Virus                                                                                   |
| <b>HCV</b>           | Hepatitis C Virus                                                                                   |
| <b>HIV</b>           | Human Immunodeficiency Virus                                                                        |
| <b>HLA</b>           | Human Leucocyte Antigen                                                                             |
| <b>HPA</b>           | Human Platelet Antigen                                                                              |
| <b>HTLV</b>          | Human T cell Lymphotropic Virus                                                                     |
| <b>IDM</b>           | Infectious Disease Markers                                                                          |
| <b>ISBT</b>          | International Society for Blood Transfusion                                                         |
| <b>IU</b>            | International Unit                                                                                  |
| <b>L</b>             | Litres                                                                                              |
| <b>MB</b>            | Methylene Blue                                                                                      |

|                 |                                                                         |
|-----------------|-------------------------------------------------------------------------|
| <b>MS</b>       | Member States of the Council of Europe                                  |
| <b>NAT</b>      | Nucleic Acid Amplification Techniques                                   |
| <b>PABD</b>     | Pre-operative Autologous Blood Donation                                 |
| <b>Ph. Eur.</b> | European Pharmacopoeia                                                  |
| <b>QA</b>       | Quality Assurance                                                       |
| <b>QC</b>       | Quality Control                                                         |
| <b>QMS</b>      | Quality Management System                                               |
| <b>QS</b>       | Quality System                                                          |
| <b>RBC</b>      | Red Blood Cells                                                         |
| <b>SD</b>       | Solvent Detergent                                                       |
| <b>SP-GS</b>    | Committee of Experts on Quality Assurance in Blood Transfusion Services |
| <b>SP-HM</b>    | Committee of Experts on Blood Transfusion                               |
| <b>TA</b>       | Transfusion Associated                                                  |
| <b>TACO</b>     | Transfusion Associated Circulatory Overload                             |
| <b>TRALI</b>    | Transfusion Related Acute Lung Injury                                   |
| <b>TTP</b>      | Thrombotic Thrombocytopenic Purpura                                     |
| <b>U</b>        | Unit                                                                    |
| <b>vCJD</b>     | Variant Creutzfeldt-Jakob disease                                       |
| <b>WB</b>       | Whole Blood                                                             |
| <b>WHO</b>      | World Health Organisation                                               |

# STUDY METHODS

The methods in this survey are, in principle, the same as those used in previous surveys, with the following modifications. As of the 2007 survey, a dedicated web-based application was developed for performing data collection. Each MS nominated an expert who was granted access to the website and could complete, repeatedly edit and, thereafter, finalise an on-line electronic datasheet for its respective MS. Data collection was completed on 1 November 2010. This report was presented in a draft form to the European Committee (Partial Agreement) on Blood Transfusion (CD-P-TS) in November 2010 for review and approval by MS representatives.

## **Trend analysis**

Comparisons with results from the previous surveys and trend analyses are foreseen. Initial trend analyses have been published (van der Poel *et al*, 2011) and comprised questionnaire data from 2001 through to 2005. Not all information requested in the Questionnaire is included in the tables reported, but these provide detail where sufficient information is available to justify presentation. Occasionally totals in the tables may not precisely match the contributing figures because of rounding. It was assumed that information was not available when information was not provided. The absence of a response is represented by empty fields in the tables.

## **Remarks to the data**

It remains the responsibility of the MS that the data reported in the questionnaires has been checked against the tables provided in the draft versions of this report.

With the launch of the web-posted questionnaire, which was set-up for collecting the data for 2007 and later surveys, the risk of errors by transcription of the data by the authors has been eliminated.

# RESULTS

## Response rate

The 46 MS of the Council of Europe (CoE) were invited to participate in the 2008 survey. Replies were received at the deadline for submission on 1 November 2010 from 33 MS; a response rate of 72%. For the 2001 to 2007 surveys, the response rates were 84%, 60%, 67%, 73%, 72%, 80% and 76%, respectively. It is possible that the longer period between the beginning and end of data collecting allowed more MS to report. It was also reported to the authors that changing blood supply systems and mergers of blood establishments (BE) hindered the process of data collection.

## Donors, first time donors and inhabitants: Table 1

The questionnaire requires data on donors ‘active during the year’, and therefore should include only those donors who actually donated during the reporting year. However, the definition ‘donors active during the year’ may require a precise query on a given donor database. In many establishments or countries, the query format on the donor database would need to be compliant. This may not always be possible. Therefore, it is not certain whether this requirement was always met in generating the data for this survey. Definitions have been largely addressed by the *European Commission (EC) Council Recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the EC (98/463/EC)*.

The terms ‘regular and repeat donors’ are defined by the EC Council Recommendation (98/463/ EC) and these definitions apply to regular donors (i.e. donors whose last previous donation was less than 2 reporting years earlier) and for repeat donors (i.e. donors whose last previous donation was more than 2 reporting years earlier). The total of the two categories represents those donors, who are known to the system or establishment and in many countries form the basis and guarantee of continuity of the blood supply. These data are needed for the calculation of the prevalence of infectious diseases among new donors and the incidence of infectious diseases among repeat and regular donors (see Table 7). For EU countries, the reporting of prevalence and incidence on these donor populations became mandatory in 2005 as of *Directive 2002/98/EC*.

In this survey, the term ‘first time tested donors’ includes all donors who are actually tested for the first time in the reporting year. ‘First time donors’ includes all donors who donated for the first time in the reporting year. There are systems where ‘applicant donors’ (98/463/ EC) are only tested, and come back for a first donation later. They become known as ‘qualified donors’ when their applicant donor infectious disease tests are returned negative. Including only ‘qualified donors’ in the report will generate bias in reporting Infectious Disease Markers (IDM) (see Table 7). The term ‘new donors’ in *Council Recommendation 98/463/EC* does not specify this and allows for the exclusion of ‘non-qualified donors’. Therefore, in this survey, the term ‘first time tested donors’ is used to include all donors who actually are tested for the first time, either at the time of donation or through pre-donation screening.

It should be taken into account that ‘first time donors’ are already a selected population and therefore the prevalence of infectious diseases markers in the general population of a given MS may be different. The ratio of first time donors to the total number of donors in general reflects the annual donor recruitment or, more generally, the turn-over rate in the donor base. This figure may, however, be influenced by recruitment programs. The number of first time donors, as compared to the total number of donors, becomes less meaningful in systems that only register donations and, less so, the uniquely identifiable donors themselves.

Excluding the 13 MS where first time donors and repeat plus regular donors were not reported separately, 19 % (range 7-53) of the total donor base consists of 'first time' donors. It is known that first time donors may have higher incidences of infectious diseases as compared to regular or repeat donors (Schreiber *et al.*, 2001) and that higher incidence translates into an enhanced risk of donations being released with undetected viraemia.

The average number of donors in relation to the general population is 29 (range 9-63) per 1000 inhabitants. This number may reflect the commitment of the population to donate blood in relation to the demand. Differences exist but, arbitrarily, less than 10 donors per 1000 inhabitants should pose a problem with supply and around 30 donors per 1000 inhabitants seems an achievable goal from the given data. Not all countries with a relatively high number of donors per 1000 inhabitants deliver high numbers of red blood cell (RBC) Units (U) to hospitals (see Table 3), but in general these figures are related. As stated before, some caution as to the interpretation of the number of 'active' donors seems justified, and bias may occur by 'inactive' donors in the database. However, maintaining 'inactive' donors in the database may be a strategy to 're-activate' known donors.

## **Profile of donations: Table 1.1**

The relative contribution of voluntary non-remunerated donations to the supply is given in Table 1.1.

## **Collection of whole blood, autologous blood and blood components: Table 2**

- **Whole blood**

Whole Blood (WB) collections are the basis of the blood supply in most countries, not only for the preparation of blood components, but also for the delivery of 'recovered plasma' as source material for the manufacture of medicinal products (see Table 3). The number of WB collections in 28 reporting MS, is on average 39 (range 9-64) per 1000 inhabitants. Given the average use of RBC of 41 (range 9-60) per 1000 inhabitants (see Table 3), the number of WB donations collected appears to either conform to the demand for RBC components or determines their use in hospitals by limiting supply. It is noteworthy that the average use of RBC is slightly higher than the average of WB collections. This is due to the fact that a number of countries with a relatively low number of collections did not provide data on RBC use. For countries that provided numbers for both collection and RBC use, the latter is on average 4% lower than the number of units collected per 1000 inhabitants.

- **Autologous blood**

Autologous donations have been promoted in relation to safe blood transfusions by limiting exposure to allogeneic blood for patients and also with the purpose of enhancing the supply of blood. In general the factor of enhancing supply appears not to be significant: in 29 countries where autologous donations are given, they contribute on average around 0.5% (range 0-4%) to the WB donations. This is in agreement with the literature and previous reporting. However it should be taken into account that surgery and anaesthesiology techniques, such as pre-operative hemodilution and intra-operative blood salvage are not included in the presented data. In this survey only pre-operative autologous blood donations (PABD) are taken into account.

- **Blood components (Apheresis)**

Plasmapheresis collections provide source plasma, including plasma with specific antibodies, for fractionation into medicinal products. In some countries plasma for transfusion referred

to as Fresh Frozen Plasma (FFP) is also collected by apheresis donations. The volume of plasma collection by apheresis per 1000 inhabitants reflects the volume of the national plasmapheresis programs. In 31 reporting MS, on average 2.6 litres (L) (range 0-20L) of plasma per 1000 inhabitants is collected by plasmapheresis. Apparently, the Czech Republic, Germany and The Netherlands stand out as countries with considerably more extensive plasmapheresis programmes, with about 10 L or more of plasmapheresis plasma per 1000 inhabitants per annum.

Platelet apheresis may be aimed at Human Leucocyte Antigen (HLA) or Human Platelet Antigen (HPA) typed donations for refractory patients, as well as to replace the provision of platelets from pooled WB donations by apheresis platelets in order to reduce donor exposure in patients. The relative importance of platelet apheresis for the total supply of platelet products is given in Table 3. In 24 reporting MS, on average 38 % (range 0-93%) of the adult therapeutic doses of platelets are produced by apheresis. The extremes may reflect different models: low access to HLA typed platelet donors or MS striving towards 100% platelet supply by apheresis.

RBC apheresis is a relatively new development and may be of particular interest for autologous programmes, and for collections of rare types of RBC donors. It appears to be increasingly used for supply reasons.

Granulocyte apheresis donations are infrequent, as indications appear to be limited.

## Use of blood and blood components for transfusion: Table 3

The term ‘the use of blood’ may be somewhat misleading as the reported data may not reflect the actual use of blood or blood components in the hospitals, but rather the number of blood components that have been delivered to hospitals by BE. This depends on the source of the data and the national infrastructure. Data on the use in hospitals are generally difficult to obtain in many MS, however in some countries such as Denmark, blood banks are hospital based and the data are related to actual transfusions issued. As component losses in hospitals are limited, for example by exceeding expiry dates, the number of blood components delivered to hospitals represents an acceptable proxy to the blood use estimate, and the heterogeneity of the given data may result in only minor deviations.

In 24 / 31 (77%) reporting MS, the use of blood is expressed as the units distributed by the blood establishments, in 7 it is reported as transfused units, and 2 MS have not reported this information.

WB must be considered as a source material and has no, or only a very restricted, use in transfusion therapy (*Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components, 8<sup>th</sup> edition, 2001*). However in countries with limited resources transfusion therapy with WB may be needed when the infrastructure for blood component preparation is lacking. In 22 reporting countries, on average 2.2% (range 0-50%) of the RBC transfusions are performed with WB. In the Former Yugoslavian Republic of Macedonia, the use of WB accounts for more than half of the total volume of RBC products used.

The use of RBC per 1000 inhabitants varies considerably. In 22 reporting MS it averages 41 total RBC products per 1000 inhabitants (range 9-60). Rejman (2000) suggested in his report on the 1997 survey that 40 – 60 WB donations per 1000 inhabitants would be needed for optimal supply, a figure largely driven by the need for RBC for transfusion. Apparently the use of RBC has been greatly reduced in the last decade. RBC’s are mainly used in surgery, obstetrics, haematology and oncology care, and in some countries programmes for ‘better use of blood’ or for ‘optimal use of blood’ have recently been established in order to reduce unnecessary donor exposure to patients. Therefore, the use of 30 to 40 RBC U per 1000 inhabitants could reflect the results of



these programmes. In 3 / 24 (13%) of the reporting MS, less than 20 units per 1000 inhabitants are used, most likely reflecting insufficient supply of blood or limited hospital care. A better benchmark may be achieved by including the number of hospital beds in a future survey, and to relate this figure to RBC use.

The use of plasma for transfusion (FFP) has been discouraged over the last decade, mainly because its clinical indications are limited and more plasma was needed as source material for fractionation into medicinal products. However, with multiple coagulation disorders, including Thrombotic Thrombocytopenic Purpura (TTP), FFP transfusions are needed. In order to provide a benchmark, the use of plasma for transfusion can be related to the use of RBC transfusions (use of FFP/RBC ratio). It should be taken into account that, in the programmes for 'better use of blood' (e.g. RBC) in some countries, the decline of RBC use increased the FFP/RBC ratio. On average the FFP/RBC ratio is 0.34 (range 0.005-1, Table 4).

In Europe, platelets are generally recovered from 4-5 buffy-coats of WB donations. Discussions on blood safety in relation to Variant Creutzfeldt-Jakob disease (vCJD) have inspired programmes to enhance the use of random single-donor platelets by apheresis in order to reduce donor exposure to recipients. These programmes may have been influential in some MS where the use of apheresis platelets in relation to recovered platelets is relatively high. The extent to which donors are willing to undergo apheresis may be limited, as no supply reaches 100% apheresis platelets. On average in 29 reporting MS, 38% (range 0-93%) of the adult therapeutic doses of platelets are produced by (random) single donor platelets by apheresis (Table 3). In 10 countries this volume amounts to more than 50%.

Cryoprecipitate may incidentally be used for fibrinogen, Von Willebrand's disease, and complex coagulation disorders. This product has largely been abandoned by most MS.

## **Plasma for fractionation: Table 4**

The total amount of plasma issued for fractionation into medicinal products differs among MS. This becomes clearer if the figure is related to the population size. In 25 reporting MS, an average yield of 8.2 L (range 0-31 L) per 1000 inhabitants is found of plasma for fractionation into medicinal products. However, 5 / 30 (17%) of reporting MS deliver 15 L or more plasma per 1000 inhabitants.

In Europe, the main supply of plasma for fractionation is recovered plasma; in 17 reporting MS, on average 51% of the plasma for fractionation is from recovered plasma (range 0-100%).

Apart from a query on the total yield of plasma for fractionation, the questionnaire encompasses two specific questions on plasma delivered for factor VIII (FVIII) production *versus* other plasma for fractionation. These specific questions are poorly understood by respondents.

## **Special processing of blood components and pathogen reduction or quarantine of plasma: Tables 5.1 and 5.2**

In 13 / 29 (45%) of reporting MS, 100% leucocyte depletion of RBC products is carried out. This is the case for platelet concentrates in 16 / 29 (55%) reporting MS (1 country applies it to 99% of platelets). Hundred percent leucocyte depletion is applied for plasma for transfusion in 9 / 27 (33%) of the reporting MS.

Irradiation of blood components is carried out in order to prevent Graft versus Host Disease (GvHD) (as a rule, this is relevant for blood components that may carry residual leucocytes), and for a selected group of recipients only. The numbers may reflect the volume of high clinical care; although, in many instances, irradiation is carried out in hospitals where it generally appears more difficult to obtain data.

FFP for transfusion, cryosupernatant plasma (CSP) and cryoprecipitate (CP) may be additionally safeguarded against infectious diseases. One method is a quarantine step where the plasma is stored and only released if the donor is negative for IDM on a subsequent donation 4-6 months later. Another method is the application of 'virus inactivation' or 'pathogen reduction' by Solvent Detergent (SD) or Methylene Blue (MB) treatment. In 10 / 24 (42%) reporting MS, nearly all FFP is safeguarded by either method, in 2 / 27 (7%) MS for 100% by quarantine, in 6 / 28 (21%) by 100% pathogen reduction (one of these MS reported for only 98% or more of FFP), and in 3 / 29 (10%) MS by a combination of both. In 38% of the reporting MS, all FFP plasma is safeguarded by one of these measures.

## **Screening for infectious agents, serological test methods: Table 6**

In all 33 reporting MS, all donations are tested for anti-HIV-1/2, HBsAg and anti-HCV. In 30 / 33 (91%) of these MS, all donations are tested for syphilis. It is debated in the literature whether systematic syphilis testing is necessary.

Testing for anti-HTLV-I/II is performed on all donations in 6 / 30 (20%) reporting MS, and only on first time donors in 2 (7%) MS.

Testing for anti-HBc is performed on all donations in 6 (21%) reporting MS, and only on first time donors in 4 (14%) MS.

## **Confirmed seropositive donors, prevalence and incidence of infectious diseases: Tables 7.1 and 7.2**

Given the limited positive predictive value of serological screening tests, donors who are found positive in blood screening for IDM generally need to be 'confirmed' with another technique aimed at diagnosing infection. Confirmed positive donors are then notified and deferred from further donations. A typical flow-chart for confirmation is given in *EC Recommendation 98/463/EC*.

In Table 7.1, the absolute numbers of 'confirmed positive' donors reported among all first time donors tested (see Table 1) and among all repeat donors tested (see Table 1) are given. Overall 28 of 33 (85%) MS were able to provide the absolute numbers of confirmed positive donors for HIV, HBV and HCV (see Table 7.1).

### **• First time donors**

The frequency of 'confirmed positive' donors among all first time donors tested (see Table 1), yields the 'prevalence' of an IDM among first time donors. This reflects the characteristics of the population from which first time donors are recruited. It should be noted that the general population may have different rates of infectious diseases than blood donors. Even at their first visit, blood donors are a selected population. The 'prevalence' of infectious diseases among first time donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of first time donors), and the ratio is given in Table 7.2.

The prevalence per 100 000 first time tested donors, as calculated from the provided data sets (excluding the entry from FYR Macedonia, which is erroneous), ranges from 0 to 747 for HIV-1/2, from 0 to 31,919 for HBV and 0 to 57,895 for HCV. Although considerable differences in geographical distribution of these infections in Europe exist, it is questionable whether the extremely high frequencies in some countries (Georgia and Bulgaria) reflect reliable data sets on actual 'confirmed positive donors' or, merely, refer only to repeat positive donors screened by Enzyme-Linked Immunosorbent Assay (ELISA) and, thereby, including many false positives (see



definitions in the questionnaire in appendix). The geographical distribution of the high prevalence areas may coincide with low resources and lack of confirmatory testing. Median estimates might, therefore, be more appropriate values as a reference for European prevalence amongst first time donors. The median prevalence amongst first time tested donors is 6.9, 115 and 63 per 100 000 donors for HIV-1/2, HBV and HCV respectively.

- **Repeat and regular donors**

The frequency of 'confirmed positive' donors among all repeat and regular donors tested yields the 'incidence' of an infectious disease among repeat and regular donors (i.e. those donors who had previously been tested, were found to be negative, and were allowed to donate again). This 'incidence' accounts for the frequency with which repeat and regular donors acquire a new infection. It is this frequency that directly relates to blood safety via the window period of infectious disease testing (Schreiber *et al.*, 1996, *Guideline on Epidemiological data EMEA/CPMP/BWP/3794/03*). The incidence of infectious diseases among repeat and regular donors was calculated from Table 7.1 (number of confirmed positive donors) and Table 1 (number of repeat and regular donors), and is given in Table 7.2. As with the prevalence data in first time donors, the extremely high incidences may refer only to repeat positive donors of ELISA screening instead of confirmed positive donors and, thereby, include many false positives (see definitions in the questionnaire). The geographical distribution of the high incidence areas coincides with high prevalence areas and may be linked to low resources and lack of confirmatory testing.

Notwithstanding the limitations of the data and the question as to whether all positive screening test donors were submitted to confirmatory testing, the prevalence and incidence rates of infectious diseases vary greatly among MS. Overall it is to be noted that, in Europe, a North-South gradient exists: HBV and HCV infections are more common in southern countries.

The incidence per 100 000 repeat tested donor years, if calculated from the provided data sets, ranges from 0 to 75 for HIV-1/2, from 0 to 1,003 for HBV and 0 to 225 for HCV. Although considerable differences in geographical distribution of these infections in Europe exist, it is doubtful whether the very high frequencies of some countries (FYR Macedonia) reflect reliable data sets or, merely, refer only to ELISA screening positive donors (including many false positives), as opposed to 'confirmed positive donors' (see definitions in the questionnaire). Again, the median incidence amongst repeat donors is 0.6, 1.7 and 2.0 per 100 000 donor years for HIV-1/2, HBV and HCV, respectively.

## **Nucleic Acid Amplification Techniques (NAT) testing and NAT-only confirmed positive donors: Tables 8.1 and 8.2**

NAT testing for HIV is performed on each donation in 17 / 29 (59%) reporting MS. NAT testing for HBV is performed on each donation in 10 / 28 (36%) reporting MS. NAT for HCV is performed on each donation in 16 / 28 (57%) of the reporting MS. Interestingly, NAT on each donation appears to be performed more often in MS where the incidence rates are relatively low (see Table 7.2 for comparison). As the effectiveness (or 'yield') of NAT testing relates to the incidence, an argument could be made for preferentially applying NAT testing in high incidence areas. Unfortunately these areas appear to coincide with limited resources.

The 'yield' of NAT is defined as the identification of a NAT-positive donor, who is not found seropositive for that virus in serological screening on the same donation, but is shown later to be a confirmed positive through detection from an additional NAT test on the same sample or by serology. The yield of NAT for HCV, HIV and HBV among first time tested donors and among repeat donors is given in Table 8.2.

## **Bacterial screening: Table 9**

A new data set for bacterial screening of platelet concentrates was added in the 2004 report. Haemovigilance data have repeatedly shown the importance of bacterial safety of platelet concentrates. This is due to the fact that the storage temperature of platelets is around 22 °C, thus allowing bacterial growth more easily. Data on bacterial testing were reported by 24 / 33 (73 %) MS. In 5 / 24 (21%) MS, culture is performed on over 80% of all platelets (concentrates recovered both from WB donations and apheresis platelets).

## **Organisation and registration: Table 10**

All 33 MS report that there are legally-binding national regulations for the collection, testing, processing, storage and distribution of blood and blood components. In 25 / 33 (76%) of the reporting MS a National Council or Expert Committee advises the Ministry of Health on transfusion related issues. In 24 / 30 (80%) MS, a national blood policy on the quality and safety of blood and blood components is being implemented.

## **Quality management: Tables 11a, 11b and 11c**

In 29 / 32 (91%) of the reporting MS, a Quality System (QS) is established and maintained by BE. In 20 / 24 (83%) of the reporting MS, 100% of the donations are covered by GMP. In 3 countries that have no GMP, 100% of donations are covered by ISO 9000. Four countries have both 100% GMP and 100% ISO. In Italy, ISO only covers 40% of all donations, but 100% of donations are covered by other regulations. In Malta, all donations are covered by other regulations (EU directive and the EDQM manual). In total 25 / 30 reporting countries (83%) have procedures covering 100% of donations.

In 29 / 33 (94%) of the reporting MS inspections are performed at least every 2 years; the large majority of these inspections (9 / 29, 69%) are (partially) carried out by the national authority.

It is requested that the labelling of donations and issued components is unique so as to allow complete traceability. Labelling according to ISBT-128 for 100% of the donation number is partially performed in 10 / 20 (50%) MS. However, labelling of all donations to either ISBT standards or another system is performed by 27 / 31 of reporting countries (87%).

Labelling of the finished component code is more complex, and generally lags behind developments in donation labelling, as it includes implementation of automation applications in hospitals. ISBT-128 labelling of all issued component is performed in 6 / 18 (33%) reporting countries. However, 24 / 28 countries (86%) report that all components are coded by either ISBT or another system.

A national haemovigilance reporting system has been established in 29 / 33 (88%) MS.

## **Haemovigilance: Table 12**

Since 2004 this survey contains data on haemovigilance i.e. the reporting of serious adverse reactions. The format for data acquisition on haemovigilance in the 2004 questionnaire in its basic form was developed by CoE experts, submitted to the EC and adapted after slight modifications by the EC into *Directive 2005/61/EC*. Reporting of serious adverse reactions, as performed in haemovigilance programmes, can be considered as a high level of surveillance, as most of these serious reactions are not unexpected untoward effects but well known complications of blood transfusion from the medical literature and commonly indicated in the 'information leaflets' for physicians and patients. Most recipients of blood transfusions are very ill

and have underlying pathology or medications that greatly influence the signs and symptoms of a possible transfusion reaction. A serious adverse reaction during or immediately after transfusion, even if most likely related to the transfusion, may be restricted to the given recipient. Therefore, in this report only those serious adverse reactions are presented which are probably or certainly (imputability grade 2 to 3, i.e. likely or certain) related to the transfusion of the blood component. The term imputability includes the causal relationship to the component properties, but also to the transfusion itself (Transfusion Associated Circulatory Overload (TACO)) or recipient properties (allergy).

In contrast to the *EC Directives 2002/98/EC* and *2005/61/EC*, haemovigilance data which may not be caused by blood component properties, such as TACO are also reported here. Haemovigilance data submitted by 23 MS, are presented in Table 12.

Of the Member States that reported having a national haemovigilance system, 23 / 29 (79%) provided actual haemovigilance data. The incidence of serious adverse reactions with high imputability (level 2 to 3) can be calculated relative to the total number of blood components (WB + RBC + plasma + platelets) issued. Taking into account the possibility of under-reporting and the differences in national reporting systems, the incidence of 6.9 serious adverse reactions per 100 000 distributed blood components seems a reasonable estimate. Haemolysis, anaphylaxis, TRALI and TACO and transfusion associated HCV infections appear to be the most frequent serious adverse reactions.

# REFERENCES

- Guide to the preparation, use and quality assurance of blood components. Recommendation No. R (85) 15, 13th edition, January 2007, Council of Europe Publishing, Strasbourg.
- Guideline on Epidemiological data on Blood Transmissible Infections for inclusion in the Guideline on the Scientific data requirements for a Plasma Master File EMEA/CPMP/BWP/3794/03
- Trends and observations on the Collection, Testing and Use of Blood and Blood Components in Europe, 2001-2005 report, Council of Europe, February 2001
- The Collection, Testing and Use of Blood and Blood Components in Europe, 2005 report, Council of Europe, February 2011.
- The Collection, Testing and Use of Blood and Blood Components in Europe, 2006 report, Council of Europe, February 2011.
- Questionnaire on the collection, testing and use of blood and blood products in Europe, Council of Europe Publishing, Strasbourg, 22 May 2004, SP-HM (2002) 12.
- The Collection, Testing and Use of Blood and Blood Products in Europe in 2001, Council of Europe Publishing, Strasbourg, 2004, [www.edqm.eu/medias/fichiers/2001](http://www.edqm.eu/medias/fichiers/2001).
- Council Recommendation 98/463/EC on the suitability of blood and plasma donors and the screening of donated blood in the European Community, European Community.
- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2004, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.
- Rejman A. The collection and use of human blood and plasma in the non- European Union Council of Europe Member States in 1997, Council of Europe Publishing, Strasbourg, 2000.
- Schreiber GB, Busch MP, Kleinman SH, Korelitz JJ. The risk of transfusion transmitted viral infections. The Retrovirus Epidemiology Study. N Engl J Med 1996; 334:1685–1690.
- Schreiber GB, Glynn SA, Busch MP, Sharma UK, Wright DJ, Kleinman SH. Retrovirus Epidemiology Donor Study. Incidence rates of viral infections among repeat donors: are frequent donors safer? Transfusion 2001;41:730-735.
- Guideline on Epidemiological data on Blood Transmissible Infections for inclusion in the Guideline on the Scientific data requirements for a Plasma Master File EMEA/CPMP/BWP/3794/03.

# TABLES

## **List of countries having participated in the survey (33 out 46 MS)**

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, FYR Macedonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Romania, Serbia, Slovak Republic, Slovenia, Sweden, Switzerland, United Kingdom

Table 1 – *Donors, first time donors and inhabitants*

| Country         | regular and repeat donors | first time donors | % first time donors | First time donors donating | First time donors tested only | total donors | inhabitants x 1000 | donors per 1000 inhabitants |    |
|-----------------|---------------------------|-------------------|---------------------|----------------------------|-------------------------------|--------------|--------------------|-----------------------------|----|
| Austria         | 286 114                   | 52 844            | 15.6                | 49 035                     | 3 809                         | 338 958      | 8 337              | 40.7                        | 1) |
| Belgium         | 247 263                   | 52 242            | 17.4                | 52 242                     | 0                             | 299 505      | 10 500             | 28.5                        |    |
| Bulgaria        | 114 974                   | 30 900            | 21.2                | 30 900                     |                               | 145 874      | 7 640              | 19.1                        |    |
| Croatia         | 84 509                    | 14 457            | 14.6                | 14 457                     | 0                             | 98 966       | 4 437              | 22.3                        |    |
| Cyprus          | 44 012                    | 4 532             | 9.3                 | 4 025                      | 0                             | 48 544       | 766                | 63.3                        | 2) |
| Czech Republic  | 313 553                   | 49 644            | 13.7                | 49 644                     | 0                             | 363 197      | 10 300             | 35.3                        |    |
| Denmark         | 229 536                   | 26 054            | 10.2                | 0                          | 26 054                        | 255 590      | 5 511              | 46.4                        |    |
| Estonia         | 24 839                    | 9 224             | 27.1                | 9 224                      | 0                             | 34 063       | 1 341              | 25.4                        |    |
| FYR Macedonia   | 20 037                    | 3 789             | 15.9                | 3 789                      | 0                             | 23 826       | 2 047              | 11.6                        |    |
| Finland         | 140 715                   | 22 572            | 13.8                | 22 572                     | 0                             | 163 287      | 5 347              | 30.5                        |    |
| France          | 1 093 021                 | 412 728           | 27.4                |                            |                               | 1 505 749    | 63 960             | 23.5                        |    |
| Georgia         | 34 947                    | 2 945             | 7.8                 | 2 533                      | 412                           | 37 892       | 4 400              | 8.6                         |    |
| Germany         | 2 376 193                 | 569 990           | 19.3                | 471 409                    | 98 581                        | 2 946 183    | 82 002             | 35.9                        |    |
| Greece          | 342 544                   | 70 604            | 17.1                |                            |                               | 413 148      | 10 500             | 39.3                        | 3) |
| Hungary         | 224 273                   | 45 703            | 16.9                | 45 703                     |                               | 269 976      | 10 040             | 26.9                        |    |
| Iceland         | 7 681                     | 1 701             | 18.1                | 0                          | 1 701                         | 9 382        | 315                | 29.7                        |    |
| Ireland         | 82 433                    | 14 558            | 15.0                | 13 001                     | 1 557                         | 96 991       | 4 451              | 21.8                        |    |
| Italy           | 1 326 000                 | 293 000           | 18.1                |                            |                               | 1 619 000    | 60 000             | 27.0                        |    |
| Latvia          | 39 323                    | 15 547            | 28.3                | 15 547                     |                               | 54 870       | 2 300              | 23.9                        |    |
| Lithuania       | 28 291                    | 31 415            | 52.6                | 31 415                     |                               | 59 706       | 3 366              | 17.7                        |    |
| Luxembourg      | 13 146                    | 1 023             | 7.2                 | 0                          | 1 023                         | 14 169       | 475                | 29.8                        |    |
| Malta           | 12 184                    | 2 946             | 19.5                | 2 946                      | 0                             | 15 130       | 400                | 37.8                        | 4) |
| Montenegro      | 6 247                     | 5 952             | 48.8                | 4 806                      |                               | 12 199       | 620                | 19.7                        | 5) |
| Netherlands     | 366 070                   | 28 517            | 7.2                 |                            | 28 517                        | 394 587      | 16 500             | 23.9                        |    |
| Norway          | 93 326                    | 13 916            | 13.0                | 0                          | 13 916                        | 107 242      | 4 799              | 22.3                        |    |
| Poland          | 625 950                   | 271 737           | 30.3                | 271 737                    |                               | 897 687      | 38 136             | 23.5                        |    |
| Romania         |                           | 113 773           |                     | 113 773                    |                               |              | 21 500             |                             | 6) |
| Serbia          |                           | 46 458            | 100.0               |                            |                               |              | 7 480              |                             |    |
| Slovak Republic | 74 188                    | 33 323            | 31.0                |                            |                               | 107 511      | 5 417              | 19.8                        | 7) |
| Slovenia        | 104 174                   | 10 589            | 9.2                 | 10 589                     | 0                             | 114 763      | 2 000              | 57.4                        |    |
| Sweden          | 246 271                   | 44 425            | 15.3                |                            | 44 425                        | 290 696      | 9 256              | 31.4                        |    |
| Switzerland     | 223 248                   | 30 705            | 12.1                | 30 705                     | 0                             | 253 953      | 7 702              | 33.0                        |    |
| United Kingdom  | 1 355 328                 | 250 281           | 15.6                | 246 113                    | 0                             | 1 605 609    | 61 113             | 26.3                        |    |

1) Regular donors: data not available

2) First time donors are testing few days before donation and if the results allow then they proceed for donation. For the donors at the mobile unit this case is not implemented

3) Only in a few centers do donors give blood samples for testing on their first visit

4) Acute Beds = 1102

5) 5 952 first-time donors were registered, of which 4806 gave blood in their first visit

6) Total estimated number of donors = 209 287

7) New donors are not tested if they are refused for donation

Table 1.1 – *Profile of donations*

| Country         | WB donations                 |                           |                          | RBC apheresis                |                          | plasmapheresis donations     | platelet apheresis           |    |
|-----------------|------------------------------|---------------------------|--------------------------|------------------------------|--------------------------|------------------------------|------------------------------|----|
|                 | % voluntary, non-remunerated | % from replacement donors | % from autologous donors | % voluntary, non-remunerated | % from autologous donors | % voluntary, non-remunerated | % voluntary, non-remunerated |    |
| Austria         | 100                          | 0                         | 0.71                     | 100                          | 143                      |                              | 91                           |    |
| Belgium         | 100                          | 0                         | 0.06                     | 100                          | 0                        | 100                          | 100                          | 1) |
| Bulgaria        | 20                           | 78                        | 0.05                     | 0                            |                          |                              | 0                            |    |
| Croatia         | 100                          | 0                         | 0.54                     |                              |                          | 100                          | 100                          | 2) |
| Cyprus          | 100                          | 0                         | 0.00                     | 98                           |                          |                              | 100                          | 3) |
| Czech Republic  | 100                          | 0                         | 4.19                     | 34                           |                          | 39                           | 34                           |    |
| Denmark         | 100                          | 0                         | 0.00                     |                              |                          | 100                          | 100                          |    |
| Estonia         | 100                          | 0                         | 0.01                     | 0                            |                          |                              | 100                          |    |
| FYR Macedonia   | 100                          | 2                         | 0.00                     | 0                            |                          |                              | 100                          |    |
| Finland         | 100                          | 0                         | 0.00                     | 0                            |                          | 4                            | 100                          |    |
| France          | 100                          |                           | 0.24                     | 100                          |                          |                              | 100                          | 4) |
| Georgia         | 3                            | 8                         | 0.00                     |                              |                          |                              |                              |    |
| Germany         |                              | 0                         | 1.21                     |                              | 25                       |                              |                              | 5) |
| Greece          | 49                           | 51                        | 0.41                     | 60                           | 0                        | 8                            | 65                           |    |
| Hungary         | 100                          |                           |                          |                              |                          |                              | 12                           |    |
| Iceland         | 100                          | 0                         | 0.00                     | 0                            | 0                        | 100                          | 100                          |    |
| Ireland         | 100                          | 0                         | 0.00                     |                              |                          |                              | 100                          |    |
| Italy           | 100                          | 0                         | 3.76                     | 100                          |                          | 100                          | 100                          |    |
| Latvia          | 98                           |                           | 0.00                     |                              |                          |                              | 0                            |    |
| Lithuania       | 33                           | 7                         |                          |                              |                          |                              |                              |    |
| Luxembourg      | 100                          | 0                         | 0.55                     | 0                            |                          | 100                          | 100                          |    |
| Malta           | 100                          | 0                         | 0.00                     |                              |                          |                              | 100                          |    |
| Montenegro      | 28                           | 72                        |                          | 0                            |                          |                              | 0                            | 6) |
| Netherlands     | 100                          | 0                         | 0.02                     | 100                          |                          | 100                          | 100                          |    |
| Norway          | 100                          | 0                         | 0.01                     | 100                          | 0                        | 100                          | 100                          |    |
| Poland          | 90                           | 10                        | 0.00                     | 100                          | 0                        | 0                            | 100                          |    |
| Romania         | 100                          |                           |                          | 0                            |                          | 100                          | 100                          |    |
| Serbia          | 100                          | 15                        | 0.02                     | 100                          | 49                       | 85                           | 100                          |    |
| Slovak Republic | 100                          | 0                         | 0.27                     | 100                          | 0                        | 100                          | 100                          |    |
| Slovenia        | 100                          | 0                         | 1.65                     | 0                            |                          | 46                           | 100                          |    |
| Sweden          | 100                          | 0                         | 0.02                     | 100                          | 1                        | 100                          | 100                          |    |
| Switzerland     | 100                          | 0                         | 0.92                     | 100                          | 11                       | 100                          | 100                          |    |
| United Kingdom  | 100                          | 0                         | 0.00                     | 100                          | 0                        | 100                          | 100                          | 7) |

- 1) Multi-component apheresis procedures = platelet + plasma
- 2) Multi-component apheresis donations = platelets + plasma
- 3) Single donor platelets are collected using a Haemonetics cell separator [MCS+]
- 4) Plasma apheresis donations: 312 419 simple plasma 100% non-remunerated donations.  
Mean volume per donation: 0.6 L
- 5) Data not available for voluntary non-remunerated donations (%) and number of granulocyte apheresis donations (procedures).  
Replacement donations not allowed
- 6) Collection of blood and blood components by apheresis procedures are not yet done in Montenegro.  
All units of blood are collected as whole blood and separated into blood components
- 7) 211 multi-component procedures are also counted as red cell and platelet procedures



Table 2 – Collection of whole blood, autologous blood and blood (apheresis) components

| Country               | WB collections |                           |                         |                |                     | apheresis collections |                                  |                         |                   |                            |                               |     |
|-----------------------|----------------|---------------------------|-------------------------|----------------|---------------------|-----------------------|----------------------------------|-------------------------|-------------------|----------------------------|-------------------------------|-----|
|                       | WB (U)         | Transfused or distributed | WB per 1000 inhabitants | autologous (U) | % autologous WB (U) | plasma apheresis (L)  | plasma in L per 1000 inhabitants | platelets apheresis (U) | RBC apheresis (U) | granulocytes apheresis (U) | multi-component apheresis (U) |     |
| <b>Austria</b>        | 484 955        | Distr.                    | 58.2                    | 3 466          | 0.7                 | 0                     | 0.00                             | 20 844                  | 2 062             | 63                         |                               | 1)  |
| <b>Belgium</b>        | 548 601        | Distr.                    | 52.2                    | 305            | 0.1                 | 47 032                | 4.48                             | 4 522                   | 4 522             | 21                         | 22 452                        | 2)  |
| <b>Bulgaria</b>       | 154 083        | Distr.                    | 20.2                    | 74             | 0.0                 | 312                   | 0.04                             | 453                     | 0                 | 0                          | 0                             | 3)  |
| <b>Croatia</b>        | 166 347        | Distr.                    | 37.5                    | 905            | 0.5                 | 409                   | 0.09                             | 1 839                   | 0                 |                            | 1 839                         | 4)  |
| <b>Cyprus</b>         | 49 294         | Distr.                    | 64.3                    | 0              | 0.0                 | 0                     | 0.00                             | 0                       | 0                 | 0                          | 0                             |     |
| <b>Czech Republic</b> | 410 594        | Trans.                    | 39.9                    | 17 197         | 4.0                 | 206 776               | 20.08                            | 18 074                  | 2 500             |                            |                               |     |
| <b>Denmark</b>        | 353 611        | Trans.                    | 64.2                    | 0              | 0.0                 | 252                   | 0.05                             | 426                     | 0                 | 5                          | 0                             | 5)  |
| <b>Estonia</b>        | 54 020         | Trans.                    | 40.3                    | 3              | 0.0                 | 0                     | 0.00                             | 823                     | 0                 | 0                          | 0                             |     |
| <b>FYR Macedonia</b>  | 20 037         | Distr.                    | 9.8                     | 0              | 0.0                 | 0                     | 0.00                             | 90                      | 0                 |                            |                               | 6)  |
| <b>Finland</b>        | 272 499        | Distr.                    | 51.0                    | 0              | 0.0                 | 2 608                 | 0.49                             | 866                     | 0                 | 0                          | 0                             | 7)  |
| <b>France</b>         | 2 367 443      | Distr.                    | 37.0                    | 5 593          | 0.2                 | 187 451               | 2.93                             | 16 900                  | 1 623             | 224                        | 159 599                       |     |
| <b>Georgia</b>        | 37 892         | Distr.                    | 8.6                     | 0              | 0.0                 | 0                     | 0.00                             | 0                       | 0                 | 0                          | 0                             |     |
| <b>Germany</b>        | 4 869 322      | Distr.                    | 59.4                    | 58 782         | 1.2                 | 1 593 554             | 19.43                            | 171 690                 | 14 136            |                            | 17 305                        | 8)  |
| <b>Greece</b>         | 634 411        |                           | 60.4                    | 2 605          | 0.4                 | 754                   | 0.07                             | 18 479                  | 1 540             |                            | 2 159                         |     |
| <b>Hungary</b>        | 417 976        | Distr.                    | 41.6                    |                |                     | 68 000                | 6.77                             | 49 109                  | 96                | 96                         | 0                             |     |
| <b>Iceland</b>        | 14 931         | Distr.                    | 47.3                    | 0              | 0.0                 | 46                    | 0.15                             | 665                     | 194               | 0                          | 0                             |     |
| <b>Ireland</b>        | 155 079        | Distr.                    | 34.8                    | 0              | 0.0                 | 0                     | 0.00                             |                         | 0                 | 0                          | 0                             | 9)  |
| <b>Italy</b>          | 2 526 000      | Trans.                    | 42.1                    | 95 000         | 3.6                 | 213 000               | 3.55                             | 80 000                  | 35 000            |                            |                               |     |
| <b>Latvia</b>         | 58 523         | Distr.                    | 25.4                    | 2              | 0.0                 |                       |                                  | 1 848                   | 0                 | 0                          |                               |     |
| <b>Lithuania</b>      | 94 992         | Distr.                    | 28.2                    |                |                     |                       |                                  | 2 850                   |                   |                            |                               |     |
| <b>Luxembourg</b>     | 20 942         | Distr.                    | 44.1                    | 115            | 0.5                 | 1 570                 | 3.31                             | 1 377                   | 0                 | 0                          | 0                             |     |
| <b>Malta</b>          | 14 810         | Distr.                    | 37.0                    | 0              | 0.0                 | 0                     | 0.00                             | 320                     | 0                 | 0                          | 0                             | 10) |
| <b>Montenegro</b>     | 14 177         | Trans.                    | 22.9                    |                |                     | 0                     | 0.00                             | 0                       | 0                 | 0                          | 0                             | 11) |
| <b>Netherlands</b>    | 569 753        | Distr.                    | 34.5                    | 110            | 0.0                 | 188 977               | 11.45                            | 5 220                   | 0                 |                            |                               |     |
| <b>Norway</b>         | 201 723        | Trans.                    | 42.0                    | 19             | 0.0                 | 3 460                 | 0.72                             | 4 077                   | 4 492             | 0                          | 1 364                         | 12) |

Table 2 (continued) – Collection of whole blood, autologous blood and blood (apheresis) components

|                 | WB collections |                           |                         |                | apheresis collections |                      |                                  |                         |                   |                            |                               |
|-----------------|----------------|---------------------------|-------------------------|----------------|-----------------------|----------------------|----------------------------------|-------------------------|-------------------|----------------------------|-------------------------------|
| Country         | WB (U)         | Transfused or distributed | WB per 1000 inhabitants | autologous (U) | % autologous WB (U)   | plasma apheresis (L) | plasma in L per 1000 inhabitants | platelets apheresis (U) | RBC apheresis (U) | granulocytes apheresis (U) | multi-component apheresis (U) |
| Poland          | 1 006 056      | Distr.                    | 26.4                    | 0              | 0.0                   | 70 486               | 1.85                             | 25 076                  | 180               | 147                        | 5                             |
| Romania         | 351 381        | Distr.                    | 16.3                    |                |                       | 46                   | 0.00                             | 3 993                   | 0                 |                            |                               |
| Serbia          | 244 516        |                           | 32.7                    | 42             | 0.0                   | 805                  | 0.11                             | 1 420                   | 72                |                            |                               |
| Slovak Republic | 184 236        | Distr.                    | 34.0                    | 504            | 0.3                   | 19                   | 0.00                             | 4 090                   | 257               | 22                         | 0                             |
| Slovenia        | 91 279         | Distr.                    | 45.6                    | 1 502          | 1.6                   | 219                  | 0.11                             | 1 474                   | 0                 | 26                         | 0                             |
| Sweden          | 497 158        | Trans.                    | 53.7                    | 97             | 0.0                   | 42 837               | 4.63                             | 7 691                   | 1 104             | 170                        | 13)                           |
| Switzerland     | 354 169        | Distr.                    | 46.0                    | 3 242          | 0.9                   | 1 298                | 0.17                             | 9 538                   | 1 492             | 0                          | 7 639<br>14)                  |
| United Kingdom  | 2 371 141      | Distr.                    | 38.8                    | 2              | 0.0                   | 261                  | 0.00                             | 93 239                  | 258               | 42                         | 211<br>15)                    |

1) Multi-component apheresis: data not available. Plasma Collection: IndustriepL,fil.,L: 112112 109151. Quarantänepl.,fil.,L: 5797

2) Multi-component apheresis procedures are platelet + plasma procedures. Red cell unit includes 3,975 red cell units for pediatric use

3) The number of blood components distributed to the hospital blood banks includes the units available at 01.01.2008 in the BTC and units collected during 2008

4) Multi-component apheresis donations = platelets + plasma; FVIII IU x 10<sup>6</sup> = 0.029

5) Whole blood has not been routinely transfused since 1985

6) Stem cell by apheresis; total 41 procedures

7) Whole blood units are reconstituted red cells in FFP

8) Data not available for voluntary non-remunerated donations (%) and number of granulocyte apheresis donations (procedures). Replacement donations not allowed

9) In addition, 1,015 whole blood, plasma-reduced RBC units were distributed to hospitals for large volume neonatal use and 1,378 Pedipacks for infant small volume RBC transfusion

10) Cryo Units = 1,066. Cryo (FVIII x 10<sup>6</sup>): 0.074620

11) Collection of blood and blood components by apheresis procedures are not yet done in Montenegro. All units of blood are collected as whole blood and separated into blood components. Platelets, plasma and cryoprecipitate data refer only to the units transfused in the Clinical Center of Montenegro - Podgorica. PLT and CP are prepared in BTC in Podgorica only

12) All FFP was Octaplas 200 ml

13) Multi-component apheresis procedures have not yet been reported

14) Total number of WB units: exclusively autologous

15) 211 multi-component procedures are also counted as red cell and platelet procedures. Figures are for single cryoprecipitate units

Table 3 – *Use of blood and blood components for transfusion*

| Country         | WB (U)  | % WB of total RBCs | RBC concentrates (U) | RBC (U) per 1000 inhabitants | plasma for transfusion (U) | platelets total (U) | platelets recovered (U) | platelets apheresis (U) | % platelets apheresis | CP (10 <sup>6</sup> IU FVIII) |     |
|-----------------|---------|--------------------|----------------------|------------------------------|----------------------------|---------------------|-------------------------|-------------------------|-----------------------|-------------------------------|-----|
| Austria         | 0       | 0.0                | 440 792              | 52.9                         | 79 112                     | 36 300              | 7 572                   | 28 728                  | 79.1                  | 0                             |     |
| Belgium         | 0       | 0.0                | 518 479              | 49.4                         | 91 777                     | 65 030              | 40 049                  | 24 981                  | 38.4                  | 0                             | 1)  |
| Bulgaria        | 775     | 0.5                | 149 033              | 19.5                         | 61 800                     | 4 029               | 3 178                   | 851                     | 21.1                  |                               | 2)  |
| Croatia         | 519     | 0.3                | 160 037              | 36.1                         | 71 957                     | 11 816              | 9 448                   | 2 368                   | 20.0                  | 0                             | 3)  |
| Cyprus          | 0       | 0.0                | 44 283               | 57.8                         | 15 735                     | 11 479              | 11 167                  | 312                     | 2.7                   | 0                             |     |
| Czech Republic  | 276     | 0.1                | 378 287              | 36.7                         | 192 905                    | 30 349              | 5 014                   | 25 335                  | 83.5                  |                               |     |
| Denmark         | 0       | 0.0                | 330 588              | 60.0                         | 67 793                     | 34 465              | 32 763                  | 1 702                   | 4.9                   | 147                           | 4)  |
| Estonia         | 12      | 0.0                | 50 340               | 37.5                         | 31 712                     | 5 899               | 4 425                   | 1 474                   | 25.0                  | 441                           |     |
| FYR Macedonia   | 20 037  | 50.1               | 39 965               | 19.5                         | 18 306                     | 12 700              | 12 400                  | 300                     | 2.4                   | 599                           | 5)  |
| Finland         | 630     | 0.2                | 253 339              | 47.4                         | 52 917                     | 37 455              | 36 785                  | 670                     | 1.8                   | 0                             | 6)  |
| France          |         |                    | 2 270 823            |                              | 327 105                    | 252 887             | 77 168                  | 175 719                 | 69.5                  | 0                             |     |
| Georgia         | 64      | 0.2                | 37 892               | 8.6                          | 37 828                     | 4 478               | 4 478                   | 0                       | 0.0                   | 284                           |     |
| Germany         | 11 457  | 0.2                | 4 698 533            | 57.3                         | 1 332 564                  | 472 346             | 184 493                 | 287 853                 | 60.9                  |                               |     |
| Greece          | 186     | 0.0                | 625 325              | 59.6                         | 263 597                    | 135 933             | 118 874                 | 17 059                  | 12.5                  |                               |     |
| Hungary         | 0       |                    | 371 905              |                              | 94 676                     | 22 931              | 18 020                  | 4 911                   | 21.4                  | 0                             |     |
| Iceland         | 0       | 0.0                | 14 563               | 46.2                         | 5 599                      | 2 195               | 931                     | 1 264                   | 57.6                  | 0                             |     |
| Ireland         | 0       | 0.0                | 141 364              | 31.8                         | 655                        | 24 739              | 10 895                  | 13 844                  | 56.0                  | 2 609                         | 7)  |
| Italy           |         |                    | 2 464 000            |                              | 506 000                    |                     |                         |                         |                       |                               |     |
| Latvia          |         |                    | 58 625               |                              | 38 273                     | 6 208               | 2 774                   | 3 434                   | 55.3                  | 4 884                         |     |
| Lithuania       | 28      |                    | 90 232               |                              | 33 781                     | 15 732              | 8 655                   | 7 077                   | 45.0                  | 880                           |     |
| Luxembourg      | 0       | 0.0                | 21 004               | 44.2                         | 5 100                      | 3 692               | 2 315                   | 1 377                   | 37.3                  | 0                             |     |
| Malta           | 0       | 0.0                | 14 485               | 36.2                         | 6 274                      | 1 169               | 849                     | 320                     | 27.4                  |                               | 8)  |
| Montenegro      | 1 515   |                    | 11 579               |                              | 8 314                      |                     |                         | 0                       |                       | 262                           | 9)  |
| Netherlands     | 0       | 0.0                | 563 696              | 34.2                         | 96 622                     | 50 784              |                         |                         |                       |                               |     |
| Norway          | 55      | 0.0                | 199 787              | 41.6                         | 47 690                     | 19 553              | 13 492                  | 6 061                   | 31.0                  |                               | 10) |
| Poland          |         |                    | 845 538              |                              | 316 782                    | 134 505             | 91 504                  | 43 001                  | 32.0                  | 7 192                         |     |
| Romania         | 85 498  |                    | 319 093              |                              | 227 773                    | 20 292              | 16 299                  | 3 993                   | 19.7                  | 17 070                        |     |
| Serbia          | 244 516 |                    | 454 892              |                              | 165 554                    |                     |                         | 1 420                   |                       | 16 368                        |     |
| Slovak Republic | 1 335   | 1.0                | 134 726              | 24.9                         | 75 895                     | 12 816              | 4 558                   | 8 258                   | 64.4                  | 1                             |     |
| Slovenia        | 0       | 0.0                | 82 730               | 41.4                         | 29 510                     | 8 056               | 5 316                   | 2 740                   | 34.0                  | 0                             |     |
| Sweden          | 0       | 0.0                | 482 987              | 52.2                         | 105 197                    | 38 941              | 25 345                  | 13 596                  | 34.9                  | 0                             |     |
| Switzerland     | 2 543   | 0.8                | 316 561              | 41.1                         | 65 823                     | 27 669              | 2 043                   | 25 626                  | 92.6                  | 0                             | 11) |
| United Kingdom  | 729     | 0.0                | 2 218 146            | 36.3                         | 294 223                    | 266 577             | 95 752                  | 170 825                 | 64.1                  | 123 814                       | 12) |

1) Red cell units include 3975 red cell units for pediatric use

2) The number of blood components distributed to the hospital blood banks includes the units available at 01.01.2008 in the BTC and units collected during 2008

3) FVIII IU x 10<sup>6</sup> = 0.029

4) Whole blood has not been routinely transfused since 1985

5) Stem cell by apheresis; total 41 procedures

6) Whole blood units are reconstituted red cells in FFP

7) In addition, 1015 whole blood, plasma reduced RBC units were distributed to hospitals for large volume neonatal use and 1378 Pedipacks for infant small volume RBC transfusion

8) Cryo Units = 1066. Cryo (FVIII x 10<sup>6</sup>): 0.074620

9) Platelets, plasma and cryoprecipitate data refer only to the units transfused in the Clinical Center of Montenegro - Podgorica. PLT and CP are prepared in BTC in Podgorica only

10) All FFP was Octaplas 200 ml

11) Total number of WB units: exclusively autologous

12) 211 multi-component procedures are also counted as red cell and platelet procedures. Figures are for single cryoprecipitate units

Table 4 – *Plasma for fractionation into medicinal products*

| Country         | plasma for fractionation (L) | plasma for fractionation per 1000 inhabitants (L) | % fractionation plasma recovered | plasma for transfusion per 1000 inhabitants (U) | plasma for transfusion total RBC ratio (U/U) |     |
|-----------------|------------------------------|---------------------------------------------------|----------------------------------|-------------------------------------------------|----------------------------------------------|-----|
| Austria         | 109 151                      | 13.09                                             | 0.00                             | 9.49                                            | 0.18                                         | 1)  |
| Belgium         | 163 089                      | 15.53                                             | 71.16                            | 8.74                                            | 0.18                                         |     |
| Bulgaria        | 11 736                       | 1.54                                              | 0.00                             | 8.09                                            | 0.41                                         |     |
| Croatia         | 18 910                       | 4.26                                              |                                  | 16.22                                           | 0.45                                         |     |
| Cyprus          | 0                            | 0.00                                              |                                  | 20.53                                           | 0.36                                         | 2)  |
| Czech Republic  | 247 330                      | 24.01                                             | 21.57                            | 18.73                                           | 0.51                                         |     |
| Denmark         | 73 440                       | 13.32                                             |                                  | 12.30                                           | 0.21                                         | 3)  |
| Estonia         | 4 758                        | 3.55                                              | 0.00                             | 23.65                                           | 0.63                                         | 4)  |
| FYR Macedonia   | 0                            | 0.00                                              |                                  | 8.94                                            | 0.46                                         |     |
| Finland         | 68 800                       | 12.87                                             | 100.00                           | 9.90                                            | 0.21                                         | 5)  |
| France          | 769 931                      | 12.04                                             | 20.51                            | 5.11                                            |                                              |     |
| Georgia         | 0                            | 0.00                                              |                                  | 8.60                                            | 1.00                                         |     |
| Germany         | 2 526 637                    | 30.81                                             | 40.13                            | 16.25                                           | 0.28                                         |     |
| Greece          | 15 402                       | 1.47                                              |                                  | 25.10                                           | 0.42                                         |     |
| Hungary         |                              |                                                   |                                  | 9.43                                            |                                              | 6)  |
| Iceland         | 0                            | 0.00                                              |                                  | 17.75                                           | 0.38                                         |     |
| Ireland         | 0                            | 0.00                                              |                                  | 0.15                                            | 0.00                                         |     |
| Italy           | 648 000                      | 10.80                                             | 65.43                            | 8.43                                            |                                              |     |
| Latvia          | 823                          | 0.36                                              |                                  | 16.64                                           |                                              |     |
| Lithuania       | 72 715                       | 21.60                                             |                                  | 10.03                                           |                                              | 7)  |
| Luxembourg      | 7 600                        | 16.00                                             | 76.49                            | 10.74                                           | 0.24                                         | 8)  |
| Malta           | 0                            | 0.00                                              |                                  | 15.69                                           | 0.43                                         | 9)  |
| Montenegro      |                              |                                                   |                                  | 13.41                                           |                                              | 10) |
| Netherlands     | 225 557                      | 13.67                                             | 69.87                            | 5.86                                            | 0.17                                         |     |
| Norway          | 54 214                       | 11.30                                             | 67.82                            | 9.94                                            | 0.24                                         | 11) |
| Poland          | 46 582                       | 1.22                                              | 88.64                            | 8.31                                            |                                              |     |
| Romania         | 0                            | 0.00                                              |                                  | 10.59                                           |                                              | 12) |
| Serbia          |                              |                                                   |                                  | 22.13                                           |                                              |     |
| Slovak Republic | 46 345                       | 8.56                                              | 84.08                            | 14.01                                           | 0.56                                         |     |
| Slovenia        | 14 096                       | 7.05                                              | 98.45                            | 14.76                                           | 0.36                                         |     |
| Sweden          | 113 419                      | 12.25                                             | 62.23                            | 11.36                                           | 0.22                                         |     |
| Switzerland     | 90 119                       | 11.70                                             | 0.00                             | 8.55                                            | 0.21                                         |     |
| United Kingdom  | 0                            | 0.00                                              |                                  | 4.81                                            | 0.13                                         |     |

1) Red cell apheresis (autologous) = 2943. Concentrates = 5886

2) The plasma collected is not further fractionated to products

3) The amount of plasma for FVIII or other components has not been stated. However, only plasma recovered from whole blood for fractionation is delivered

4) Only plasma is supplied to fractionators

5) Other plasma is used for production of pooled, virus-inactivated fresh frozen plasma (Octaplas)

6) HNBT Service has no information on the data collection of private plasmapheresis processes

7) Plasma for fractionation in units only (72 715 units)

8) Octapharma carries out fractionation for Luxembourg: albumin, gammaglobulins, Factor VIII, PPSB

9) No components were delivered for manufacture of medicinal products

10) Collection of plasma by apheresis procedures is not yet done in Montenegro

11) Total plasma includes plasma for Octaplas production

12) No contract for fractionation

Table 5.1 – *Special processing of blood components*

| Country         | RBC                  |              | plasma for transfusion |              | platelets            |              |               |     |
|-----------------|----------------------|--------------|------------------------|--------------|----------------------|--------------|---------------|-----|
|                 | % leucocyte depleted | % irradiated | % leucocyte depleted   | % irradiated | % leucocyte depleted | % irradiated | path.inact. % |     |
| Austria         | 100                  | 9            | 100                    | 0            | 100                  | 49           | 0             | 1)  |
| Belgium         | 100                  |              | 100                    | 0            | 100                  |              | 13            |     |
| Bulgaria        | 6                    | 1            | 1                      | 1            | 27                   | 1            |               |     |
| Croatia         | 18                   | 77           | 1                      |              |                      |              |               |     |
| Cyprus          | 100                  | 0            | 0                      | 0            | 0                    | 0            | 0             |     |
| Czech Republic  | 21                   | 6            | 0                      | 1            | 73                   | 29           | 0             |     |
| Denmark         | 31                   | 2            | 0                      | 1            | 99                   | 29           | 0             |     |
| Estonia         | 5                    | 3            | 0                      | 0            | 44                   | 21           | 0             |     |
| FYR Macedonia   | 5                    | 0            | 0                      | 0            | 1                    | 0            | 0             |     |
| Finland         | 100                  | 3            | 0                      | 0            | 100                  | 35           | 0             | 2)  |
| France          | 100                  |              | 100                    |              | 100                  |              |               |     |
| Georgia         | 0                    | 0            | 0                      | 0            | 0                    | 0            | 0             |     |
| Germany         | 100                  | 4            |                        | 0            | 100                  | 34           | 0             | 3)  |
| Greece          | 35                   | 16           | 38                     | 11           | 70                   | 19           |               |     |
| Hungary         | 11                   | 5            | 16                     | 2            | 71                   | 12           | 0             |     |
| Iceland         | 22                   | 10           | 3                      | 2            | 100                  | 68           | 17            | 4)  |
| Ireland         | 100                  | 24           | 100                    | 0            | 100                  | 100          | 0             | 5)  |
| Italy           |                      |              |                        |              |                      |              |               |     |
| Latvia          | 15                   | 2            | 0                      | 0            | 100                  | 28           | 0             |     |
| Lithuania       | 9                    |              |                        |              | 40                   |              |               |     |
| Luxembourg      | 100                  | 1            | 100                    | 0            | 100                  | 2            | 0             |     |
| Malta           | 100                  | 26           | 100                    | 0            | 100                  | 0            | 0             |     |
| Montenegro      |                      |              |                        |              |                      |              |               | 6)  |
| Netherlands     | 100                  |              | 100                    |              | 100                  |              | 0             |     |
| Norway          | 100                  | 7            | 0                      | 0            | 100                  | 34           | 16            | 7)  |
| Poland          |                      |              | 0                      | 0            |                      |              |               |     |
| Romania         |                      |              |                        | 0            | 20                   |              | 0             |     |
| Serbia          | 50                   | 2            |                        |              | 7                    | 1            |               |     |
| Slovak Republic | 13                   |              | 8                      |              | 62                   |              | 0             | 8)  |
| Slovenia        | 45                   | 5            | 0                      | 0            | 74                   | 36           | 0             |     |
| Sweden          | 83                   | 4            | 94                     | 2            | 100                  | 56           | 4             |     |
| Switzerland     | 100                  |              | 100                    |              | 100                  |              |               | 9)  |
| Turkey          |                      |              |                        |              |                      |              |               |     |
| Ukraine         |                      |              |                        |              |                      |              |               |     |
| United Kingdom  | 100                  | 8            | 100                    | 0            | 100                  | 54           | 0             | 10) |

1) Cryoprecipitate: no production in the BE

2) Plasma for transfusion is virus-inactivated: pooled, virus-inactivated fresh frozen plasma (Octaplas)

3) Data on leucocyte-depleted plasma for transfusion are not collected. Cryoprecipitate-reduced plasma components and cryoprecipitate: not in use

4) Virus-inactivated platelets: 3-month project

5) 98% of plasma for transfusion was Solvent Detergent treated, Octaplas. The small amount of FFP used was leucocyte-depleted

6) Leucocyte-depleted and irradiated blood components (RC and PLT) are prepared in specific cases only

7) Plasma inactivated = Octaplas

8) Blood components are irradiated by blood banks. No data

9) Virus-inactivated : SD plasma

10) Scotland - Cryoprecipitate for use in neonates and children under 16 is imported from North America. It is treated with Methylene Blue and supplied as individual donations (i.e. not pooled) – approx. 800 units per year

Table 5.2 – *Inactivation or quarantine of plasma*

| Country         | FFP           |                     | CP reduced plasma |                     | cryoprecipitate |                     |     |
|-----------------|---------------|---------------------|-------------------|---------------------|-----------------|---------------------|-----|
|                 | % quarantined | % virus inactivated | % quarantined     | % virus inactivated | % quarantined   | % virus inactivated |     |
| Austria         | 26            | 74                  | 0                 | 0                   | 0               | 0                   | 1)  |
| Belgium         | 0             | 100                 | 0                 | 0                   | 0               | 0                   |     |
| Bulgaria        | 0             | 0                   | 0                 | 0                   | 0               |                     |     |
| Croatia         |               |                     |                   |                     |                 |                     |     |
| Cyprus          | 0             | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Czech Republic  | 100           | 0                   | 100               |                     |                 |                     |     |
| Denmark         | 0             | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Estonia         | 0             | 0                   | 0                 | 0                   | 0               | 0                   |     |
| FYR Macedonia   | 0             | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Finland         | 0             | 100                 | 0                 | 0                   | 0               | 0                   | 2)  |
| France          | 35            | 100                 |                   |                     |                 |                     |     |
| Georgia         | 19            | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Germany         | 94            | 6                   | 0                 | 0                   | 0               | 0                   | 3)  |
| Greece          | 15            | 11                  |                   |                     |                 |                     |     |
| Hungary         | 0             | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Iceland         | 0             | 0                   | 0                 | 0                   | 0               | 0                   | 4)  |
| Ireland         |               | 98                  | 0                 | 0                   | 0               | 0                   | 5)  |
| Italy           |               |                     |                   |                     |                 |                     |     |
| Latvia          | 59            | 0                   |                   |                     | 100             | 0                   |     |
| Lithuania       | 60            |                     |                   |                     |                 |                     |     |
| Luxembourg      | 0             | 100                 | 0                 | 0                   | 0               | 0                   |     |
| Malta           | 50            | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Montenegro      |               |                     |                   |                     |                 |                     | 6)  |
| Netherlands     | 100           | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Norway          | 0             | 100                 | 0                 | 0                   | 0               | 0                   | 7)  |
| Poland          |               | 0                   |                   |                     |                 | 0                   |     |
| Romania         | 50            | 0                   | 50                | 0                   |                 | 0                   |     |
| Serbia          |               |                     |                   |                     |                 |                     |     |
| Slovak Republic | 49            | 0                   | 0                 | 0                   | 0               | 0                   | 8)  |
| Slovenia        | 0             | 0                   | 0                 | 0                   | 0               | 0                   |     |
| Sweden          | 0             | 1                   | 0                 | 0                   | 0               | 0                   |     |
| Switzerland     | 85            | 15                  |                   |                     |                 |                     | 9)  |
| United Kingdom  | 0             | 4                   | 0                 | 0                   | 0               | 1                   | 10) |

1) Cryoprecipitate: no production in the BE

2) Plasma for transfusion virus-inactivated: pooled, virus-inactivated fresh frozen plasma (Octaplas)

3) Data on leucocyte-depleted plasma for transfusion are not collected. Cryoprecipitate-reduced plasma components and cryoprecipitate: not in use

4) Virus inactivated platelets: 3-month project

5) 98% of plasma for transfusion was Solvent Detergent treated, Octaplas. The small amount of FFP used was leucocyte-depleted

6) Leucocyte-depleted and irradiated blood components (RC and PLT) are prepared in specific cases only

7) Plasma inactivated = Octaplas

8) Blood components are irradiated by blood banks: no data

9) Virus-inactivated : SD plasma

10) Scotland - Cryoprecipitate for use in neonates and children under 16 is imported from North America. It is treated with Methylene Blue and supplied as individual donations (i.e. not pooled) – approx. 800 units per year

Table 6 – Donation testing strategy for infectious agents

| Country               | anti-HIV 1+2 | HIVAg | HBsAg | Anti-HBc | anti-HCV | HCVAg | anti-HTLV I/II | Syphilis | Malaria | Other                                                                                                                                                                        |
|-----------------------|--------------|-------|-------|----------|----------|-------|----------------|----------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Austria</b>        | 100          | 100   | 100   | 21       | 100      | 0     | 0              | 100      | 0       | Neopterin-Screening-Elisa-Test (Brahms, IBL): Testing every donation. ALT (Abbott, Roche, Dade/Siemens): Testing 29% anti-CMV (IgG, IgM), Abbott, Dade/Siemens: Testing 34%. |
| <b>Belgium</b>        | 100          | 0     | 100   | First    | 100      | 0     | 0              | 100      |         |                                                                                                                                                                              |
| <b>Bulgaria</b>       | 100          | 100   | 100   | 0        | 100      | 100   | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Croatia</b>        | 100          | 100   | 100   | 0        | 100      | 100   | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Cyprus</b>         | 100          | 0     | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Czech Republic</b> | 100          | 100   | 100   | 0        | 100      | 35    | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Denmark</b>        | 100          | 100   | 100   | 0        | 100      | 0     |                | 0        |         |                                                                                                                                                                              |
| <b>Estonia</b>        | 100          | 100   | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>FYR Macedonia</b>  | 100          | 100   | 100   | 100      | 100      | 100   | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Finland</b>        | 100          | 100   | 100   | 0        | 100      | 0     | 23             | 100      | 0       |                                                                                                                                                                              |
| <b>France</b>         | 100          | 0     | 100   | 100      | 100      | 0     | 100            | 100      |         |                                                                                                                                                                              |
| <b>Georgia</b>        | 100          | 0     | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Germany</b>        | 100          |       | 100   | 100      | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Greece</b>         | 100          |       | 100   |          | 100      |       | 100            | 100      |         |                                                                                                                                                                              |
| <b>Hungary</b>        | 100          | 0     | 100   | First    | 100      | 0     |                | 100      | 0       |                                                                                                                                                                              |
| <b>Iceland</b>        | 100          | 100   | 100   | 0        | 100      | 0     | 0              | 0        |         |                                                                                                                                                                              |
| <b>Ireland</b>        | 100          | 0     | 100   | 100      | 100      | 0     | 100            | 100      | 0       |                                                                                                                                                                              |
| <b>Italy</b>          | 100          | 0     | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Latvia</b>         | 100          | 0     | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Lithuania</b>      | 100          |       | 100   |          | 100      |       |                | 100      |         |                                                                                                                                                                              |
| <b>Luxembourg</b>     | 100          | 100   | 100   | First    | 100      | 0     | First          | 100      | 1       |                                                                                                                                                                              |
| <b>Malta</b>          | 100          | 100   | 100   | 100      | 100      | 100   | 0              | 100      | 0       | CMV Ab: Testing 10%.                                                                                                                                                         |
| <b>Montenegro</b>     | 100          | 100   | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |
| <b>Netherlands</b>    | 100          | 0     | 100   | 0        | 100      | 0     | 100            | 100      |         |                                                                                                                                                                              |
| <b>Norway</b>         | 100          | 100   | 100   |          | 100      | 0     | 0              | First    | 1       |                                                                                                                                                                              |
| <b>Poland</b>         | 100          | 0     | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                                                                                                                                              |



Table 6 (continued) – *Donation testing strategy for infectious agents*

| Country         | anti-HIV 1+2 | HIVAg | HBsAg | Anti-HBc | anti-HCV | HCVAg | anti-HTLV I/II | Syphilis | Malaria | Other                                               |
|-----------------|--------------|-------|-------|----------|----------|-------|----------------|----------|---------|-----------------------------------------------------|
| Romania         | 100          | 100   | 100   |          | 100      | 100   | 100            | 100      | 0       | ALT: Testing every donation.                        |
| Serbia          | 100          | 0     | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                     |
| Slovak Republic | 100          | 100   | 100   | 100      | 100      | 0     | 0              | 100      | 0       |                                                     |
| Slovenia        | 100          | 100   | 100   | 0        | 100      | 0     | 0              | 100      | 0       |                                                     |
| Sweden          | 100          | 0     | 100   | First    | 100      | 0     | First          | 100      | 0       |                                                     |
| Switzerland     | 100          | 50    | 100   | 0        | 100      | 0     | 0              | 100      | 1       | ALT : Testing every donation. CMV : Testing 2%.     |
| United Kingdom  | 100          | 100   | 100   | 1        | 100      | 0     | 100            | 100      | 1       | Chagas' disease: Testing 1%. Anti-CMV: Testing 30%. |

1) Anti-HBc: about 90,000 donations tested annually

2) Malaria: on demand

3) Anti-HIV: HIV Ag/Ab combo. HIV Ag: HIV Ag/Ab combo. Anti-HCV: HCV Ag/Ab combo. HCV Ag: HCV Ag/Ab combo

4) (1) Anti-HIV+2, HBsAg and anti-HCV are performed with an ELISA method. (2) Syphilis testing uses a haemagglutination technique

5) Anti-HIV: HIV Ag/Ab combined test in use. HIV Ag: HIV Ag/Ab combined test in use. HCV Ag: combined Ag/Ab test is used in about 35% of donations

6) Anti-HTLV: first-time donors and donors having travelled to endemic areas. Malaria: donors having travelled to endemic areas

7) HIV Ag/Att in 100% of donations

8) Anti-HIV: anti-HIV/p24 antigen combitest. Anti-HTLV: anti-HTLV testing was terminated in August 2008. Malaria: donors having visited or born in malaria areas are tested

9) Malaria: only if donor has travelled to or lived in endemic areas. Chagas disease: only if donor has travelled to or lived in endemic areas

10) HIV Ag: no data. Antibody-Antigen-Combitests for HIV-1+2 are used by some blood establishments. Anti-HBc: donors that test positive for anti-HBc can donate blood if a sensitive assay for HBV genome is negative and if anti-HBs antibody-titer stays above 100 IU/l. Syphilis: not required for donations of plasma for fractionation

11) Anti-HIV: data on 568 210 donations. HIV Ag: when required. HBsAg: data on 568 210 donations. Anti-HBc: when required. Anti-HCV: data on 568 210 donations. HCV Ag: when required. Anti-HTLV: data on 568 210 donations. Syphilis: data on 568 210 donations. Malaria: when required

12) Malaria: only if having travelled in malaria area (few tests/year)

13) A significant proportion of Blood Services (not yet defined) perform HIVAg/Ab combo tests

14) HIV Ag: serologic test with P24 detection. Malaria: after having travelled in malaria area

15) Screening of collected units of blood is done by ELISA tests from different manufacturers

16) Malaria: only donors with a history of malaria are tested

17) HIV Ag: not a requirement, but always done. Anti-HBc: all new donors and all donors when more than 6 months has elapsed since previous donation. Malaria: no requirement – optional for blood banks that want to reduce quarantine time

18) Anti-HIV: 100% testing with Ag/Ab anti HIV (Combo test) reagent. HIV Ag: 100% testing with Ag/Ab anti HIV (Combo test) reagent. Anti-HCV: 100% testing with Ag/Ab anti HCV reagent. HCV Ag: 100% testing with Ag/Ab anti HCV reagent

19) HIV Ag: use of combo test anti-HIV

20) HIV Ag: combined antibody-antigen tests are available and will be a requirement. HCV Ag: combined antibody-antigen tests will be a requirement when available. Syphilis: every unit is tested for fractionators, the legal requirement is currently only for new donors

21) Malaria: after staying > 6 months in countries at risk. CMV: immuno-deficient patients and neonates

22) HIV Ag: screened using HIV-Ag/Ab Combo assay. Chagas' disease: donor acceptable if at least 6 months following the date of last exposure, a validated test for *T. cruzi* antibody is negative

Table 7.1 – *Confirmed seropositive donors (absolute numbers)*

| Country         | HIV 1 / 2         |               | HBV               |               | HCV               |               | HTLV-I/II         |               | syphilis          |               |
|-----------------|-------------------|---------------|-------------------|---------------|-------------------|---------------|-------------------|---------------|-------------------|---------------|
|                 | first time donors | repeat donors | first time donors | repeat donors | first time donors | repeat donors | first time donors | repeat donors | first time donors | repeat donors |
| Austria         | 1                 | 8             | 61                | 5             | 34                | 24            |                   |               | 16                | 32            |
| Belgium         | 4                 | 1             | 40                | 3             | 22                | 5             |                   |               | 11                | 17            |
| Bulgaria        |                   |               | 1900              | 66            | 160               | 9             | 0                 |               | 600               | 12            |
| Croatia         | 1                 | 4             | 27                | 11            | 8                 | 3             |                   |               | 6                 | 6             |
| Cyprus          | 1                 | 0             | 20                | 8             | 10                | 5             | 0                 | 0             | 13                | 12            |
| Czech Republic  | 1                 | 1             | 27                | 5             | 63                | 13            |                   |               | 9                 | 10            |
| Denmark         | 2                 | 1             | 10                | 0             | 3                 | 0             | 1                 | 0             |                   |               |
| Estonia         | 3                 | 2             | 15                | 4             | 65                | 6             |                   |               | 19                | 34            |
| FYR Macedonia   | 20037             | 15            | 20037             | 201           | 20037             | 45            | 0                 | 0             | 20037             | 8             |
| Finland         | 1                 | 1             | 3                 | 2             | 14                | 3             | 0                 | 0             | 0                 | 3             |
| France          |                   |               |                   |               |                   |               |                   |               |                   |               |
| Georgia         | 22                |               | 940               |               | 1705              |               |                   |               | 380               |               |
| Germany         | 39                | 61            | 779               | 34            | 408               | 53            |                   |               | 177               | 106           |
| Greece          | 25                | 20            | 980               | 293           | 281               | 89            | 3                 | 1             | 102               | 52            |
| Hungary         | 5                 | 3             | 155               | 198           | 144               | 56            |                   |               | 46                | 43            |
| Iceland         | 0                 | 0             | 1                 | 0             | 0                 | 0             |                   |               |                   |               |
| Ireland         | 1                 | 0             | 4                 | 2             | 3                 | 0             | 0                 | 0             | 5                 | 2             |
| Italy           | 56                | 48            | 844               | 101           | 404               | 25            | 0                 | 0             | 221               | 107           |
| Latvia          | 9                 | 9             |                   |               |                   |               |                   |               |                   |               |
| Lithuania       | 13                |               | 96                |               | 178               |               |                   |               | 42                |               |
| Luxembourg      | 0                 | 0             | 0                 | 0             | 0                 | 0             | 0                 | 0             | 2                 | 0             |
| Malta           | 0                 | 0             | 5                 | 0             | 0                 | 0             |                   |               | 0                 | 0             |
| Montenegro      | 1                 | 0             | 31                | 2             |                   |               |                   |               |                   |               |
| Netherlands     | 2                 | 1             | 16                | 4             | 4                 | 0             | 0                 | 1             | 11                | 8             |
| Norway          | 0                 | 0             | 5                 | 1             | 13                | 1             |                   |               | 2                 | 2             |
| Poland          |                   |               |                   |               |                   |               |                   |               |                   |               |
| Romania         |                   |               |                   |               |                   |               |                   |               |                   |               |
| Serbia          |                   |               |                   |               |                   |               |                   |               |                   |               |
| Slovak Republic | 2                 | 2             | 34                | 9             | 20                | 9             |                   |               | 4                 | 3             |
| Slovenia        | 0                 | 0             | 10                | 0             | 4                 | 0             | 0                 | 0             | 3                 | 3             |
| Sweden          | 0                 | 2             | 11                | 1             | 19                | 0             | 1                 |               | 8                 | 9             |
| Switzerland     | 3                 | 1             | 39                | 8             | 24                | 0             |                   |               | 21                | 5             |
| United Kingdom  | 15                | 13            | 87                | 1             | 76                | 7             | 13                | 1             | 66                | 36            |

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

1) Figures show total number of confirmed cases. There are no separate statistics for repeat or first-time donors

2) Donations not tested for HTLV I/II

3) Data on 70 604 first-time donors and on 342 544 repeat donors

4) Previous data on HBsAg + a-HBc positive samples was incorrect, hence the increase in confirmed seropositive results

5) Coverage 92.3% of donations

6) Total of confirmed seropositive tests is presented (first and repeat tested donors)

7) No testing for HTLV I/II

8) Confirmatory testing on HCV and syphilis was not done in 2008 because of the lack of tests

9) HTLV I/II tests are not performed on repeat tested donors. Data are collected on syphilis for the first year

10) Northern Ireland - repeat tested donors subjected to new syphilis screening test since last donation and in all cases of past syphilis treatment

Table 7.2 – *Prevalance and incidence calculated per 100 000 donors*

| Country         | HIV 1 / 2                                       |                                     | HBV                                             |                                     | HCV                                             |                                     |     |
|-----------------|-------------------------------------------------|-------------------------------------|-------------------------------------------------|-------------------------------------|-------------------------------------------------|-------------------------------------|-----|
|                 | prevalance per 100 000 first time tested donors | incidence per 100 000 repeat donors | prevalance per 100 000 first time tested donors | incidence per 100 000 repeat donors | prevalance per 100 000 first time tested donors | incidence per 100 000 repeat donors |     |
| Austria         | 1.89                                            | 2.80                                | 115.43                                          | 1.75                                | 64.34                                           | 8.39                                | 1)  |
| Belgium         | 7.66                                            | 0.40                                | 76.57                                           | 1.21                                | 42.11                                           | 2.02                                |     |
| Bulgaria        |                                                 |                                     | 6148.87                                         | 57.40                               | 517.80                                          | 7.83                                |     |
| Croatia         | 6.92                                            | 4.73                                | 186.76                                          | 13.02                               | 55.34                                           | 3.55                                |     |
| Cyprus          | 22.07                                           | 0.00                                | 441.31                                          | 18.18                               | 220.65                                          | 11.36                               | 2)  |
| Czech Republic  | 2.01                                            | 0.32                                | 54.39                                           | 1.59                                | 126.90                                          | 4.15                                |     |
| Denmark         | 7.68                                            | 0.44                                | 38.38                                           | 0.00                                | 11.51                                           | 0.00                                |     |
| Estonia         | 32.52                                           | 8.05                                | 162.62                                          | 16.10                               | 704.68                                          | 24.16                               |     |
| FYR Macedonia   | 528820.27                                       | 74.86                               | 528820.27                                       | 1003.14                             | 528820.27                                       | 224.58                              |     |
| Finland         | 4.43                                            | 0.71                                | 13.29                                           | 1.42                                | 62.02                                           | 2.13                                |     |
| France          |                                                 |                                     |                                                 |                                     |                                                 |                                     |     |
| Georgia         | 747.03                                          |                                     | 31918.51                                        |                                     | 57894.74                                        |                                     | 3)  |
| Germany         | 6.84                                            | 2.57                                | 136.67                                          | 1.43                                | 71.58                                           | 2.23                                |     |
| Greece          | 35.41                                           | 5.84                                | 1388.02                                         | 85.54                               | 397.99                                          | 25.98                               | 4)  |
| Hungary         | 10.94                                           | 1.34                                | 339.15                                          | 88.29                               | 315.08                                          | 24.97                               | 5)  |
| Iceland         | 0.00                                            | 0.00                                | 58.79                                           | 0.00                                | 0.00                                            | 0.00                                |     |
| Ireland         | 6.87                                            | 0.00                                | 27.48                                           | 2.43                                | 20.61                                           | 0.00                                |     |
| Italy           | 19.11                                           | 3.62                                | 288.05                                          | 7.62                                | 137.88                                          | 1.89                                | 6)  |
| Latvia          | 57.89                                           | 22.89                               |                                                 |                                     |                                                 |                                     |     |
| Lithuania       | 41.38                                           |                                     | 305.59                                          |                                     | 566.61                                          |                                     | 7)  |
| Luxembourg      | 0.00                                            | 0.00                                | 0.00                                            | 0.00                                | 0.00                                            | 0.00                                |     |
| Malta           | 0.00                                            | 0.00                                | 169.72                                          | 0.00                                | 0.00                                            | 0.00                                | 8)  |
| Montenegro      | 16.80                                           | 0.00                                | 520.83                                          | 32.02                               |                                                 |                                     | 9)  |
| Netherlands     | 7.01                                            | 0.27                                | 56.11                                           | 1.09                                | 14.03                                           | 0.00                                |     |
| Norway          | 0.00                                            | 0.00                                | 35.93                                           | 1.07                                | 93.42                                           | 1.07                                |     |
| Poland          |                                                 |                                     |                                                 |                                     |                                                 |                                     |     |
| Romania         |                                                 |                                     |                                                 |                                     |                                                 |                                     | 10) |
| Serbia          |                                                 |                                     |                                                 |                                     |                                                 |                                     |     |
| Slovak Republic | 6.00                                            | 2.70                                | 102.03                                          | 12.13                               | 60.02                                           | 12.13                               | 11) |
| Slovenia        | 0.00                                            | 0.00                                | 94.44                                           | 0.00                                | 37.78                                           | 0.00                                |     |
| Sweden          | 0.00                                            | 0.81                                | 24.76                                           | 0.41                                | 42.77                                           | 0.00                                |     |
| Switzerland     | 9.77                                            | 0.45                                | 127.02                                          | 3.58                                | 78.16                                           | 0.00                                |     |
| United Kingdom  | 5.99                                            | 0.96                                | 34.76                                           | 0.07                                | 30.37                                           | 0.52                                |     |

1) Regular Donors: data not available

2) First time donors are tested a few days before donation and, if the results allow, then they proceed for donation. For donors at the mobile unit, this is not implemented

3) Figures show total number of confirmed cases. There are no separate statistics for repeat or first time donors

4) Data on 70 604 first time donors and on 342 544 repeat donors. Only in a few centers do donors give blood samples for testing on their first visit

5) Previous data on HBsAg + a-HBc positive samples was incorrect, hence the increase in confirmed seropositive results

6) Coverage 92.3% of donations

7) Total of confirmed seropositive tests is presented (first and repeat tested donors)

8) Acute Beds = 1102

9) Confirmatory testing on HCV and syphilis was not done in 2008 because of the lack of tests. 5952 first-time donors were registered, of which 4806 gave blood on their first visit

10) Total estimated number of donors = 209 287

11) New donors are not tested if they are refused for donation

Table 8.1 – Nucleic Acid Amplification Techniques (NAT) testing

| Country               | HIV NAT          |               | HBV NAT          |               | HCV NAT          |               | Other NAT tests (separated by ';')                                       |               |
|-----------------------|------------------|---------------|------------------|---------------|------------------|---------------|--------------------------------------------------------------------------|---------------|
|                       | Donations tested | Size Minipool | Donations tested | Size Minipool | Donations tested | Size Minipool | Donations tested                                                         | Size Minipool |
| <b>Austria</b>        | All              | 96            | All              | 96            | All              | 96            | All HAV;Frankfurt, Wiesenheid, Linz; All PB19;Frankfurt,Wiesenheid, Linz | 96; 96        |
| <b>Belgium</b>        | All              | 8             | None             |               | All              | 8             |                                                                          |               |
| <b>Bulgaria</b>       | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Croatia</b>        | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Cyprus</b>         | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Czech Republic</b> | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Denmark</b>        | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Estonia</b>        | All              | 12            | None             |               | All              | 12            |                                                                          |               |
| <b>FYR Macedonia</b>  | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Finland</b>        | All              | 1             | All              | 1             | All              | 1             | All HAV RNA; All Parvovirus B 19                                         | 96; 96        |
| <b>France</b>         | All              |               | None             |               | All              |               |                                                                          |               |
| <b>Georgia</b>        | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Germany</b>        | All              | 96            |                  |               | All              | 96            |                                                                          |               |
| <b>Greece</b>         | All              | 1             | All              | 1             | All              | 1             |                                                                          |               |
| <b>Hungary</b>        |                  |               |                  |               |                  |               |                                                                          |               |
| <b>Iceland</b>        | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Ireland</b>        | All              | 8             | None             |               | All              | 8             |                                                                          |               |
| <b>Italy</b>          | All              |               | All              |               | All              |               |                                                                          |               |
| <b>Latvia</b>         | All              | 24            | All              | 24            | All              | 24            |                                                                          |               |
| <b>Lithuania</b>      | All              | 6             | All              | 6             | All              | 6             |                                                                          |               |
| <b>Luxembourg</b>     | All              | 50            | All              | 50            |                  | 50            | All PARVOVIRUS B19                                                       | 50            |
| <b>Malta</b>          | None             |               | None             |               | None             |               |                                                                          |               |
| <b>Montenegro</b>     |                  |               |                  |               |                  |               |                                                                          |               |
| <b>Netherlands</b>    | All              | 48            | None             |               | All              | 48            |                                                                          |               |
| <b>Norway</b>         |                  |               |                  |               |                  |               |                                                                          |               |
| <b>Poland</b>         | All              |               | All              |               | All              |               |                                                                          |               |

Table 8.1 (continued) – *Nucleic Acid Amplification Techniques (NAT) testing*

| Country         | HIV NAT          |               | HBV NAT          |               | HCV NAT          |               | Other NAT tests (separated by ‘;’) |               |
|-----------------|------------------|---------------|------------------|---------------|------------------|---------------|------------------------------------|---------------|
|                 | Donations tested | Size Minipool | Donations tested | Size Minipool | Donations tested | Size Minipool | Donations tested                   | Size Minipool |
| Portugal        |                  |               |                  |               |                  |               |                                    |               |
| Romania         | None             |               | None             |               | None             |               |                                    |               |
| Serbia          |                  |               |                  |               |                  |               |                                    |               |
| Slovak Republic | None             |               | None             |               | None             |               |                                    |               |
| Slovenia        | All              |               | All              |               | All              |               |                                    |               |
| Sweden          | None             |               | None             |               | None             |               |                                    | 16)           |
| Switzerland     | All              | 8             | All              | 1             | All              | 8             |                                    | 17)           |
| United Kingdom  | All              |               | None             |               | All              |               |                                    | 18)           |

1) HIV: pool size = 3-30-24-96. HBV: pool size = 3-24-40-96. HCV: pool size = 3-24-40-96. HAV: Frankfurt, Wiesemheid, Linz. PB19: Frankfurt, Wiesemheid, Linz

2) NAT has not yet been introduced in the Blood Center

3) HIV: results of NAT testing of plasma sent to fractionating company are reported back. HBV: results of NAT testing of plasma sent to fractionating company are reported back. HCV: results of NAT testing done on plasma by fractionating company are reported back

4) HIV: ID NAT was implemented 01 Jan. 2009. HBV: ID NAT was implemented 01 Jan. 2009. HCV: ID NAT was implemented 01 Jan. 2009

5) HAV: RNA. Parvovirus B 19: cut off =  $10^4$  IU/ml

6) HIV: pool size = 24 and 8 (2 different techniques used). HCV: pool size = 24 and 8 (2 different techniques used)

7) HIV: pool size for NAT tests = 10 to 96. HBV: no data - NAT test performed by blood donation service on a voluntary basis for approximately 75% of all donations. HCV: pool size for NAT tests = 10 to 96

8) HIV: data on 568 210 donations. HBV: data on 568 210 donations. HCV: data on 568 210 donations

9) NAT tests are used by the confirmation process

10) HIV: Procleix HCV/HIV-1 duplex assay. HCV: Procleix HCV/HIV-1 duplex assay

11) 60 % individual NAT testing, 40 % minipools (size 6)

12) Parvovirus B19

13) Data not available

14) NAT testing is not yet performed in Montenegro

15) HIV: by fractionator. HBV: by fractionator. HCV: by fractionator. Parvo B19: by fractionator

16) Samples from all plasma units are tested by the fractionators and any verified positive results are reported to the blood establishments

17) HIV: size of minipools ranges from 1- 24. HBV: NAT testing individually (Tigris) and 6 pools (Roche Cobas S201); 3 were anti-Hbc pos. HCV: size of minipools ranges from 1-24

18) HIV: size of minipools = 48 (NHSBT England & Wales), 96 (Northern Ireland), maximum 95 (SNBTS). HCV: size of minipools = 48 (NHSBT England & Wales), 96 (Northern Ireland), maximum 95 (SNBTS)

Table 8.2 – *NAT-only positive donors*

| Country         | HIV 1                    |               | HBV                      |               | HCV                      |               |
|-----------------|--------------------------|---------------|--------------------------|---------------|--------------------------|---------------|
|                 | first time tested donors | repeat donors | first time tested donors | repeat donors | first time tested donors | repeat donors |
| Austria         | 0                        | 0             | 0                        | 0             | 0                        | 0             |
| Belgium         | 0                        | 1             |                          |               | 0                        | 0             |
| Bulgaria        |                          |               |                          |               |                          |               |
| Croatia         |                          |               |                          |               |                          |               |
| Cyprus          |                          |               |                          |               |                          |               |
| Czech Republic  |                          |               |                          |               |                          |               |
| Denmark         |                          |               |                          |               |                          |               |
| Estonia         | 0                        | 0             |                          |               | 0                        | 2             |
| FYR Macedonia   |                          |               |                          |               |                          |               |
| Finland         | 0                        | 1             | 0                        | 1             | 0                        | 0             |
| France          |                          |               |                          |               |                          |               |
| Georgia         |                          |               |                          |               |                          |               |
| Germany         | 0                        | 3             | 0                        | 2             | 2                        | 5             |
| Greece          | 0                        | 0             | 40                       | 12            | 0                        | 0             |
| Hungary         |                          |               |                          |               |                          |               |
| Iceland         |                          |               |                          |               |                          |               |
| Ireland         | 0                        | 0             |                          |               | 0                        | 0             |
| Italy           | 0                        | 2             | 20                       | 64            | 3                        | 2             |
| Latvia          |                          |               |                          |               | 2                        |               |
| Lithuania       |                          |               |                          |               |                          |               |
| Luxembourg      | 0                        | 0             | 0                        | 0             | 0                        | 0             |
| Malta           |                          |               |                          |               |                          |               |
| Montenegro      |                          |               |                          |               |                          |               |
| Netherlands     | 0                        | 0             |                          |               | 0                        | 0             |
| Norway          |                          |               |                          |               |                          |               |
| Poland          |                          |               |                          |               |                          |               |
| Portugal        |                          |               |                          |               |                          |               |
| Romania         |                          |               |                          |               |                          |               |
| Serbia          |                          |               |                          |               |                          |               |
| Slovak Republic |                          |               |                          |               |                          |               |
| Slovenia        | 0                        | 8             | 0                        | 7             | 0                        | 1             |
| Sweden          |                          |               |                          |               |                          |               |
| Switzerland     | 0                        | 0             | 0                        | 5             | 0                        | 0             |
| United Kingdom  | 1                        | 0             |                          |               | 1                        | 0             |

Table 9 – *Bacterial screening*

| Country         | total platelets issued (adult therapeutic doses) | % bacterial screened |           | % of platelet adult doses screened | % of screened units confirmed positive |     |
|-----------------|--------------------------------------------------|----------------------|-----------|------------------------------------|----------------------------------------|-----|
|                 |                                                  | recovered            | apheresis |                                    |                                        |     |
| Austria         | 36 300                                           | 27                   | 27        | 54                                 | 54                                     | 1)  |
| Belgium         | 65 030                                           | 96                   | 65        | 86                                 | 0                                      | 2)  |
| Bulgaria        | 4 029                                            | 3                    | 0         | 3                                  | 0                                      |     |
| Croatia         | 11 816                                           | 4                    | 5         | 4                                  | 1                                      |     |
| Cyprus          | 11 479                                           | 0                    | 0         | 0                                  | 0                                      |     |
| Czech Republic  | 30 349                                           |                      |           |                                    |                                        | 3)  |
| Denmark         | 34 465                                           |                      |           | 89                                 | 0                                      |     |
| Estonia         | 5 899                                            | 100                  | 100       | 100                                | 1                                      |     |
| FYR Macedonia   | 12 700                                           | 1                    | 0         | 1                                  | 3                                      |     |
| Finland         | 37 455                                           | 0                    | 0         | 0                                  | 0                                      | 4)  |
| France          | 252 887                                          |                      |           |                                    |                                        |     |
| Georgia         | 4 478                                            | 100                  | 0         | 2                                  | 0                                      |     |
| Germany         | 472 346                                          |                      |           |                                    |                                        | 5)  |
| Greece          | 135 933                                          | 10                   | 8         | 6                                  | 12                                     |     |
| Hungary         | 22 931                                           | 17                   | 20        | 23                                 | 0                                      |     |
| Iceland         | 2 195                                            | 0                    | 0         | 0                                  |                                        | 6)  |
| Ireland         | 24 739                                           | 100                  | 100       | 100                                | 0                                      |     |
| Italy           |                                                  |                      |           |                                    |                                        |     |
| Latvia          | 6 208                                            |                      |           |                                    |                                        |     |
| Lithuania       | 15 732                                           |                      |           | 3                                  |                                        |     |
| Luxembourg      | 3 692                                            | 0                    | 2         | 2                                  | 0                                      |     |
| Malta           | 1 169                                            | 20                   | 20        | 20                                 | 0                                      |     |
| Montenegro      |                                                  |                      |           |                                    |                                        | 7)  |
| Netherlands     | 50 784                                           | 100                  | 100       | 100                                | 100                                    |     |
| Norway          | 19 553                                           |                      |           | 76                                 | 0                                      |     |
| Poland          | 134 505                                          |                      |           |                                    |                                        |     |
| Romania         | 20 292                                           |                      |           |                                    |                                        | 8)  |
| Serbia          |                                                  |                      | 3         | 1                                  |                                        |     |
| Slovak Republic | 12 816                                           |                      |           |                                    |                                        | 9)  |
| Slovenia        | 8 056                                            | 3                    | 2         | 3                                  | 0                                      |     |
| Sweden          | 38 941                                           |                      |           | 36                                 | 0                                      |     |
| Switzerland     | 27 669                                           |                      |           | 0                                  |                                        | 10) |
| United Kingdom  | 266 577                                          | 17                   | 16        | 15                                 | 1                                      | 11) |

1) Screening and positive culture: all granulocytes = 0.12% (n=29); apheresis granulocytes = 0.059% (n=14); pooled granulocytes = 0.064% (n=15)

2) Remainder = pathogen-inactivated

3) Bacterial screening is done only as a “statistical” quality control in about 1% of products

4) No in-process screening for bacteria. All out-dated platelet components are cultured for bacteria

5) Sterility testing as a statistical process control  $0.4 \times \text{SQR}(n)$  at the end of shelf life

6) No screening of bacteria

7) Screening for presence of bacteria in PLT preparations is done occasionally

8) Screening performed on BactAlert/Hemoline (data not available)

9) Bacterial screening only as quality control in accordance with recommendation N°R15, not as routine practice to prolong shelf life

10) Only QC on outdated units

11) NHSBT (England) - no routine bacterial screening performed

Table 10 – *Organisation, registration and labelling*

| Country         | National Council or Expert Committee | national blood policy |              | national regulations |
|-----------------|--------------------------------------|-----------------------|--------------|----------------------|
|                 |                                      | on quality and safety | implementing |                      |
| Austria         | Yes                                  | Yes                   | Yes          | Yes                  |
| Belgium         | Yes                                  | Yes                   | Yes          | Yes                  |
| Bulgaria        | No                                   | Yes                   | Yes          | Yes                  |
| Croatia         | Yes                                  | No                    | No           | Yes                  |
| Cyprus          | No                                   | No                    |              | Yes                  |
| Czech Republic  | Yes                                  | Yes                   | Yes          | Yes                  |
| Denmark         | Yes                                  | Yes                   | Yes          | Yes                  |
| Estonia         | No                                   | No                    | No           | Yes                  |
| FYR Macedonia   | Yes                                  | Yes                   | Yes          | Yes                  |
| Finland         | No                                   | Yes                   | Yes          | Yes                  |
| France          | Yes                                  | Yes                   | No           | Yes                  |
| Georgia         | Yes                                  | No                    | No           | Yes                  |
| Germany         | Yes                                  | Yes                   | Yes          | Yes                  |
| Greece          | Yes                                  | Yes                   | Yes          | Yes                  |
| Hungary         | Yes                                  | Yes                   | Yes          | Yes                  |
| Iceland         | No                                   | No                    | No           | Yes                  |
| Ireland         | No                                   | No                    | No           | Yes                  |
| Italy           | Yes                                  | Yes                   | Yes          | Yes                  |
| Latvia          | Yes                                  | Yes                   | Yes          | Yes                  |
| Lithuania       | Yes                                  | Yes                   | Yes          | Yes                  |
| Luxembourg      | Yes                                  | Yes                   | Yes          | Yes                  |
| Malta           | No                                   | Yes                   | Yes          | Yes                  |
| Montenegro      | Yes                                  | Yes                   | Yes          | Yes                  |
| Netherlands     | Yes                                  | Yes                   | Yes          | Yes                  |
| Norway          | Yes                                  | Yes                   | Yes          | Yes                  |
| Poland          | Yes                                  | Yes                   |              | Yes                  |
| Romania         | Yes                                  | Yes                   | Yes          | Yes                  |
| Serbia          | Yes                                  | Yes                   | Yes          | Yes                  |
| Slovak Republic | Yes                                  | Yes                   | Yes          | Yes                  |
| Slovenia        | Yes                                  | Yes                   |              | Yes                  |
| Spain           |                                      |                       |              |                      |
| Sweden          | Yes                                  | Yes                   | Yes          | Yes                  |
| Switzerland     | No                                   | Yes                   | Yes          | Yes                  |
| United Kingdom  | Yes                                  | Yes                   | Yes          | Yes                  |

1) Currently, the National Blood Policy is in the process of adoption by the Ministry of Health and Social Welfare

2) Directives have been transposed into law. Most of the articles are empirically followed and implemented by personnel. No national regulations have been officially regulated by the Ministry of Health

3) The Swedish Blood Alliance and the Swedish Society for Transfusion Medicine participate in the consultation procedures for new regulations

4) Guidelines for the Blood Transfusion Services in the UK (7<sup>th</sup> Edition)



Table 11a – *Quality management related issues*

| Country               | QMS established and maintained | % donations covered by |          |       | Other procedures                                                                                                                                          | Inspections every second year | Description of Other organisation/body                  | System of educ. and training |
|-----------------------|--------------------------------|------------------------|----------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------------------------------|------------------------------|
|                       |                                | GMP                    | ISO 9000 | Other |                                                                                                                                                           |                               |                                                         |                              |
| <b>Austria</b>        | Yes                            | 100                    | 100      |       | Blutsicherheitsgesetz, Blutspenderverordnung, Richtlinien für Blutgruppenserologie u. Transfusionsmedizin, Verordnung: Arzneimittel aus menschlichem Blut | National                      | AGES PharmMed (Nationale Einrichtung)                   | Yes                          |
| <b>Belgium</b>        | Yes                            | 100                    | 35       |       |                                                                                                                                                           | National+Other                | national authority and fractionator                     | Yes                          |
| <b>Bulgaria</b>       | Yes                            | 100                    |          |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Croatia</b>        | Yes                            | 100                    | 50       |       |                                                                                                                                                           | National                      | Inspection is performed only in CITM, but each 5 years. | Yes                          |
| <b>Cyprus</b>         | Planned                        | 0                      | 0        | 0     | 0                                                                                                                                                         | No                            |                                                         | No                           |
| <b>Czech Republic</b> | Yes                            | 100                    | 40       |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Denmark</b>        | Yes                            | 100                    |          | 15    | ISO15189                                                                                                                                                  | National                      |                                                         |                              |
| <b>Estonia</b>        | Yes                            | 100                    | 100      |       |                                                                                                                                                           | National                      |                                                         | No                           |
| <b>FYR Macedonia</b>  | Yes                            |                        |          |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Finland</b>        | Yes                            | 100                    | 0        |       |                                                                                                                                                           | National                      | National Agency for Medicines                           | Yes                          |
| <b>France</b>         | Yes                            |                        | 100      |       |                                                                                                                                                           | National                      | AFSSAPS                                                 | Yes                          |
| <b>Georgia</b>        | Planned                        |                        | 0        |       |                                                                                                                                                           | National                      |                                                         | No                           |
| <b>Germany</b>        | Yes                            | 100                    |          |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Greece</b>         | Yes                            | 75                     | 12       |       |                                                                                                                                                           | Other                         | EKEVYL, ELLOT for some centers only                     | Yes                          |
| <b>Hungary</b>        | Yes                            | 100                    |          |       |                                                                                                                                                           | National+Other                | Plasma fractionation factory                            | Yes                          |
| <b>Iceland</b>        | Yes                            |                        | 100      |       |                                                                                                                                                           | National+Other                |                                                         | No                           |
| <b>Ireland</b>        | Yes                            | 100                    | 0        |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Italy</b>          | Yes                            | 0                      | 40       | 100   | Regional authorisation and accreditation                                                                                                                  | No                            |                                                         | Yes                          |
| <b>Latvia</b>         | Yes                            |                        | 100      |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Lithuania</b>      |                                | 60                     |          |       |                                                                                                                                                           | National                      |                                                         | Yes                          |
| <b>Luxembourg</b>     | Yes                            | 100                    | 100      | 100   | EFS BORDEAUX for FFP                                                                                                                                      | National+Other                | EFS BORDEAUX                                            | Yes                          |
| <b>Malta</b>          | Yes                            |                        |          | 100   | EU Directive 2002/98/EC / EDQM Manual                                                                                                                     | National                      |                                                         | Yes                          |
| <b>Montenegro</b>     | Planned                        |                        |          |       |                                                                                                                                                           | National                      |                                                         | No                           |
| <b>Netherlands</b>    | Yes                            | 100                    | 100      |       |                                                                                                                                                           | National                      |                                                         | Yes                          |

Table 11a (continued) – *Quality management related issues*

| Country         | QMS established and maintained | % donations covered by |          |       | Other procedures                                                                  | Inspections every second year | Description of Other organisation/body                                      | System of educ. and training |
|-----------------|--------------------------------|------------------------|----------|-------|-----------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------|------------------------------|
|                 |                                | GMP                    | ISO 9000 | Other |                                                                                   |                               |                                                                             |                              |
| Norway          | Yes                            | 100                    | 42       |       |                                                                                   | National                      |                                                                             | No                           |
| Poland          | Yes                            | 100                    |          |       |                                                                                   | National                      |                                                                             | No                           |
| Romania         | Yes                            |                        |          |       |                                                                                   | National                      |                                                                             |                              |
| Serbia          | Yes                            |                        | 3        |       |                                                                                   | Other                         |                                                                             | Yes                          |
| Slovak Republic | Yes                            | 100                    | 0        |       |                                                                                   | National+Other                | fractionator                                                                | Yes                          |
| Slovenia        | Yes                            | 100                    |          |       |                                                                                   | National+Other                | organisations accredited to perform the ISO 9001:2000 certification process | Yes                          |
| Sweden          | Yes                            | 100                    | 0        | 64    | ISO/IEC 17025 or ISO/IEC 15189                                                    | National+Other                | ISO/IEC 17025 or ISO/IEC 15189                                              | Yes                          |
| Switzerland     | Yes                            | 100                    | 65       | 90    | All RBTS comply also with ISO 17025                                               | National+Other                | METAS : national accreditation body                                         | Yes                          |
| United Kingdom  | Yes                            | 100                    | 4        | 0     | 4 UK Blood Services each have its own National; procedures – ISO 9000 Wales only. | National+Other                | Wales only – BSI ISO series every 6 months                                  | Yes                          |

Table 11b - Quality management related issues

| Country               | % donations labelled according to |                | component code |                | Comments                                                                                                                                                                                                | Haemovigilance system    |                                                                                                                                                                        |
|-----------------------|-----------------------------------|----------------|----------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                       | ISBT 128                          | another system | ISBT 128       | another system |                                                                                                                                                                                                         | Available / organisation | Description of Other organisation/body                                                                                                                                 |
| <b>Andorra</b>        |                                   |                |                |                |                                                                                                                                                                                                         |                          |                                                                                                                                                                        |
| <b>Armenia</b>        |                                   |                |                |                |                                                                                                                                                                                                         |                          |                                                                                                                                                                        |
| <b>Azerbaijan</b>     |                                   |                |                |                |                                                                                                                                                                                                         |                          |                                                                                                                                                                        |
| <b>Albania</b>        |                                   |                |                |                |                                                                                                                                                                                                         |                          |                                                                                                                                                                        |
| <b>Austria</b>        | 100                               |                |                | 100            | Verschiedene Systeme                                                                                                                                                                                    | National                 | AGES PharmMed (Nationale Einrichtung)                                                                                                                                  |
| <b>Belgium</b>        | 93                                | 7              | 93             | 7              |                                                                                                                                                                                                         | National                 |                                                                                                                                                                        |
| <b>Bulgaria</b>       |                                   | 100            |                | 100            |                                                                                                                                                                                                         | National                 |                                                                                                                                                                        |
| <b>Croatia</b>        |                                   | 90             |                | 50             | Codabare                                                                                                                                                                                                | National+Other           | Croatian Institute of Transfusion Medicine (CITM)                                                                                                                      |
| <b>Cyprus</b>         | 0                                 | 0              | 0              | 0              |                                                                                                                                                                                                         | No                       |                                                                                                                                                                        |
| <b>Czech Republic</b> |                                   | 100            |                | 100            | national labelling system using code 128 and standardised producer / donation / component number                                                                                                        | National                 |                                                                                                                                                                        |
| <b>Denmark</b>        | 100                               |                | 100            |                |                                                                                                                                                                                                         | National+Other           | Danish Society for Clinical Immunology                                                                                                                                 |
| <b>Estonia</b>        | 100                               | 0              | 0              | 100            | Local component coding is implemented                                                                                                                                                                   | National                 |                                                                                                                                                                        |
| <b>FYR Macedonia</b>  |                                   | 100            |                | 100            | PROGESA Softver                                                                                                                                                                                         | No                       |                                                                                                                                                                        |
| <b>Finland</b>        | 100                               | 0              | 100            | 0              |                                                                                                                                                                                                         | Other                    | Finnish Red Cross Blood Service                                                                                                                                        |
| <b>France</b>         |                                   | 100            |                | 100            | Monarch Barcode                                                                                                                                                                                         | National+Other           | Hospitals, EFS and competent authority (AFSSAPS)                                                                                                                       |
| <b>Georgia</b>        |                                   | 100            |                |                |                                                                                                                                                                                                         | No                       |                                                                                                                                                                        |
| <b>Germany</b>        |                                   |                |                |                | Any unique code, mostly used is Eurocode.                                                                                                                                                               | National                 |                                                                                                                                                                        |
| <b>Greece</b>         |                                   | 85             |                | 85             | "Percentage donations labelled according to ISBT 128 (% donation numbers): Planned.<br>Percentage components labelled according to another system (% component codes): Blood Med and Blood-Pliroforiki" | Other                    | National Coordinating Haemovigilance Centre (SKAE) of the Hellenic Centre of Diseases Control and Prevention (KEELPNO) of the Ministry of Health and Social Solidarity |
| <b>Hungary</b>        | 100                               | 0              |                | 100            |                                                                                                                                                                                                         | National                 |                                                                                                                                                                        |
| <b>Iceland</b>        | 100                               | 0              | 100            | 0              | codabar                                                                                                                                                                                                 | National                 |                                                                                                                                                                        |

Table 11b (continued) - *Quality management related issues*

| Country         | % donations labelled according to |                | component code |                | Comments                                                                                                                                               | Haemovigilance system    |                                                |
|-----------------|-----------------------------------|----------------|----------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------------------------|
|                 | ISBT 128                          | another system | ISBT 128       | another system |                                                                                                                                                        | Available / organisation | Description of Other organisation/body         |
| Ireland         | 0                                 | 100            | 0              | 100            | CODABAR modulus 11                                                                                                                                     | National                 |                                                |
| Italy           | 0                                 | 100            | 0              | 100            | National regulation (UNI 10529); A new regional and national inspection system will be implemented starting from 2010 in compliance with EU directives | National                 |                                                |
| Latvia          | 100                               |                | 100            |                |                                                                                                                                                        | National                 |                                                |
| Lithuania       |                                   | 100            |                | 100            |                                                                                                                                                        | National                 |                                                |
| Luxembourg      | 0                                 | 100            | 0              | 100            | LOCAL SYSTEM: ISBT 128 IS TOO EXPENSIVE                                                                                                                | Other                    | CTS and HOSPITALS                              |
| Malta           | 0                                 | 100            | 0              | 100            | Codabar                                                                                                                                                | National                 |                                                |
| Montenegro      |                                   | 100            |                |                |                                                                                                                                                        | No                       |                                                |
| Netherlands     | 100                               | 0              | 100            | 0              |                                                                                                                                                        | National+Other           | TRIP                                           |
| Norway          | 98                                | 2              | 98             | 2              |                                                                                                                                                        | National                 |                                                |
| Poland          |                                   |                |                |                |                                                                                                                                                        | Other                    | Institute of Haematology and Blood Transfusion |
| Portugal        |                                   |                |                |                |                                                                                                                                                        |                          |                                                |
| Romania         |                                   | 100            |                |                |                                                                                                                                                        | National                 |                                                |
| Serbia          | 13                                |                | 13             |                |                                                                                                                                                        | Other                    |                                                |
| Slovak Republic | 0                                 | 100            | 0              | 100            |                                                                                                                                                        | National                 |                                                |
| Slovenia        |                                   | 100            |                | 100            | codabar system                                                                                                                                         | National+Other           | Blood Transfusion Centre of Ljubljana          |
| Sweden          | 84                                | 16             | 85             | 15             | previous national Blood-Id system still applied by 2 Blood establishments                                                                              | National+Other           | The Swedish Society for Transfusion Medicine   |
| Switzerland     | 100                               |                | 100            |                |                                                                                                                                                        | National                 |                                                |
| Ukraine         |                                   |                |                |                |                                                                                                                                                        |                          |                                                |
| United Kingdom  | 100                               | 0              | 0              | 100            | Codabar; Donation numbers ISBT 128, Product labels Codabar                                                                                             | National+Other           | MHRA (SABRE) & SHOT                            |

Table 12 - Haemovigilance

| Country        | total number components transfused: WB + RBC + FFP + Platelets (U) | Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3) |                                |                   |     |             |       |      |     |     |     |             |           |         |           | Incidence high imputability serious adverse reactions per 100 000 component U |      |               |
|----------------|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------------|-------------------|-----|-------------|-------|------|-----|-----|-----|-------------|-----------|---------|-----------|-------------------------------------------------------------------------------|------|---------------|
|                |                                                                    | haemolysis ABO                                                                                                  | haemolysis other allo antibody | Non immun. Hemol. | PTP | Anaphylaxis | TRALI | GVHD | HBV | HCV | HIV | Other viral | Bacterial | Malaria | Parasitic |                                                                               | TACO | Other serious |
| Austria        | 556 204                                                            |                                                                                                                 |                                |                   |     |             |       |      |     |     |     |             |           |         |           |                                                                               |      | 1)            |
| Belgium        | 675 286                                                            | 4                                                                                                               | 4                              | 1                 |     | 10          | 3     |      |     |     |     | 4           |           |         |           | 4                                                                             | 7    | 5.5           |
| Bulgaria       | 214 862                                                            |                                                                                                                 |                                |                   |     |             |       |      |     |     |     |             |           |         |           |                                                                               |      |               |
| Croatia        | 243 810                                                            |                                                                                                                 |                                |                   |     |             |       |      |     |     |     |             |           |         |           |                                                                               |      | 2)            |
| Cyprus         | 71 497                                                             | 0                                                                                                               | 0                              | 0                 | 0   | 0           | 0     | 0    | 0   | 0   | 0   | 0           | 0         | 0       | 0         | 0                                                                             | 0    | 0.0           |
| Czech Republic | 601 541                                                            | 2                                                                                                               | 1                              | 0                 | 0   | 7           | 2     | 0    | 0   | 0   | 0   | 0           | 0         | 0       | 0         | 0                                                                             | 0    | 2.0           |
| Denmark        | 432 846                                                            | 1                                                                                                               | 1                              |                   |     |             |       |      |     |     |     | 1           |           |         |           |                                                                               |      | 0.7           |
| Estonia        | 87 951                                                             | 0                                                                                                               | 1                              | 2                 |     | 1           |       |      |     |     |     |             |           |         |           |                                                                               |      | 4.5           |
| FYR Macedonia  | 70 971                                                             |                                                                                                                 |                                |                   |     |             |       |      |     |     |     |             |           |         |           |                                                                               |      |               |
| Finland        | 343 711                                                            | 2                                                                                                               | 1                              | 1                 | 0   | 3           | 0     | 0    | 0   | 0   | 0   | 0           | 0         | 0       | 0         | 0                                                                             | 0    | 2.0           |
| France         | 2 850 815                                                          | 3                                                                                                               | 7                              |                   |     | 47          | 26    |      | 56  | 207 | 39  |             | 5         |         |           | 107                                                                           |      | 17.4          |
| Georgia        | 80 198                                                             |                                                                                                                 |                                |                   |     |             |       |      |     |     |     |             |           |         |           |                                                                               |      |               |
| Germany        | 6 503 443                                                          | 5                                                                                                               | 6                              | 1                 | 1   | 12          | 15    | 1    |     |     |     | 6           |           |         |           |                                                                               |      | 0.7           |
| Greece         | 1 024 855                                                          | 8                                                                                                               | 9                              |                   |     | 20          | 4     |      |     |     |     | 2           |           |         |           | 11                                                                            | 4    | 5.7           |
|                |                                                                    |                                                                                                                 |                                |                   |     |             |       |      |     |     |     |             |           |         |           |                                                                               |      | 5)            |

Table 12 (continued) - Haemovigilance

| Country     | total number<br>components<br>transfused:<br>WB + RBC<br>+ FFP +<br>Platelets (U) | Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3) |                                      |                         |     |             |       |      |     |     |     |                |           |         |           | Incidence<br>high<br>imputability<br>serious<br>adverse<br>reactions<br>per 100 000<br>component U |      |                  |
|-------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------------------|-------------------------|-----|-------------|-------|------|-----|-----|-----|----------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------|------|------------------|
|             |                                                                                   | haemolysis<br>ABO                                                                                               | haemolysis<br>other allo<br>antibody | Non<br>immun.<br>Hemol. | PTP | Anaphylaxis | TRALI | GVHD | HBV | HCV | HIV | Other<br>viral | Bacterial | Malaria | Parasitic |                                                                                                    | TACO | Other<br>serious |
| Hungary     | 489 512                                                                           | 2                                                                                                               | 2                                    | 1                       | 0   | 0           | 6     | 0    | 0   | 0   | 0   | 0              | 0         | 0       | 0         | 0                                                                                                  | 0    | 2.2              |
| Iceland     | 22 357                                                                            |                                                                                                                 |                                      |                         |     | 1           |       |      |     |     |     |                |           |         |           |                                                                                                    | 1    | 8.9              |
| Ireland     | 166 758                                                                           | 0                                                                                                               | 4                                    | 0                       | 0   | 34          | 0     | 0    | 0   | 0   | 0   | 0              | 0         | 0       | 0         | 27                                                                                                 | 24   | 53.4             |
| Italy       | 2 970 000                                                                         |                                                                                                                 |                                      |                         |     |             |       |      |     |     |     |                |           |         |           |                                                                                                    |      |                  |
| Latvia      | 103 106                                                                           |                                                                                                                 |                                      |                         |     |             | 4     |      |     |     |     |                |           |         |           | 1                                                                                                  |      | 4.8              |
| Lithuania   | 139 745                                                                           |                                                                                                                 |                                      |                         |     |             | 2     |      |     |     |     |                |           |         |           |                                                                                                    |      | 1.4              |
| Luxembourg  | 29 796                                                                            | 0                                                                                                               | 0                                    | 0                       | 0   | 0           | 0     | 0    | 0   | 0   | 0   | 0              | 0         | 0       | 0         | 0                                                                                                  | 0    | 0.0              |
| Malta       | 21 928                                                                            | 1                                                                                                               | 1                                    | 0                       | 0   | 0           | 0     | 0    | 0   | 0   | 0   | 0              | 0         | 0       | 0         | 0                                                                                                  | 0    | 9.1              |
| Montenegro  | 19 893                                                                            |                                                                                                                 |                                      |                         |     |             |       |      |     |     |     |                |           |         |           |                                                                                                    |      |                  |
| Netherlands | 711 102                                                                           | 7                                                                                                               | 4                                    |                         |     | 32          | 17    | 1    |     |     |     |                |           |         | 16        |                                                                                                    |      | 10.8             |
| Norway      | 267 030                                                                           | 1                                                                                                               | 2                                    |                         |     | 2           |       |      |     |     |     | 1              | 1         |         | 7         |                                                                                                    |      | 5.2              |
| Poland      | 1 296 825                                                                         |                                                                                                                 |                                      |                         |     |             |       |      |     |     |     |                |           |         |           |                                                                                                    |      |                  |
| Romania     | 567 158                                                                           |                                                                                                                 |                                      |                         |     |             |       |      |     |     |     |                |           |         |           |                                                                                                    |      |                  |
| Serbia      | 620 446                                                                           |                                                                                                                 |                                      |                         |     |             |       |      |     |     |     |                |           |         |           |                                                                                                    |      |                  |

6)

7)

Table 12 (continued) - *Haemovigilance*

| Country         | total number components transfused: WB + RBC + FFP + Platelets (U) | Absolute number of serious adverse reactions with likely, probable or certain imputability (level 2 or level 3) |                                |                   |     |             |       |      |     |     |     |             |           |         |           |      | Incidence high imputability serious adverse reactions per 100 000 component U |               |
|-----------------|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------------|-------------------|-----|-------------|-------|------|-----|-----|-----|-------------|-----------|---------|-----------|------|-------------------------------------------------------------------------------|---------------|
|                 |                                                                    | haemolysis ABO                                                                                                  | haemolysis other allo antibody | Non immun. Hemol. | PTP | Anaphylaxis | TRALI | GVHD | HBV | HCV | HIV | Other viral | Bacterial | Malaria | Parasitic | TACO |                                                                               | Other serious |
| Slovak Republic | 223 437                                                            | 0                                                                                                               | 1                              | 0                 | 0   | 0           | 0     | 0    | 0   | 0   | 0   | 0           | 0         | 0       | 0         | 0    | 0                                                                             | 0.4           |
| Slovenia        | 120 296                                                            | 0                                                                                                               | 0                              | 0                 | 0   | 4           | 0     | 0    | 0   | 0   | 0   | 0           | 0         | 0       | 0         | 3    | 0                                                                             | 5.8           |
| Sweden          | 627 125                                                            | 4                                                                                                               | 2                              |                   |     | 13          | 4     |      |     |     |     | 3           |           |         |           | 3    |                                                                               | 4.6           |
| Switzerland     | 410 053                                                            |                                                                                                                 | 2                              |                   |     | 20          | 2     |      |     |     |     | 1           |           |         |           | 2    | 4                                                                             | 7.6           |
| United Kingdom  | 2 778 946                                                          | 4                                                                                                               | 30                             | 0                 | 1   | 68          | 10    |      |     |     |     | 6           |           |         |           |      | 58                                                                            | 6.4           |
| Total           |                                                                    | 44                                                                                                              | 78                             | 6                 | 2   | 280         | 89    | 0    | 58  | 207 | 39  | 1           | 29        | 0       | 0         | 181  | 98                                                                            |               |

1) Febrile transfusion reactions = 169. Allergic transfusion reactions = 215

2) Haemovigilance reporting system covers all reactions, not only serious ones. Therefore, data on all reactions presented here

3) Data collected for adverse reactions submitted to EU Regulatory Committee, but not available here

4) Only serious adverse reactions with a certain imputability are reported. Other serious adverse reactions: 1 FNHR, 1 epileptic seizure, 15 unknown

5) Data on 844 885 issued blood components

6) Only 16 non-serious adverse reactions reported in 2008 with imputability level I (7) and level II (9)

7) Haemovigilance systems on the national, regional and local levels are being prepared

8) All allergic reactions presented with dermatological symptoms - purpura (not anaphylaxis). Other serious reactions are febrile reactions

# APPENDIX

Questionnaire on the collection, testing and use of blood and  
blood components in Europe  
The 2008 survey



Strasbourg, 31 March 2006

# QUESTIONNAIRE ON THE COLLECTION, TESTING AND USE OF BLOOD AND BLOOD COMPONENTS IN EUROPE

## THE 2008 SURVEY

This questionnaire consists of three sections:

- A. Collection and use of blood and blood components,
- B. Testing of blood and blood components, and
- C. General information.

At the end of each section, please provide any additional information and comments that you think may be useful for the interpretation of the data and for the future improvement of the questionnaire. When information or data on specific terms is not available, please indicate “n.a.” (=data not yet available).

This questionnaire has been elaborated by and is copyright of Dr Olof Akerblom and Dr C.L. van der Poel. Revisions and additions have been made to comply with a World Health Organisation (WHO) questionnaire on selected indicators. Any questions you might have when filling out the questionnaire should be directly addressed to Dr C.L. van der Poel, [c.vanderpoel@sanquin.nl](mailto:c.vanderpoel@sanquin.nl)

*Directive 2002/98/EC*, Annex II, requests Member States of the European Union to report annually on the blood establishment's activity. This request includes figures also asked for in this questionnaire (No. 1.1 + 1.2.1, 2.1-5, 3.1-5, 4.1-2, 7.1 + 8.3.1, 7.2 + 8.3.2, and 12.2).

The questionnaire is to be completed and returned by 15 September 2006 to Dr C.L. van der Poel, [c.vanderpoel@sanquin.nl](mailto:c.vanderpoel@sanquin.nl), copy to the Secretariat, Health Division, Council of Europe, F-67075 Strasbourg Cedex, Fax: + 33 388 41 2726; e-mail: [sophie-marie.leguilloux@coe.int](mailto:sophie-marie.leguilloux@coe.int)

|                                |  |
|--------------------------------|--|
| <b>COUNTRY</b>                 |  |
| <b>Information provided by</b> |  |
| <b>Institution</b>             |  |
| <b>Address</b>                 |  |
| <b>Tel. &amp; fax.</b>         |  |
| <b>e-mail address</b>          |  |

  

|                                      |  |
|--------------------------------------|--|
| <b>Population in country, number</b> |  |
|--------------------------------------|--|

## SECTION A: Collection and use of blood and blood components

### 1. Donors active during the year

|            |                                                                |  |
|------------|----------------------------------------------------------------|--|
| <b>1.1</b> | <b>Regular and repeat donors,*</b> number                      |  |
| <b>1.2</b> | <b>First time donors,*</b> total number                        |  |
| 1.2.1      | - on first visit donating blood or blood components, number    |  |
| 1.2.2      | - on first visit giving blood samples for testing only, number |  |

\* Definition according to the Council Recommendation 98/463/EC and Council of Europe Guide to the preparation, use and quality assurance of blood components, Appendix 1.

First time donor      Someone who has never donated either blood or plasma

Repeat donor      Someone who has donated before but not within the last two years in the same blood establishment

Regular donor      Someone who donated blood or plasma within the last two years in the same blood establishment

|                                              |
|----------------------------------------------|
| <b>Comments to the data given in Table 1</b> |
|                                              |

### 2. Collection of blood and blood components

|            |                                                                                       |   |
|------------|---------------------------------------------------------------------------------------|---|
| <b>2.1</b> | <b>Whole blood,</b> total <b>number</b> of donations                                  |   |
| 2.1.1      | - voluntary non-remunerated, <b>per cent</b> of donations                             | % |
| 2.1.2      | - replacement donations, <sup>1</sup> <b>per cent</b> of donations                    | % |
| 2.1.3      | - autologous donations, pre-deposit, <b>number</b>                                    |   |
| <b>2.2</b> | <b>Red cells apheresis,</b> total <b>number</b> of donations (procedures)             |   |
| 2.2.1      | - voluntary non-remunerated, <b>per cent</b> of donations                             | % |
| 2.2.2      | - autologous donations, pre-deposit, <b>number</b>                                    |   |
| <b>2.3</b> | <b>Plasma apheresis,</b> total in <b>litres</b>                                       |   |
| 2.3.1      | - collected from voluntary non-remunerated, <b>litres</b>                             |   |
| <b>2.4</b> | <b>Platelets apheresis,</b> total <b>number</b> of donations (procedures)             |   |
| 2.4.1      | - voluntary non-remunerated, <b>per cent</b> of donations                             | % |
| <b>2.5</b> | <b>Granulocytes apheresis,</b> <b>number</b> of donations (procedures)                |   |
| <b>2.6</b> | <b>Multi-component apheresis,<sup>2</sup></b> <b>number</b> of donations (procedures) |   |

<sup>1</sup> Replacement donations      Donations collected from donors recruited by patients to enable them to undergo therapy, which requires blood transfusion

<sup>2</sup> Multi-component apheresis      means the collection in one session of two or more different types of blood components, *i.e.* erythrocytes + plasma, platelets + plasma, etc.

**Comments to the data given in Table 2****3. Use of blood and blood components intended for transfusion**

|                                                                                                                                                                                           |                                                                                       |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|--|
| Please, indicate if the figures given relate to blood and blood components<br><input type="checkbox"/> distributed to hospital blood banks, <u>or</u> <input type="checkbox"/> transfused |                                                                                       |  |
| <b>3.1</b>                                                                                                                                                                                | <b>Whole blood, units<sup>1</sup>, total number</b>                                   |  |
| <b>3.2</b>                                                                                                                                                                                | <b>Red cells</b> (red cells for transfusion, <i>excl.</i> autol.), units <sup>2</sup> |  |
| 3.2.1                                                                                                                                                                                     | - <b>red cells autologous</b> , pre-deposit, units                                    |  |
| <b>3.3</b>                                                                                                                                                                                | <b>Plasma</b> (plasma or FFP for transfusion), units <sup>2</sup>                     |  |
| <b>3.4</b>                                                                                                                                                                                | <b>Platelets</b> (adult therapeutic doses <sup>3</sup> ), total number                |  |
| 3.4.1                                                                                                                                                                                     | - recovered from whole blood (adult therapeutic doses <sup>3</sup> )                  |  |
| 3.4.2                                                                                                                                                                                     | - collected by platelet apheresis (adult therapeutic doses <sup>3</sup> )             |  |
| <b>3.5</b>                                                                                                                                                                                | <b>Cryoprecipitate</b> , FVIII IU x 10 <sup>6</sup>                                   |  |

<sup>1</sup> A unit of whole blood consists of approximately 450 or 500 mL of blood, collected in a suitable amount of anticoagulant solution.

<sup>2</sup> A unit of red cells or plasma is red cells or plasma recovered from one unit of whole blood or a comparable volume of red cells or plasma collected by apheresis.

<sup>3</sup> An adult therapeutic dose usually consists of 200 – 450 x 10<sup>9</sup> platelets.

**Comments to the data given in Table 3**

#### 4. Blood components delivered for the manufacture of medicinal products

|            |                                                                      |  |
|------------|----------------------------------------------------------------------|--|
| <b>4.1</b> | <b>Plasma for fractionation, total, litres<sup>1</sup></b>           |  |
| 4.1.1      | - human plasma for fractionation into FVIII, litres                  |  |
| 4.1.1.1    | - recovered from whole blood donations, litres                       |  |
| 4.1.1.1    | - from plasmapheresis (source plasma), litres                        |  |
| 4.1.2      | - for preparation of specific immunoglobulines <sup>2</sup> , litres |  |
| 4.1.3      | - other plasma, litres                                               |  |
| <b>4.2</b> | <b>Other components</b> (e.g. erythrocytes, buffy coat), units       |  |

<sup>1</sup> litres = kg x 0.975

<sup>2</sup> e.g. anti-D, anti-HBs, anti-Zoster, etc.

#### Comments to the data given in Table 4

#### 5. Special processing of blood components

| <b>5.1</b> | <b>Blood components leucocyte depleted (&lt;1x10<sup>6</sup>/unit), pre-storage, and irradiated blood components</b> | Percent leucocyte depleted | Percent irradiated |
|------------|----------------------------------------------------------------------------------------------------------------------|----------------------------|--------------------|
| 5.1.1.     | Red cells                                                                                                            | %                          | %                  |
| 5.1.2      | Plasma (for transfusion)                                                                                             | %                          | %                  |
| 5.1.3      | Platelets                                                                                                            | %                          | %                  |

| <b>5.2</b> | <b>Plasma components (for transfusion) quarantined or virus inactivated</b> | <b>Percent of plasma components</b> |                   |
|------------|-----------------------------------------------------------------------------|-------------------------------------|-------------------|
|            |                                                                             | quarantined                         | virus inactivated |
| 5.2.1.     | Plasma                                                                      | %                                   | %                 |
| 5.2.2      | <b>Cryoprecipitate reduced plasma</b>                                       | %                                   | %                 |
| 5.2.3      | Cryoprecipitate                                                             | %                                   | %                 |

#### Comments to the data given in Table 5

## SECTION B: Testing of blood and blood components

### 6. Screening for infectious agents, serological test methods

Screening tests required *only* by plasma fractionators should *not* be reported below.

| 6.1     | Screening test performed | only 1 <sup>st</sup> time donation | Every donation           | (if not all donations tested:) % donations tested | Comments |
|---------|--------------------------|------------------------------------|--------------------------|---------------------------------------------------|----------|
| 6.1.1   | anti-HIV 1+2             | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.1.1 | HIV-Ag                   | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.2   | HBsAg                    | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.2.1 | anti-HBc                 | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.3   | anti-HCV                 | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.3.1 | HCV-Ag                   | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.4   | anti-HTLV I/II           | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.5   | Syphilis <sup>1</sup>    | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.6   | Malaria                  | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
| 6.1.7   | Others <sup>2</sup>      | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
|         |                          | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
|         |                          | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |
|         |                          | <input type="checkbox"/>           | <input type="checkbox"/> |                                                   |          |

<sup>1</sup> e.g. TPHA, RPR, VDRL, or other screening tests.

<sup>2</sup> Please specify, e.g. Chagas' disease, brucellosis, WNV, anti-CMV

#### Comments to the data given in Table 6.1

|  |
|--|
|  |
|--|

| 6.2   | <b>The use of simple rapid tests</b>                                                 |                           |                            |                          |                 |
|-------|--------------------------------------------------------------------------------------|---------------------------|----------------------------|--------------------------|-----------------|
|       | Are any of these screening test performed using a rapid test technique <i>ONLY</i> ? |                           |                            |                          |                 |
|       | <b>Screening test</b>                                                                | <b>Yes, all donations</b> | <b>Yes, % of donations</b> | <b>No</b>                | <b>Comments</b> |
| 6.2.1 | anti-HIV 1+2                                                                         | <input type="checkbox"/>  | <input type="checkbox"/> % | <input type="checkbox"/> |                 |
| 6.2.2 | HBsAg                                                                                | <input type="checkbox"/>  | <input type="checkbox"/> % | <input type="checkbox"/> |                 |
| 8.2.3 | anti-HCV                                                                             | <input type="checkbox"/>  | <input type="checkbox"/> % | <input type="checkbox"/> |                 |

**Comments to the data given in Table 6.2**
**7. Confirmatory testing**

|            |                                                                                                                                                                                                                          |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>7.1</b> | <b>Are repeatedly reactive screening test results subjected to confirmatory testing?</b><br><input type="checkbox"/> Yes, always <input type="checkbox"/> Yes, approximately _____ % of them <input type="checkbox"/> No |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**7.2 Confirmed seropositive test results**

| <b>7.2</b> | <b>Confirmed seropositive<sup>1</sup></b>      | HIV 1/2 | HBsAg | HCV | HTLV I/II | Syphilis |
|------------|------------------------------------------------|---------|-------|-----|-----------|----------|
| 7.2.1      | First time tested donors <sup>2</sup> , number |         |       |     |           |          |
| 7.2.2      | Repeat tested donors <sup>3</sup> , number     |         |       |     |           |          |

<sup>1</sup> **Confirmed seropositive:** Repeatedly reactive ( $\geq 2$  times reactive) in a screening test *plus* positive in at least one supplementary test based on another principle.

<sup>2</sup> **First time tested donor:** Person who is tested for the first time (with or without donation) without report of prior serological testing in the blood establishment.

<sup>3</sup> **Repeat tested donor:** Donor who has been subjected to previous serological testing in a given blood establishment.

**Comments to the data given in Table 7**

## 8. Nucleic Acid Testing, NAT

The testing performed by plasma fractionators should *not* be reported below.

| 8.1   | Screening for infectious agents, NAT (minipools) |                                 |                          |                 |
|-------|--------------------------------------------------|---------------------------------|--------------------------|-----------------|
|       | Screening test performed                         | only 1 <sup>st</sup> time donor | every donation           | Comments        |
| 8.1.1 | HIV NAT                                          | <input type="checkbox"/>        | <input type="checkbox"/> |                 |
| 8.1.2 | HBV NAT                                          | <input type="checkbox"/>        | <input type="checkbox"/> |                 |
| 8.1.3 | HCV NAT                                          | <input type="checkbox"/>        | <input type="checkbox"/> |                 |
| 8.1.4 | other NAT                                        | <input type="checkbox"/>        | <input type="checkbox"/> | please specify: |

|     |                      |      |      |      |
|-----|----------------------|------|------|------|
| 8.2 | Size of mini-pool(s) | HIV: | HBV: | HCV: |
|-----|----------------------|------|------|------|

| 8.3   | NAT only positive <sup>4</sup> test results, number | HIV | HBV | HCV |
|-------|-----------------------------------------------------|-----|-----|-----|
| 8.3.1 | First time donors                                   |     |     |     |
| 8.3.2 | Regular plus repeat donors                          |     |     |     |

<sup>4</sup> NAT only positive:

Positive in a NAT assays for a specific virus (HIV, HCV or HBV), not found seropositive for that virus in serological screening *plus* shown to be true positive by separate PCR or later serology.

### Comments to the data given in Table 8

|  |
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## 9. Screening for the presence of bacteria in platelet preparations

|       |                                                                 |   |
|-------|-----------------------------------------------------------------|---|
| 9.1   | % of platelet adult doses screened for the presence of bacteria | % |
| 9.1.1 | - recovered platelet pools (adult doses)                        | % |
| 9.1.2 | - apheresis platelets (adult doses)                             | % |
| 9.2   | % of screened units confirmed positive by further testing       | % |

### Comments to the data given in Table 9

|  |
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|  |
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## SECTION C: General Information

### 10. National co-ordination

|             |                                                                                                           |                              |                             |
|-------------|-----------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| <b>10.1</b> | <b>National council or expert committee</b><br>to advise Ministry of Health on transfusion related issues | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|-------------|-----------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|

|             |                                                                                             |                              |                             |
|-------------|---------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| <b>10.2</b> | <b>National Blood Policy</b>                                                                |                              |                             |
| 10.2.1      | - is there a national blood policy on the quality and safety of blood and blood components? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
|             | If yes,                                                                                     |                              |                             |
| 10.2.2      | - is there a national blood plan on implementing the national blood policy?                 | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

|             |                                                                                                                                                     |                              |                             |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------|
| <b>10.3</b> | <b>National Regulations</b>                                                                                                                         |                              |                             |
|             | - are there national regulations, legally binding, for the collection, testing, processing, storage and distribution of blood and blood components? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

**Comments to the information given in Table 10**

|  |
|--|
|  |
|--|

**11. Quality management related issues**

|             |                                                                          |     |                                                                                           |                             |         |
|-------------|--------------------------------------------------------------------------|-----|-------------------------------------------------------------------------------------------|-----------------------------|---------|
| <b>11.1</b> | <b>Quality system established and maintained in blood establishments</b> |     | <input type="checkbox"/> Yes <input type="checkbox"/> Planned <input type="checkbox"/> No |                             |         |
|             | Percent of donations covered by                                          | GMP | ISO 9000 series                                                                           | Local SOPs and instructions | Other * |
|             |                                                                          | %   | %                                                                                         | %                           | %       |
|             | * please, specify:                                                       |     |                                                                                           |                             |         |
|             |                                                                          |     |                                                                                           |                             |         |

|             |                                                                                                                                                                                                                                                  |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>11.2</b> | Are <b>inspections</b> performed at least each second year?<br><input type="checkbox"/> No <input type="checkbox"/> Yes, by<br><input type="checkbox"/> a national authority<br><input type="checkbox"/> another qualified body or organisation* |
|             | * please, specify:                                                                                                                                                                                                                               |
|             |                                                                                                                                                                                                                                                  |

|             |                                                                                                                                                                                         |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>11.3</b> | <b>Education and training</b><br>- is there a system of education and regular training of staff in blood transfusion medicine? <input type="checkbox"/> Yes <input type="checkbox"/> No |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|             |                                                                                 |          |                 |
|-------------|---------------------------------------------------------------------------------|----------|-----------------|
| <b>11.4</b> | <b>System used for identification and labelling of donations and components</b> |          |                 |
|             | Percent donations labelled according to                                         | ISBT 128 | Another system* |
| 11.4.1      | donation number                                                                 | %        | %               |
| 11.4.2      | component code                                                                  | %        | %               |
|             | * please, specify                                                               |          |                 |
|             |                                                                                 |          |                 |

|                                                      |
|------------------------------------------------------|
| <b>Comments to the information given in Table 11</b> |
|                                                      |

## 12. Haemovigilance

|             |                                                                                                                                                                                                                                                  |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>12.1</b> | Is there a <b>haemovigilance reporting system</b> on national level?                                                                                                                                                                             |
|             | <input type="checkbox"/> No<br><input type="checkbox"/> Yes, - operated by a national authority<br><input type="checkbox"/> Yes, - operated by another organisation*<br>- if "Yes", please give haemovigilance data, if available, in Table 12.2 |
|             | *please, specify:                                                                                                                                                                                                                                |
|             |                                                                                                                                                                                                                                                  |

| 12.2 Haemovigilance data<br>Serious adverse reactions* observed in recipients of blood or blood components: |                     | Serious adverse reactions* reported |                            |       |   |   |
|-------------------------------------------------------------------------------------------------------------|---------------------|-------------------------------------|----------------------------|-------|---|---|
|                                                                                                             |                     | - total                             | - with imputability level* |       |   |   |
|                                                                                                             |                     | number                              | NA                         | 0 - 1 | 2 | 3 |
| Immunological haemolysis due to                                                                             | ABO incompatibility |                                     |                            |       |   |   |
|                                                                                                             | other allo-antibody |                                     |                            |       |   |   |
| Non-immunological haemolysis                                                                                |                     |                                     |                            |       |   |   |
| Post-Transfusion Purpura                                                                                    |                     |                                     |                            |       |   |   |
| Anaphylaxis / hypersensitivity                                                                              |                     |                                     |                            |       |   |   |
| Transfusion Related Acute Lung Injury                                                                       |                     |                                     |                            |       |   |   |
| Graft Versus Host Disease                                                                                   |                     |                                     |                            |       |   |   |
| Transfusion-associated viral infection                                                                      | HBV                 |                                     |                            |       |   |   |
|                                                                                                             | HCV                 |                                     |                            |       |   |   |
|                                                                                                             | HIV-1/2             |                                     |                            |       |   |   |
|                                                                                                             | Other               |                                     |                            |       |   |   |
| Transfusion-associated bacterial infection                                                                  |                     |                                     |                            |       |   |   |
| Transfusion-associated parasitical infection                                                                | Malaria             |                                     |                            |       |   |   |
|                                                                                                             | Other               |                                     |                            |       |   |   |
| Circulatory overload                                                                                        |                     |                                     |                            |       |   |   |
| Other serious reactions                                                                                     |                     |                                     |                            |       |   |   |

\* When completing this table, please use the definitions of serious adverse reaction and imputability presented on the next page.

**12.3 Definitions** to be used in this section:

**12.3.1 *Serious adverse reaction*** – an unintended response in a patient associated with the transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

**12.3.2 *Imputability*** - the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused.

**Imputability scale to assess serious adverse reactions:**

| Imputability scale |                  | Explanation                                                                                                                          |
|--------------------|------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| NA                 | Not assessable   | When there is insufficient data for imputability assessment.                                                                         |
| 0                  | Excluded         | When there is conclusive evidence beyond reasonable doubts for attributing the adverse reaction to alternative causes.               |
| 0                  | Unlikely         | When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.       |
| 1                  | Possible         | When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes. |
| 2                  | Likely, Probable | When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.                          |
| 3                  | Certain          | When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.      |

|                                                      |
|------------------------------------------------------|
| <b>Comments to the information given in Table 12</b> |
| <br><br><br><br><br><br><br><br><br><br>             |



*For further information concerning the work of the Council of Europe / EDQM in the area of blood transfusion please contact:*

Dr Marie-Emmanuelle Behr-Gross  
Department of Biological Standardisation,  
OMCL Network & HealthCare  
EDQM, Council of Europe  
7 allée Kastner  
CS 30026  
F-67081 STRASBOURG  
FRANCE  
Tel: +33 (0)3 90 21 41 08  
Fax: +33 (0)3 88 41 27 71  
E-mail: [marie-emmanuelle.behr-gross@edqm.eu](mailto:marie-emmanuelle.behr-gross@edqm.eu)

**European Directorate for  
the Quality of Medicines &  
HealthCare (EDQM)**  
Council of Europe  
7 allée Kastner  
CS 30026  
F-67081 STRASBOURG  
FRANCE  
Website: [www.edqm.eu](http://www.edqm.eu)  
For ordering: [www.edqm.eu/store](http://www.edqm.eu/store)  
FAQs & EDQM HelpDesk: [www.edqm.eu/hd](http://www.edqm.eu/hd)



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Quality of Medicines & HealthCare

