

# EBA ANNUAL REPORT 2014

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# ABOUT EBA

**THE EUROPEAN BLOOD ALLIANCE (EBA) IS AN ASSOCIATION OF NON-PROFIT BLOOD ESTABLISHMENTS, WITH 25 MEMBERS / COUNTRIES THROUGHOUT THE EUROPEAN UNION AND EUROPEAN FREE TRADE AREA. THE MISSION OF THE EBA IS TO CONTRIBUTE TO THE SAFETY, SECURITY AND COST EFFECTIVENESS OF THE BLOOD AND TISSUE AND CELL (T&C) SUPPLY FOR THE CITIZENS OF EUROPE, BY DEVELOPING AND MAINTAINING AN EFFICIENT AND STRONG COLLABORATION AMONGST EUROPEAN BLOOD AND T&C SERVICES.**



## MESSAGE FROM THE PRESIDENT

For the European Blood Alliance (EBA), the year 2014 was the first implementing the new strategy adopted in 2013 for the period 2014 – 2018. The following achievements are good examples of the EBA capacity to activate members' collaboration, primarily geared to the benefit of patients and donors.

Patient blood management (PBM), recently developed as re-emergence of well-known basic transfusion medicine principles, is a patient centred, multidisciplinary approach, aiming to optimize the use of blood products. In 2014, EBA launched the PaBloE (patient blood management in Europe) project, coordinating a consortium of experts from teaching hospitals and blood establishments in six countries. Three studies, initiated to investigate the current knowledge and use of PBM practices, already brought interesting results.

The large Ebola virus disease (EVD) outbreak in West-Africa, with imported cases in several European countries, led the European Centre for Disease Prevention and Control to consult the EBA Emerging Infectious Disease (EID) Monitor network about guidance on blood safety measures for involved donors (e.g. returning from affected areas). EID Monitor has also been consulted, among other experts, about the WHO guidance on the use of convalescent whole blood or plasma collected from recovered patients, as an empirical treatment of EVD. Consequently, EBA organised information collection on EVD cases and plasma from recovered patients within its membership.

In the perspective of a likely revision of the EU Directives on blood and blood components in the near future, an EBA working group has been created to consider proposals from EBA members to address the revision of the Directive 2004/33/EC on donor selection. Their analysis led to write and submit a scientific article to propose measures to help in decision making in donor-selection policies.

To increase the EBA Office capacity, structural changes have been brought: an additional manager has been hired to develop collaborative procurement within EBA membership, job descriptions have been (re)designed and the EBA staff moved to a new EBA office located in Amsterdam. These changes, introduced at the end of the year, have already proved to be effective in ensuring both continuity and continuous improvement for the missions of EBA for patients and donors.

We warmly thank all EBA members who have contributed to the work realised and all the voluntary non-remunerated donors who make safe transfusion available for patients.

*Philippe Vandekerckhove*  
*President*

**IN 1998,**  
**NINE (MEDICAL) DIRECTORS OF BLOOD ESTABLISHMENTS DECIDED TO COME TOGETHER TO DISCUSS THE PLANS OF THE EUROPEAN COMMISSION TO ESTABLISH A DIRECTIVE ON BLOOD SAFETY AND DONOR SELECTION. ACCORDING TO A NEWS ITEM IN VOX SANGUINIS<sup>1</sup>, THE GOAL OF THEIR MEETING WAS TO SEE IF THEY COULD SPEAK WITH ONE VOICE TO BRUSSELS. BESIDES DISCUSSING THE EU DIRECTIVES, THE GROUP FOUND THAT NETWORKING AND LIAISING ON PARTICULAR ITEMS WAS VERY HELPFUL IN THEIR DAILY MANAGERIAL LIVES. THE GROUP GREW AND IN 2014 COMPRISED 25 MEMBERS (SEE MAP BELOW).**

<sup>1</sup> European Blood Alliance founded. Vox Sanguinis, 1998, 75: 25. <http://dx.doi.org/10.1046/j.1423-0410.1998.7530259.x>

**MISSION OF THE ALLIANCE:** To contribute to the safety, security and cost effectiveness of the blood and tissue and cell supply for the citizens of Europe by developing and maintaining an efficient and strong collaboration amongst European blood and tissue and cell services.

For the period 2014-2018, four strategic objectives have been defined:

**Safe and secure self-sufficiency from voluntary non-remunerated donations (VNRD).** Our aim is to increase public and professional awareness of, and further promote, voluntary non-remunerated donations of blood and blood components and self-sufficiency from VNRD.

**Support to national and European authorities to promote best practice.** We intend to provide technical and professional support to national and European authorities, particularly those involved in preparation / revision of regulations, standards, recommendations, guidelines, to promote best practice.

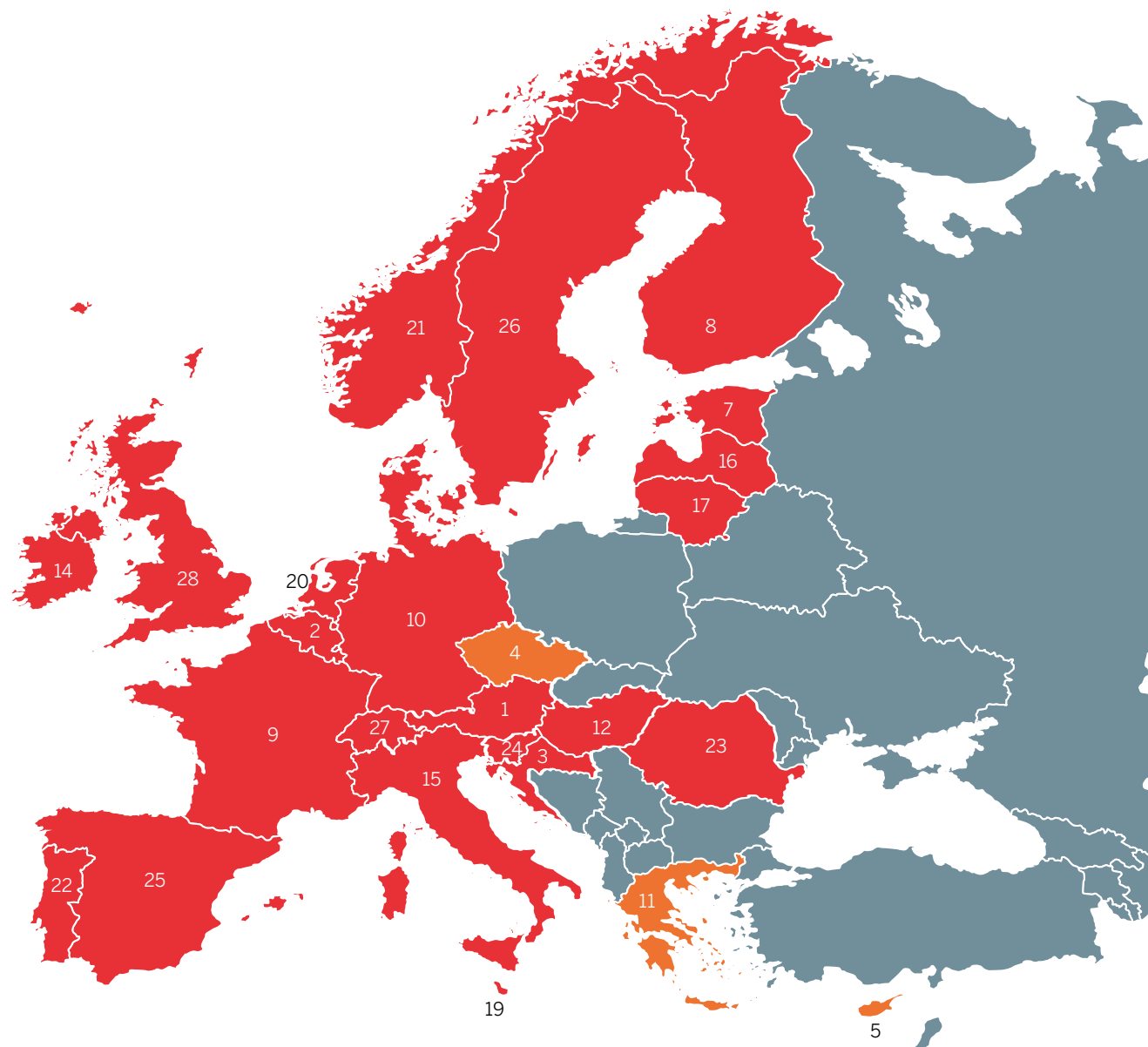
**Performance improvement through collaboration.** We aim to assist European blood and tissue and cell services to improve their performance, based on scientific and ethical principles, for the benefit of patients, and to encourage joint activities and projects between members to enhance the capability of the members.

**Information exchange and dissemination.** We will exchange information on developments in the field of blood transfusion and tissue and cell transplantation, and disseminate relevant information on relevant issues.

This report presents the main achievements on the part of the EBA in fulfilling these strategic objectives for the year 2014.

**EBA MEMBERS**

1. Austria
2. Belgium
3. Croatia
4. Czech Republic (dormant)
5. Cyprus (dormant)
6. Denmark
7. Estonia
8. Finland
9. France
10. Germany
11. Greece (dormant)
12. Hungary
13. Iceland
14. Ireland
15. Italy
16. Latvia
17. Lithuania
18. Luxembourg
19. Malta
20. the Netherlands
21. Norway
22. Portugal
23. Romania
24. Slovenia
25. Spain
26. Sweden
27. Switzerland
28. United Kingdom



# SAFE AND SECURE SELF- SUFFICIENCY FROM VNDR

## 1.1. IMPROVING BLOOD SUPPLY MANAGEMENT

Blood Supply Management (BSM) is defined as “a series of processes and procedures that ensures the availability of safe blood components for patients requiring transfusions.”<sup>2</sup> Ensuring the efficacy of the primary process from donor to patient is at the core of each Blood establishment’s practice. Up to 2013, the Council of Europe (CoE) Working Group (WG) on Blood Supply Management, chaired by the EBA Executive Director, had developed and validated tools for assessing and improving the management of the blood supply chain in blood establishments and hospitals. In 2014, the Proceedings of the CoE Symposium on BSM held in October 2012 and the Report of the CoE Survey conducted on BSM in 2012 were published in an E-book format on the EDQM website. Both documents, together with the questionnaire and method for BSM developed by the CoE WG (considered as very helpful to assess and improve the BSM), can be directly accessed on the [CoE website](#).

In November 2014, the working party on BSM, drawn from the International Society for Blood Transfusion (ISBT) and co-chaired by the EBA Executive Director, launched an international survey to assess the blood product component wastage in the hospital segment of the supply chain. Understanding why and where blood products are wasted in the hospital, including those expiring in the hospital blood bank itself, is an important component necessary to ensure a stable inventory. The working party has identified participants from around the world to complete the survey. The main outcomes are expected to be presented at the ISBT congress in June 2015.

2) Mpuntsha L, Folléa G. ISBT Working party on Blood Supply Management, ISBT Transfusion Today, 2013, 97: 4-6.

## 1.2. IMPROVING PLASMA SUPPLY MANAGEMENT

Self-sufficiency in plasma and plasma-derived medicinal products (PDMP) for European patients is considered crucial by all involved stakeholders. These include patients, plasma fractionation industry, blood establishments, donor organisations, regulators (including DG SANTE), and the Council of Europe, WHO.

Self-sufficiency in PDMP could be defined as the following ratio: produced PDMP from plasma collected /PDMP demand, in a given territory and period of time. It depends on three main parameters:

- (i) The volume of plasma available for fractionation (PfF)
- (ii) The fractionation yield for each PDMP
- (iii) The PDMP demand.

The review of available data helped EBA to assess PfF self-sufficiency for polyvalent immunoglobulin (IG) manufacturing, the current driver for PfF procurement for PDMPs. Our work was greatly assisted by data derived from the International Plasma Fractionation Association (IPFA) for polyvalent immunoglobulin (IG) demand and available PfF volumes in Europe.

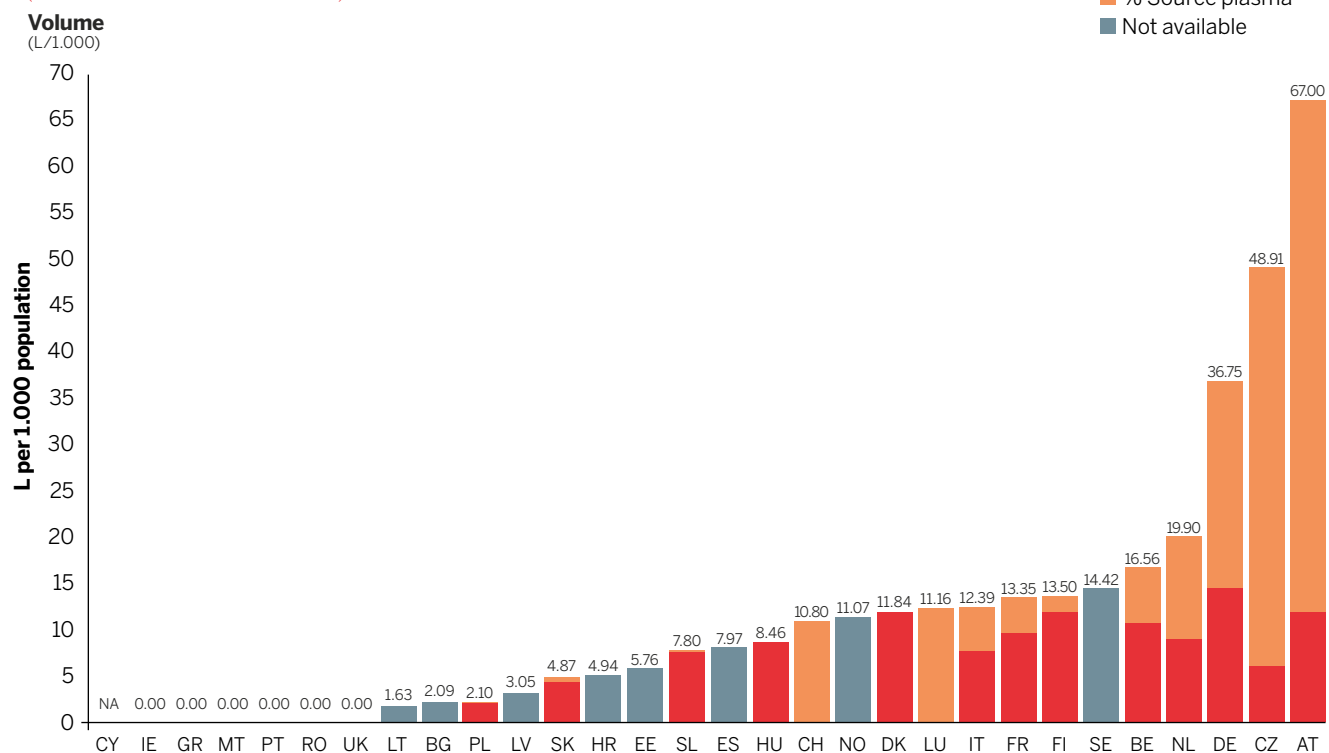
An average yield of 4.0 g of IG fractionated per litre of plasma, meeting an average demand of 70 grams IG per 1,000 population, would require 17.5 L PfF per 1,000 population. As illustrated in the figure below, the EBA study showed that the

collected PfF was estimated to be sufficient to meet all PDMP demand in only four EU countries: Austria, Czech Republic, Germany and the Netherlands. The analysis of the proportion of recovered plasma (separated from whole blood) and source plasma (collected by plasmapheresis) showed the essential role of plasmapheresis in reaching self-sufficiency.

Overall, Europe was only 81 % self-sufficient. In recent years the contribution from VNRD (41% in 2011) had decreased, while that from Industry had rapidly increased (40 % in 2011). This data and analysis have been presented and acknowledged in various audiences: European Compliance Academy (Industry); Italian Society of Transfusion Medicine; Grifols

### PLASMA FOR FRACTIONATION COLLECTED IN EU AND EFTA COUNTRIES IN 2011

(SOURCE: EDOM/CD-P-TS REPORT)





## Roundtable on Ethics of Compensated Plasma Donation.

The presentation of this data at the Spring Board meeting helped first to consider PfF self-sufficiency as a critical strategic objective for Europe. Stopping PfF importation from the USA for any reason, (e.g. an outbreak of an equivalent of variant Creutzfeld-Jacob disease) would be a threat for patients who would lack some PDMPs. The data analysis also led the EBA Board to consider, as a major objective for EBA, developing plasmapheresis from VNRD in order to contribute to PfF self-sufficiency in Europe. In addition, the board initiated the following two projects.

The first project was to activate a WG headed by the CoE. Agreement to this initiative was obtained in 2014, and the EBA Executive director was invited to participate. The objectives of the WG, denominated 'Plasma supply management' (TS093) were determined in the kick-off meeting as follows:

- i) To assess self-sufficiency in PfF and PDMP in member states of the CoE and observer states as Australia, Canada and New Zealand
- ii) To develop tools/ advice to achieve a higher degree of self-sufficiency in PfF and PDMP;
- iii) To help establish that plasma of the required quality is used to its full potential

- iv) To develop sustainable and safe plasmapheresis collection activity.

The first action of this group has been to develop a questionnaire to conduct a survey aimed at achieving a better understanding of PfF management supply practices and the level of self-sufficiency in PfF within CoE member states. The survey was launched in January 2015.

The second project came from a joint initiative from EFS and Sanquin to investigate ways to reduce the costs of plasma from plasmapheresis. This led to the development of a questionnaire for an EBA survey with the objective of assessing existing processes and investigating ways to reduce the costs of plasmapheresis. The survey was launched in November 2014 in ten EBA countries. The main outcomes are expected to be presented at the Board meeting in April 2015.

## 1.3. MASTERING MANAGEMENT OF EMERGING INFECTIOUS DISEASES

Through its monthly teleconference and regular information exchange, EID Monitor continued to scan emerging infectious diseases and to exchange data about blood safety measures in the area of EBA and ABO membership (Europe, Australia, Canada, USA). The circulation of the teleconferences' minutes in a short timeframe ensured a quick spread of infor-

mation and recommendations to EBA and ABO members. The following topics were particularly important in 2014.

### West Nile Virus (WNV)

Since the start of WNV season, this year a total of 163 WNV cases have been reported on the European continent (European Centre for Disease Control –ECDC- update November 2014). All cases were in the same regions/ countries as previous years, except one autochthonous case in Vienna. This case was a blood donor and was identified through WNV NAT blood screening. The number of reported cases in Europe appeared to be limited compared to 2012 and 2013 (resp. 338 and 539 cases), most likely due to lower temperatures during summertime in Europe.

### Chikungunya virus in the Western hemisphere

Since December 2013 an outbreak, which is still ongoing, occurred in the Caribbean, spreading rapidly on the American continent. Because the Caribbean is already considered as a dengue risk area, donor deferral for 28 days after travel already existed in most members states (MS). Outbreaks in Europe are possible because of the presence of the vector *Aedes albopictus* in the Mediterranean area and *Aedes aegypti* in Madeira. A cluster of 11 locally acquired chikungunya cases around one patient was observed in France in 2014. Following local anti-vectorial

**'ACHIEVING SELF-SUFFICIENCY IN PLASMA FOR FRACTIONATION REMAINS A TOP PRIORITY FOR EBA'**



measures, no specific blood safety measures were implemented. The low proportion of asymptomatic chikungunya infections with the absence of transfusion transmissible (TT)-Chikungunya infections makes the threat of spread less likely but it cannot be ignored. So far, temporary donor deferral has been the only blood safety measure implemented, and there has been no significant impact on the blood supply.

### Hepatitis E virus (HEV)

The UK retrospective study, which screened for HEV both 225,000 blood donations and recipients who received any blood components from donations containing HEV, was published in the *Lancet*. While the article highlighted the potential for a substantial number of cases of transfusion transmission in the UK, it noted that transfusion was a relatively minor transmission route and that the clinical outcome of infection was generally mild. The article concluded that the case for immediate blood donor screening was not compelling and that other public health interventions might be more cost-effective. However, there was also an accompanying editorial by a French transplant clinician interpreting their observation of chronic hepatitis in three infected patients as clear evidence of the need for implementation of HEV RNA testing of blood donors. A WG of the UK Advisory Committee on Safety of Blood, Tissues and Organs (SaBTO) has been

formed to consider these issues and to make a recommendation to UK governments.

### Ebola virus

The large Ebola virus disease (EVD) outbreak in West-Africa involved 20,206 (probable, confirmed and suspected) cases and a high case-fatality rate of 7,905 deaths, as reported by the World Health Organization (WHO) on 28 December 2014.

Ebola virus is highly transmissible by direct contact with infected blood, secretions, tissues, organs or other bodily fluids of dead or living infected persons. Cases of EVD transmission through transfusion and transplantation were not reported, but transmission might be possible. Because there are no EU regulations for donation of substances of human origin (SoHO) for patients recovered from EVD or persons who have been in contact with the blood or bodily fluids of infected patients, the European Centre for Disease Prevention and Control (ECDC) consulted EID Monitor about guidance on safety measures for donors returning from affected areas, donors monitored after exposure, donors infected and/or recovered from EVD and convalescent recovered donors, both for blood components and tissues, cells and organs.

Because the concerned countries are endemic malarial areas, potential donors are already temporarily deferred for

donation after return from these affected areas, except in the case of their making donations for plasma derived medicinal products. The pathogen reduction steps used during plasma fractionation can be considered to remove the Ebola virus sufficiently. The contribution of the EBA EID Monitor has been incorporated in the ECDC recommendations about the risk of transmission of Ebola virus via donated blood and other SoHOs in the EU, disseminated in October 2014<sup>3</sup>.

EBA EID Monitor has also been consulted among other experts for the WHO guidance document entitled "Use of Convalescent Whole Blood or Plasma Collected from Patients Recovered from Ebola Virus Disease for Transfusion, as an Empirical Treatment during Outbreaks", disseminated in October<sup>4</sup>.

To help in developing this initiative, EBA organised information collection on EVD cases and plasma from convalescent plasma within EBA membership, starting in November. A more complete version was developed by NHSBT through a protocol with two objectives: first, to ensure availability of up-to-date information on the total stock of convalescent plasma

3) [http://ecdc.europa.eu/en/publications/\\_layouts/forms/Publication\\_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113d9b90&ID=1178](http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113d9b90&ID=1178)

4) [http://apps.who.int/iris/bitstream/10665/135591/1/WHO\\_HIS\\_SDS\\_2014.8\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/135591/1/WHO_HIS_SDS_2014.8_eng.pdf?ua=1)

available in Europe; second, to make that plasma available to the most appropriate patients through the creation of a European Expert Panel of infectious diseases and transfusion medicine specialists who would approve plasma release. This protocol became effective at the end of December.

#### 1.4. OPTIMISING THE USE OF BLOOD: THE PABLOE PROJECT

Patient blood management (PBM), a patient centred, multidisciplinary approach aimed at optimizing the use of blood products has been recently developed and this can be considered as re-emergence of well-known basic transfusion medicine principles.

In 2013, EBA coordinated a consortium of experts from teaching hospitals and blood establishments in seven countries (Odense, Denmark; Frankfurt, Germany; Torino, Italy; Malta, Nijmegen, the Netherlands; Stockholm, Sweden; Manchester, UK) to respond to an EU call for tender on PBM. Although EBA has not been granted the tender, given the major importance of this topic, the Executive members have decided to move forward the project under the coordination of EBA.

The objectives of the Patient Blood Management in Europe (PaBloE) project have been defined as follows.

- i) To derive good practices in PBM on focused indications – mainly surgery,

anaesthesiology and intensive care – from experience and expertise in the participating PaBloE teams and ways to develop their implementation in PaBloE participating teaching hospitals.

- ii) To promote a patient centred approach, in shifting focus from blood product to patient needs.
- iii) To conceive action plans that are easy, quick and cheap to implement, to cope with current financial constraints.

Two WGs have been created. The PaBloE WG1 carried out two surveys. One extended the Red Blood Cell Issue Trace Audit Cycle, performed annually in England, to the six participating teaching hospitals. The second collected data on blood and blood component use and PBM practices in the participating PaBloE organisations.

The PaBloE WG4 prepared one survey – to investigate clinician knowledge about PBM in the participating hospitals.

Outcomes from the three surveys are expected to be presented at the spring 2015 EBA Board meeting and submitted for publication in a peer-reviewed journal.

The EBA Executive Director was invited to present a lecture on PBM at the 5th Transfusion Medicine Congress of Serbia, in Belgrade. This was an opportunity to present the scientific basis for, and to discuss possible ways for implementing

PBM in Serbia. This also led to a formal request by the Blood Transfusion Institute of Serbia to become an EBA observer.

#### 1.5. PROMOTING VNRD

In 2013, a high-level Policy-makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on VNRD, was organised by the World Health Organization (WHO) in Rome, Italy. As the representative of many countries in the world and other international organisations, EBA was invited to participate in this forum. The main achievement of this forum was the so called “Rome Declaration: Achieving Self-sufficiency in *Safe Blood and Blood Products, based on Voluntary Non-Remunerated Donation*”.

As a follow up to this forum, WHO created a core WG on self-sufficiency of blood products from VNRD, in which EBA was also invited to participate. In March 2014, this WG drafted a “*framework on universal access to safe blood and blood products through self-sufficiency, based on VNRD*”. This relied on the four pillars promoted by EBA: patient blood management, blood supply management, donor management and steering.

Later on, important re-organisation within WHO (the creation of a new department ‘Service Delivery and Safety’), was followed by a re-orientation of the preparation of a new Resolution on blood products and

**‘SURVEYS IN HOSPITALS PRODUCED VALUABLE INFORMATION FOR FURTHER ANALYSIS ON HOW TO OPTIMIZE USE OF BLOOD PRODUCTS’**

VNRD towards a Decision on Medical Products of Human Origin. This Decision, named *'Principles for global consensus on the donation and management of blood and other medical products of human origin'*, was adopted by the WHO Executive Board in January 2015.

On a different matter, the EBA Executive director was invited as a speaker at a meeting of a panel initiated and headed by Grifols (a major company in the field of plasma derived products) on bioethical issues around compensated plasma donation. This represented a further opportunity to voice the EBA position on this subject and also to continue the discussions initiated one year ago with PPTA (plasma protein therapeutic association) Europe on plasma issues, in agreement with the EBA Board.

At the request of our colleagues in Lithuania, the EBA Executive director was invited to present an EBA position on how to achieve self-sufficiency in PfF and PDMP based on VNRD in Lithuania. The request arose from the concern expressed by those anxious to adhere to the law voted in 2013, stating that *'Blood donation is based on voluntary donations'*. This concern arose in the face of pressure from the plasma industry to open plasmapheresis centres in Lithuania. The presentation of EBA was appreciated by the representatives of the national BE, the national competent authority, and the Ministry of Health.

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**'WE CONTRIBUTED TOWARD A SELF-SUFFICIENCY IN LITHUANIA FOR BLOOD PRODUCTS, MORE AND MORE FROM VOLUNTEER NON-REMUNERATED DONORS' – GILLES FOLLÉA**

# PERFOR- MANCE IMPROVE- MENT

## **2.1. BENCHMARKING**

### **2.1.1. 9th EBA Scorecard**

The 2013-14 Blood and Tissues Survey was issued in May 2014, extending the gathering of data for the blood supply benchmarking exercise to include tissues and cells data. There has been significant alignment of the EBA Scorecard and the scorecard of the Alliance of Blood Operators (ABO), which, besides Europe, includes multiple organisations from Australia, Canada and the United States. This has led to clearer performance indicators and supporting definitions ensuring that the data is comparable.

### **2.1.2. EBA Benchmarking Workshop on Transport and Logistics**

In total 36 EBA and ABO member representatives participated in the Copenhagen Workshop in September 2014, hosted by the Organisation of Transfusion Centres in Denmark. The event showcased a number of new systems, processes and technologies aimed at optimising the efficiency of transport and logistics in Blood Establishments. Because of this Workshop, an informal network of Transport and Logistics experts has now been established. It is expected that this will open opportunities for a rich exchange of business cases, SOPs and other useful documentation for informal discussion and for exchange visits to see alternative systems in practice.

### **2.1.3. Best Practice Library**

In 2014, the group worked with the ABO Benchmarking Group in developing a set of case studies that examines good practice in detail, and in establishing a “performance improvement programme” aimed at proposing pragmatic ways to improve member efficiency. EBA decided to join the programme in April 2015.

Global collaboration was also sparked because of an 'in depth' session at the autumn Board Meeting 2014: NHSBT and the Danish Blood Service presented their improvements in set-up and pack-down of mobile donor session and donor end-to-end time, through interactive presentations. These were picked up by America's Blood Centers, who decided to dedicate a Webinar to what was called – "small changes, big impact." This webinar was held in January 2015.

#### **2.1.4. EBA Flying Squad**

The Flying Squad is a group of experts in Lean Manufacturing (a set of methods to reduce "waste" and improve efficiency), where they scan for performance improvement opportunities. Experts are volunteered by their EBA member employers to visit other blood establishments. Each visit ends with a formal proposal to the EBA member CEO for an improvement programme.

In 2014, a follow up visit was organised at the Finnish Red Cross Blood Service in Helsinki and was much appreciated. An expression of interest was received from the Slovenian Blood Service, and a visit will be arranged.

The EBA Executive has issued new rules concerning the activities of the Flying Squad, and the appointment of external consultants to support such activities. A new consultant contract will apply from 2015.

#### **2.1.5. Scorecard Data**

Over the course of 2014, based on a request from members of the EBA BMG and many Board representatives, the EBA Executive confirmed the need to clarify the rules governing access to confidential EBA member data. The new rules were adopted in December 2014.

### **2.2 TISSUES AND CELLS**

The EBA Tissues and Cells (T&C) WG also aims at improving the performance of T&C activities in involved EBA BEs. Leadership of the T&C WG evolved in 2014, as the two previous co-chairs stepped down. At the end of the year, the EBA T&C website was migrated by EBA Office to a temporary access controlled OneDrive website. Over the course of the year, the group had two face-to-face meetings and several teleconferences. The work of the WG is organized by four subgroups with the following key objectives:

- **T&C benchmarking subgroup 1: preparing and analysing EBA T&C Questionnaire 2013**

The objective of this subgroup, based on the initial EBA benchmarking WG (BMG), is to compare practices within membership in order to derive good practices thereby improving the quality of T&C supplied, and efficiency of related activities. The main tool used was the initial tool developed by the EBA core BMG. The second annual questionnaire to investigate data for the year 2013 was sent

out in collaboration with the core BMG survey in June and the first analyses were discussed in November at the second face-to-face meeting in Ghent. The final report is to be presented in spring 2015.

- **T&C subgroup 2 on tissues: preparing a benchmarking workshop on bone banking**

A detailed questionnaire regarding banking of femoral heads from living donors was sent to the members of the WG to prepare for a workshop on this topic. The goal is to organize a workshop to seek best practices in this area.

- **T&C subgroup 3 on cellular therapies**

This group had been preparing for a joint grant application to the EU Horizon 2020 program, but at a face-to-face meeting it was decided not to submit an application in this very competitive field. The group decided instead to focus on GMP and quality systems in cellular therapy, considered to be a core competence for BEs.

- **T&C subgroup 4 on education and training: collecting relevant T&C training information.**

This group focused on finding relevant educational programmes for training and educating personnel from members, to be displayed on a subpage on the T&C website.

### **2.3 COLLABORATIVE PROCUREMENT**

EBA collaborative procurement is an initiative based on four recommended pillars: common specifications (e.g. 80%

common for the EBA “Eurobloodpack” specifications); common validation protocols (established by the EBA collaborative quality management (CQM) WG); collaborative supplier audit reports (established with the CQM WG); and common fault monitoring systems.

The expected advantage of this initiative will be to streamline the processes and reduce the costs linked to procurement, both for EBA members and suppliers, so that savings could contribute to some complementary funding of EBA missions and activities. In 2014, the EBA collaborative procurement worked on one type of medical device, blood bags, according to EBA common specifications for the so called Eurobloodpack. Two EBA members (with five BEs) and two non-EBA members benefited from the collaborative contract commenced in 2013. The savings were significant.

EBA decided to hire its own Collaborative Procurement Manager (CPM) after the first EBA CPM Neil Beckman, left his position at NHSBT. Joëlle Guerra, formerly working for Établissement Français du Sang, was hired as of November 1st 2014. On her arrival, a meeting was organised between Joëlle and the main involved stakeholders at EBA and NHSBT with the following objectives: i) to review the existing collaborative procurement activities (both direct and indirect through collaborations); ii) to establish a mapping of these activities (current and future); iii) to set up an action plan for the new EBA manager in compliance with EBA strategic objectives. The main outcomes consisted of an action plan for the new manager, which has been approved by the Executive members in December.

## 2.4. COLLABORATIVE QUALITY MANAGEMENT

The EBA WG on Collaborative Quality Management (CQM WG) consists of two subgroups: Validation and Supplier audit.

In 2014 the Validation subgroup actively shared local validation documents amongst the group and produced different validation templates for all EBA members.

As an example, templates for validating the Eurobloodpack were created, as this project involves Collaborative Procurement activities. A validation template for an automated blood grouping analyser has also been developed.

The Supplier Audit subgroup created an audit register, based on the questionnaire sent out in 2013, containing key data of audits performed by the EBA members. This subgroup also created the necessary standards regarding collaborative supplier audits: policy, procedure, pre-audit questionnaire, audit plan and report.

A project site, as a part of the EBA internal website, was created. This allowed publication of all the documents created by the WG, including the audit register on this website, making all these documents available for EBA members.

Based on a Board decision to integrate the CQM WG as a subgroup of the EBA Collaborative Procurement WG, as support activity, the EBA CQM WG has started to study how to align its activities with the Collaborative Procurement WG.

## 2.5. RISK BASED DECISION MAKING

The Alliance of Blood Operators (ABO) is a network of over 90 blood operators from America's Blood Centers, American Red Cross, Australian Red Cross Blood Service, NHSBT and EBA. ABO seeks to be a high

**‘THERE LIE GREAT OPPORTUNITIES FOR EBA MEMBERS TO OPTIMIZE THEIR PROCUREMENT PERFORMANCE. I’M LOOKING FORWARD TO START PROJECTS IN 2015’ – JOËLLE GUERRA**



performing international collaboration of blood operators which drives local performance improvement, knowledge exchange and resolution of global strategic issues for the benefit of the patients and health systems served by its members. ABO is the initiator of the Risk Based Decision Making (RBDM) Project, aiming to provide an overall risk framework with health economics and outcomes tools specially designed for blood safety, stakeholder engagement guidelines and a web portal.

In 2014, the RBDM Project Team conducted consultation events with a broad range of stakeholders interested in the risk based decision-making framework. This included a face-to-face meeting with the WHO Blood Regulators Network. The feedback received has been rich and valuable and they are now using it to improve the framework. The second focus was a feasibility test to “stress” the framework, with the objective of identifying if there were gaps in the framework or sections that needed to be adjusted.

Using a fictional scenario that described a newly emerging pathogen with the potential to negatively affect the blood supply, specially assigned teams stepped through the RBDM process, identifying the issues related to the scenario, developing the problem statement, identifying the risk management options, and then

undertaking relevant risk assessments. This exercise did highlight a few areas where the framework could benefit from various refinements, a more user-friendly approach, and some additional tools. The group is now making the necessary adjustments.

The framework was also a focal point at the American Association of Blood Banks annual meeting in Philadelphia where an education session was held, explaining key components of the framework, the importance of stakeholder engagement, and how health economics is used in the decision making process. The session was well attended and many of the attendees visited the RBDM exhibitors’ booth to obtain more information.

## 2.6. HARMONISING TRANSFUSION MEDICINE TRAINING IN THE EU

EBA is partner in the Donor Health Care (DoHeCa) project, headed by Sanquin and co-funded by the EU, in the framework of the Life Long Learning Programme. The DoHeCa project, in which 15 organisations from several European countries have joined forces, aims to develop a high quality curriculum for medical professionals in Donor Health Care.

This curriculum will comply with the following criteria:

- i) Conformity with European Directives and standards

- ii) the demands of (prospective) involved professionals in the different countries and institutions
- iii) the expectation of donors and society with respect to protection of the donor and safe and efficient use of substances of human origin (blood, cells, tissues and organs).

The project started in October 2013 and the educational framework and learning objectives have been defined. Over the course of 2014, EBA collaborated in drafting the Working Package 2, and in drafting the chapter on Basic Principles of Donor Health Care, for the DoHeCa manual. When ready, starting from 2016 the training programme will be hosted by the Academic Medical Centre of the University of Amsterdam, with an e-learning platform.

The progress of DoHeCa was presented and discussed during the EBA meeting in Paris, October 2014. During that event it was agreed to perform an EBA survey to get a general estimate of the number of expected participants for the course in 2016. EBA will be also involved at the end of the project in the Working Package 9, Project dissemination. More information on the DoHeCa project is accessible on its website, at [www.donorhealthcare.org](http://www.donorhealthcare.org).



# REGULATORY

## SUPPORT TO NATIONAL AND EUROPEAN AUTHORITIES TO PROMOTE BEST PRACTICE

### 3.1. REVISION OF MD AND IVD DIRECTIVES

The recast of the Medical Devices (MD) and In Vitro Diagnostics (IVD) EU regulations was initiated at the EC level in 2011. EBA had detected in 2012 a possible threat to patients' safety if the EC draft Regulation for IVDs maintained unchanged – a proposal making it obligatory that any IVD manufactured by blood establishments be CE-marked, even if for internal use only.

This potential threat (patient harmed by lack of specific tests) led EBA to propose a new wording, authorizing niche IVDs produced and used by blood establishments not to be CE-marked (under strict quality rules). This new wording was proposed to members of the EU Parliament (MEP) through intense lobbying. The EBA proposal was integrated in an amended version of the Regulation adopted by the European Parliament in the plenary vote of October 2013. The preparatory work at the European Council (third step of the EU regulatory process) level continued after this successful outcome. In 2014, three member states that expressed objections to the position defended by EBA were contacted and all agreed to move to a position in agreement with the EBA proposal. The final vote of the Regulation by the European Council is expected in 2015.

### 3.2. COLLABORATION WITH ECDC

#### 3.2.1. European Up Front Risk Assessment Tool (EUFRAT)

EID-Monitor participated in the evaluation of the risk assessment tool for contamination of blood donations during outbreaks of infectious diseases. A few members were invited to evaluate the tool with only one agent / outbreak: dengue (Australia); Hepatitis A virus (France); Tick Borne Encephalopathy virus (Germany); WNV (Greece); Chikungunya (Italy); Q-fever (The Netherlands);

HEV (UK), WNV (USA); and *Trypanosoma cruzii* (USA). The evaluation has been written up in a manuscript and submitted to a peer reviewed journal.

Changes were needed to consolidate and improve the EUFRAT tool regarding validity of the estimates, relevance of the results and diseases included, user-friendliness, risk assessment of travelers, and simplification of some steps. EBA made funding available for modifications and improvements of the tool. Some EID Monitor members were involved in reviewing the proposed updated functionalities before implementation of the tool. A training course for end-users of the EUFRAT tool has been planned in May 2015.

### 3.2.2. Pre-qualification of new donors

From a case of HIV transmission reported in Austria, DG SANTE (the new name of DG SANCO since January 2015) requested ECDC to investigate the potential value of pre-qualification of new donors. A meeting has been organized by the National Blood Centre of Italy in Rome with contributions from ECDC and EBA. The decision to create a WG to further explore this topic was made at the end of this meeting. Experts of EID Monitor participated in this WG.

The WG, co-chaired by ECDC and EBA, under the aegis of DG SANTE, has been divided into two subgroups. The first concerns Transfusion Transmittable

Infections (TTIs) and the second group evaluates the value of pre-qualification of new donors to improve donor management and donor education. A TTI survey on HIV, HBV, HCV and syphilis has been designed and launched. The population assessed was the voluntary non-remunerated donors donating blood and blood components in Blood Establishments in the 28 EU MS, whatever the type of donation. The analysis of the outcomes from this survey is expected in 2015.

## 3.3. ACTION AT THE EU COMMISSION

### 3.3.1. Revision of EU directive on Donor Selection

A revision of the four EU Directives on blood and blood components, issued ten years ago or more, is expected to be launched by the new EU Commission appointed in 2014. In this regard, EBA has created the first WG to consider proposals from EBA members to address the revision of the Directive 2004/33/EC on donor selection. Based on recent examples illustrated in the scientific literature (e.g. deferral of men having sex with men), the WG observed that the donor selection criteria in the current Directive were not sufficiently evidence based and flexible, thus leaving too much room for conflicting interpretations and keeping selection criteria in force that are out of date. Attention to risks for donor (e.g. iron deficiency) was insufficient and consideration of this aspect as part of the decision

on eligibility was weak. Furthermore, the current trend consisting of increasing or tightening selection criteria, although marginally beneficial to recipients, often resulted in large numbers of extra deferrals not easily justified to donors.

Based on this analysis, and in line with the Council of Europe Resolution CM/Res(2013)3 on sexual behaviours of blood donors that have an impact on **transfusion safety**, adopted by 36 countries, a first scientific article has been written to propose two measures. The first measure would further promote the collection of epidemiological data on the incidence and prevalence of conditions at risk for transfused patients (e.g. sexually transmitted infections) in the general population and in blood donors, for use as a basis for decision making in donor-selection policies. The second measure would include allowance for differential deferral criteria throughout Europe, based on factual risk levels.

In the Council of Europe Resolution CM/Res(2013)3, health authorities were encouraged to support blood establishments by publicly communicating the relationship between available data on the safety of the blood supply and subsequent decisions on donor-selection criteria. This should lead to better acceptance of the fact that donor deferral criteria could vary from country to country in line with differing epidemio-

**‘THE EUFRAT TOOL  
WILL ALLOW  
MEMBER STATES  
TO ASSESS  
THE RISK OF  
TRANSMISSION  
OF EMERGING  
INFECTIONS  
BY BLOOD  
TRANSFUSION  
AND THEN ACT  
UPON THIS RISK’**

logical data. This first article was submitted for publication in a peer-reviewed journal in early 2015.

### 3.3.2. EU Directive amendment on West Nile Virus (WNV)

The European Commission (EC) introduced an amendment to EU directive 2004/33 to replace the formulation of donor selection criteria of temporary deferral for WNV as follows: *“28 days after leaving a risk area of locally acquired West Nile Virus unless an individual Nucleic Acid Test (NAT) is negative.”* Although EBA EID Monitor drew attention of the EC on the risks of introducing a new term, *“area of locally acquired WNV”*, and limiting testing to individual NAT, the amendment has been adopted by EU Parliament and Council. EBA will be invited to participate in the review process of the EU WNV preparedness plan, as already done in 2011 for the current version (2012). This review process is expected to be launched by the EC in 2015.

### 3.3.3. DG SANTE – National Authority meetings

Since 2014, no experts from blood establishments have been invited to the regular meetings of the National Competent Authorities (NCA) on Blood and Blood Components at DG SANTE. In the years 2011-2013, the EBA Executive director had been invited to participate in these meetings, which allowed him to submit important topics for discussion and

propose solutions, several of which were adopted (e.g. IVD Regulation, see 3.1 above; new donor pre-qualification, see 3.2.2 above).

The decision made by DG SANTE in 2014 to stop inviting an EBA representative resulted in the absence of any designated representative of blood establishments. It is important to keep in mind the article 25: *“The Commission shall hold regular meetings with the competent authorities designated by the Member States, delegations of experts from blood establishments and other relevant parties to exchange information on the experience acquired with regard to the implementation of this Directive.”*

Beyond the regulatory question, the trend to limit consultations to national competent authorities only, as illustrated by the amendment of EU Directive about WNV (see 3.3.2 above), is problematic, especially in relation to the revision of the EU Directives on blood and blood components. EBA action to re-establish consultation of BE experts, as done in other jurisdictions (e.g. USA), has started to contribute to the effectiveness and cost-effectiveness of new regulations, and to the stability of the donor base, donor safety and patient safety.

### 3.3.4. Consultation on DEHP

DEHP (di-(2-ethylhexyl) phthalate) is used as a plasticizer in commonly-used medical devices, including blood bags and tubing.

Such DEHP-containing medical devices offer many advantages, such as being easier to sterilize and to handle, and is less damaging to red blood cells. However, there are concerns that high-level DEHP-exposure through the use of these products could pose a health risk to patients. The 2014 update of SCENIHR's (Scientific Committee on Emerging and Newly Identified Health Risks) Opinion of 2008 aims to evaluate any such health risks. It focused on vulnerable groups like neonates, infants, pregnant and breastfeeding women, taking into consideration the benefits of DEHP-containing medical devices, such as the survival of premature infants.

In October, the EU Commission launched a public consultation on the SCENIHR preliminary opinion on *‘The safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk’* (2014 update). Interested parties were invited to submit comments on the scientific evidence before 30 November 2014. An EBA response was set up and posted with the help of an internationally renowned expert in the field, Dirk de Kort. EBA mainly asked for better clarity on the reason for the revision of the initial opinion and reiterated its support for research on alternatives. The major importance for appropriate validations to assess the technical/physical properties and the physiological features for blood component properties

and storage, for both known and new materials, was emphasised to ensure optimal quality and safety for patients.

### 3.3.5. ATMP classification

In June, the European Medicines Agency (EMA) launched a public consultation on the classification procedure for Advanced Therapeutic Medicinal Products (ATMP), based on scientific recommendation for the ATMP classification by the EU Committee for Advanced Therapies (CAT). This recommendation was underpinned by the ATMP Regulation which enables the EMA, in close collaboration with the European Commission, to determine whether or not a given product meets the scientific criteria which define ATMPs. The ATMP classification procedure has been established in order to address, as early as possible, questions of borderline overlap with other areas such as cosmetics or medical devices, transplants etc.

The aim of the discussion paper from the CAT was to provide guidance on the ATMP classification procedure, as well as on the interpretation of key concepts of the definition of gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products, and combined ATMPs. The guidance reflects the experience gained in the application of the classification procedure. The CAT issues scientific recommendations determining whether or not the referred

product falls within the definition of an ATMP in the European Union. The EBA T&C WG established and posted comments by the deadline, as many EBA members are concerned about this regulation. EBA largely welcomed the initiative of the CAT, but called for better guidance as to the different regulatory pathways to be followed for classification of a given ATMP.

### 3.4 Managed Regulatory Convergence: apheresis connectors

In 2009, following the death of an apheresis donor resulting from a human error involving a misconnection of saline and anticoagulant, EBA initiated collaboration between apheresis device suppliers, blood establishments and regulators to look for solutions to prevent such future occurrences. In 2011, an international meeting gathering all these stakeholders initiated a project of apheresis connectors ISO standardization led by the industry with collaboration from EBA.

In 2013, the Consensus Standard for the apheresis connector for anticoagulant was approved by all concerned suppliers and EBA. The process of establishing and adopting ISO-standards for apheresis connectors progressed up to the second phase (of three) with the help of the industry and ISO-sub committees. The full standardization process is expected to be completed in 2016. In 2014, two apheresis connector industry meetings agreed to

set up an implementation plan and a communication plan, denominating the new connectors as the 'Correct Connect system'.

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**'THE CORRECT CONNECT SYSTEM OFFERS A UNIQUE CONNECTION TYPE FOR EACH APHERESIS SOLUTION' – GILLES FOLLÉA**

# INFORMATION EXCHANGE AND DISSEMI- NATION

## 4.1 INTERNAL COMMUNICATION AND INFORMATION

### 4.1.1. Information monitoring and managing

In 2014, seven EBA Newsletters were sent out, providing members with updated news on EBA activities and ongoing in blood establishments' current affairs. The Coordinating Committee of WG Chairs, installed in 2013, fully played its role in reviewing and completing the Newsletters before issuance. The Newsletters included the main following items:

- Achievements and progress from EBA WGs
- News from members
- Requests for and outcomes from member consultations on various subjects
- Regulatory changes within members' countries and at EU level
- Achievements and progress from ABO WGs
- News and publications from other organisations such as WHO, Council of Europe, FDA.

### 4.1.2. Consultations and Surveys

To help members to share their experiences and expertise from daily life, members can request a consultation. The consultation requester will formulate a questionnaire, and afterwards will collate and summarize the information for all the Board Members. This system proved to work well again in 2014. As in 2013, the main outcomes from many consultations have been briefly presented and discussed at the Board meetings, to strengthen the potential impact of this experience sharing.

The main member consultations led by EBA in 2014 are listed in the table on the next page.

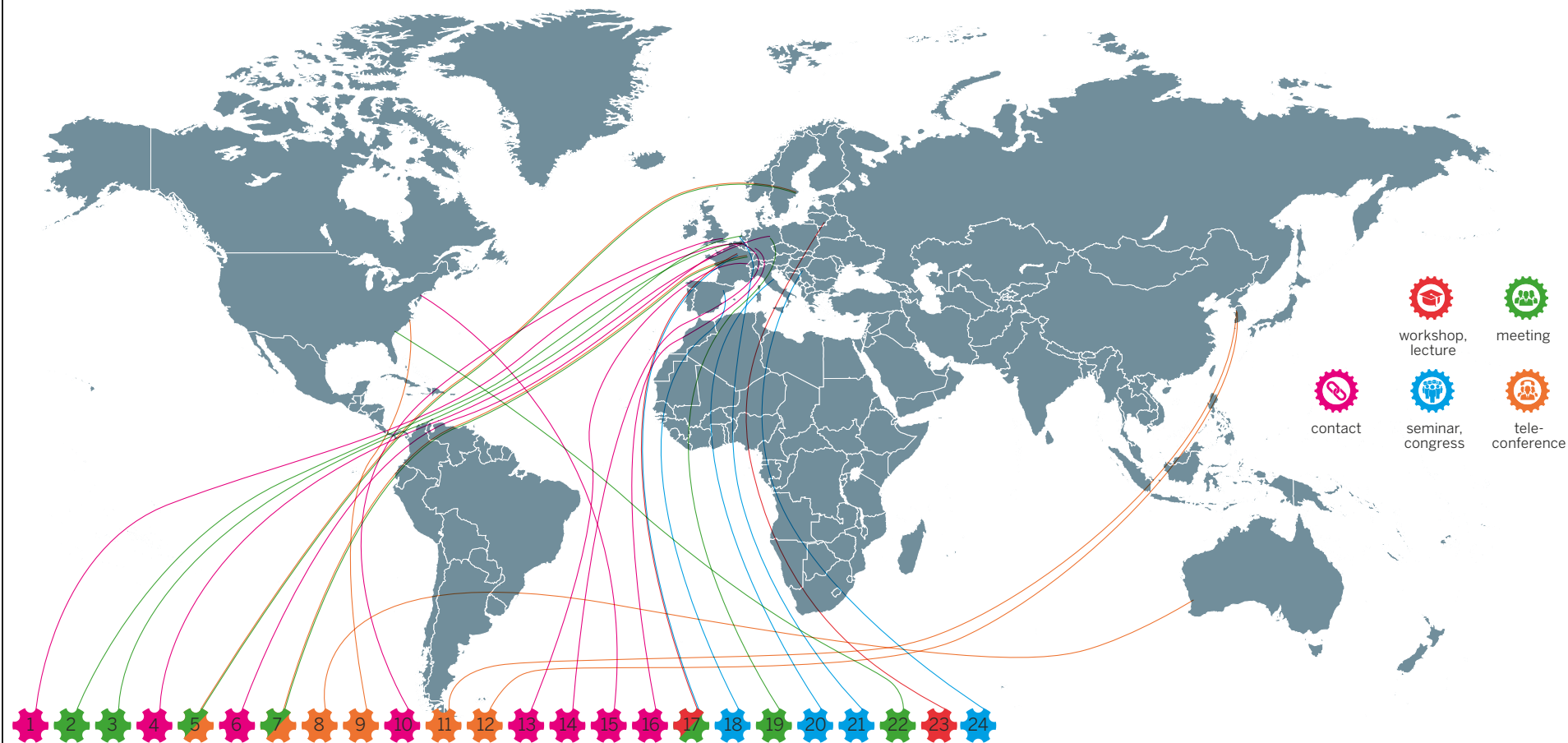
| CONSULTATION   | STARTER         |
|--|-----------------|
| Blood component testing policy   | NHSBT (UK)      |
| Functionalities and services to donors online                                    | IBTS (Ireland)  |
| Methods of bacterial screening of platelet concentrates                          | NHSBT (UK)      |
| Apheresis platelet manufacture with additive solution                            | NHSBT (UK)      |
| Red blood cell demand forecasting  | NHSBT (UK)      |
| Washed and frozen red cells and platelets use, manufacturing and quality control | NHSBT (UK)      |
| Flu vaccination for donors   | ABC (USA), EBA  |
| Ebola convalescent plasma  | EBA, NHSBT (UK) |
| Plasmapheresis costs   | EFS (France)    |
| Pre-donation donor interviews carried out by non-medical staff                   | EFS (France)    |

## 4.2. LEVERAGING EBA INFLUENCE

In 2014, EBA was actively involved in actions aiming to leverage EBA influence, first in European institutions, then in other international organisations. This was facilitated by regular update of the EBA website to make available appropriate documentation on EBA, its objectives, projects and ongoing actions. To improve the visibility of EBA, the new EBA Logo approved at the end of 2013, with a view to making it more contemporary, was implemented in early 2014.

The EBA actions led with European and national institutions, and other international organisations are summarised in the figure below.

## EUROPEAN AND NATIONAL INSTITUTIONS AND INTERNATIONAL COLLABORATION



### 4.2.1. EUROPEAN AND NATIONAL INSTITUTIONS

The Executive Director was involved in the following actions:

- |  |  |   |  |  |   |
|--|--|---|--|--|---|
| <p>1. EU Council: contacting the Health Attachés of each EU member state to present and explain the EBA position</p> | <p>2. NHS European Office (with NHSBT colleagues): meetings to present and explain the EBA position on IVD Regulation (Brussels)</p> | <p>3. Dutch Health Institution (with Sanquin colleagues): meeting to present and promote the EBA position on IVD Regulation (Amsterdam)</p> | <p>4. German Health Institution (with German Red Cross colleagues): contact to present and promote the</p> | <p>5. ECDC: meetings and teleconferences of the WG on new donor pre-qualification, as co-chair (see 3.2.2 above) (Stockholm)</p> | <p>6. European Commission: contact to</p> |
|--|--|---|--|--|---|



present and promote the EBA position on EU Directive amendment on WNV (see 3.3.2 above) (Brussels)

- ✿✿ 7. CD-P-TS (Council of Europe) TS093 on Plasma Supply Management: kick-off meeting and teleconference (see 1.2 above) (Strasbourg)

#### 4.2.2. INTERNATIONAL COLLABORATION

##### The Executive Director participated in the following international WGs:

- ✿ 8. ABO Point of contact (POC) group and EBA POC liaison to the ABO Chief Executive group – via teleconference (Perth, Australia)
- ✿ 9. ABO medical group (Washington DC) – via teleconference
- ✿ 10. PLUS (Plasma Users Coalition) – ABO WG on Risk Based Decision Making; (London)
- ✿ 11. ISBT (international Society of Blood Transfusion) working party on blood supply management, as co-chair South Korea (via teleconference)
- ✿ 12. ISBT standing committee on ethics South Korea (via teleconference)
- ✿ 13. WHO (World Health Organization) core group on self-sufficiency in safe blood and blood components Geneva
- ✿ 14. Eucomed blood safety group (Brussels)
- ✿ 15. Apheresis connector Industry group (Philadelphia)
- ✿ 16. Abbott Global Transfusion Safety meeting, as scientific chair (Wiesbaden)

##### The Executive Director was invited to participate in the following meetings:

- ✿✿ 17. Seminar on transfusion safety, National Institute of Blood Transfusion, Paris, 15 January, as speaker (lecture on « Facing the transfusion risks (blood components): European diversity)
- ✿ 18. 16th International Haemovigilance Seminar, Barcelona, 5 March 2014, as speaker (communication on “Benchmarking blood donor safety practices: a first experience”)
- ✿ 19. European Compliance Academy meeting on Blood, Blood Products and Plasma – Quality and Safety, 8 - 9 April 2014, Berlin, Germany, as speaker (lecture on “Patient blood management, blood supply management, and plasma self-sufficiency: interlinked challenges in Europe”)
- ✿ 20. 41st National Convention of Transfusion Medicine, 16 May, Rimini, Italy, as speaker (lecture on “Is it possible to achieve self-sufficiency in plasma-derived medicines (PDMP) based on volunteer non-remunerated donors?”)
- ✿ 21. 1st European Conference on Donor Health & Management, The Hague, 4 September, as chair of a session on donor blood collection
- ✿ 22. Grifols Roundtable Meeting on Ethics of Compensated Plasma Donation, Raleigh, USA, 13 October 2014 (joined by teleconferencing), as speaker (lecture on “Why achieving self-sufficiency in plasma-derived medicines based on volunteer non-remunerated donors is now more important than ever?”)
- ✿ 23. Voluntary blood donor recruitment workshop for specialists and volunteers, Vilnius, Lithuania, 29 October, as speaker (lecture on “Why achieving self-sufficiency in blood products based on volunteer non-remunerated donors is now more important than ever? The EBA point of view for Lithuania”)
- ✿ 24. 5th Transfusion Medicine Congress of Serbia, Belgrade, 8 November, as speaker (lecture on “Patient blood management: scientific bases and possible ways for implementation in Serbia”)

# EBA ORGANISATION AND ADMINI- STRATION

## 5.1 COORDINATION/ COLLABORATION

The Coordinating Committee of WG Chairs was installed in 2013, to help coordinate the EBA WG activities and strengthen the relationship between the WGs and the EBA executive and Board members. The objectives of the Committee are as follows: i) to organise appropriate information exchange between the EBA WGs on their respective activities; ii) to coordinate the activities of the EBA WGs to optimise their achievements for EBA members; iii) to provide EBA WG members and all EBA members with better visibility on EBA WG's life and achievements.

The Committee meets once a year to review the outcomes from and the ongoing projects of each WG. The proposals for projects and actions are presented to and discussed by the Executive members on the following day. The proposals as finalised with the Executive are then submitted to the Board on the same day. The second meeting of the committee took place in Paris in October. It mainly resulted in practical measures to further develop awareness of the WG members and achievements by EBA WGs within the EBA membership.

## 5.2 EBA WORKING ORGANISATION

In March 2014, the EBA Executive decided to have the EBA head office located in Amsterdam, and hosted on the Sanquin Blood Supply premises. The Secretariat was already located there, but the decision was made to base the Executive Director there also, starting with the successor to the current Executive Director. As the current Executive Director will retire in May 2015, the search for a successor was started in the spring of 2014. The process was concluded when Kari Aranko was contracted. He started on November 1st. Coinciding with this was the appointment of Joëlle

Guerra, as the Collaborative Procurement Manager for EBA (see 2.3 above).

This growth of EBA staff was actively planned during 2014, with a larger working place accommodating four persons, a new lease contract between Sanquin and EBA, and the move of the IT system from the Sanquin one to a new external one. This IT system has been designed to allow for hosting an EBA members' intranet site, to be developed and implemented in 2015. In this context, the handover plan proved to be effective and Kari Aranko will take over as Executive Director as of February 1st 2015.

### 5.3. EXECUTIVE ELECTIONS

**Philippe Vandekerckhove**, elected in 2013 to replace **Jeroen de Wit**, took over as EBA President as of 1st January. As the Vice President, **Yves Charpak**, left his organi-

sation (French Blood Establishment, France), a new Vice President was elected: **Erhard Seifried** (Blood Transfusion Centre of the German Red Cross, Germany). This along with the retirement of **Lynda Hamlyn** (NHSBT, UK) required an election to replace the vacant Executive seats. Two new Executive members were elected: **Lorna Williamson** (NHSBT, UK) and **Rudolf Schwabe** (SwissTransfusion SRC, Switzerland). At the end of the year, **Jørgen Georgsen** (Odense University Hospital, Denmark) was elected for a second mandate of three years. The second term of **Andy Kelly** will end in 2015.

### 5.4. EBA HONORARY PRESIDENTS

In the Board Meeting of April 2014, the board honoured Jeroen de Wit as the previous president. He was named Honorary President, acknowledging his accomplishments for EBA. This honour was also

extended to EBA's second president, Martin Gorham. Both former presidents can now be invited to all Executive and Board Meetings at the invitation of the current president.

### 5.5. FINANCES

#### 5.5.1. Auditing committee

To comply with a specific requirement in the EBA statutes, the Board decided to establish an Internal Audit Committee known as the "Audit Committee". This Committee will assist the Board in the review of the financial statements and other published financial information, including the administrative procedures. The two independent Board members (not on the Executive) appointed at the April Board meeting were Mary Morgan (Scottish National Blood Transfusion Service, UK) and Rudolf Schwabe (Swiss-Transfusion SRC, Switzerland). Because



**Philippe Vandekerckhove**



**Erhard Seifried**



**Lorna Williamson**



**Rudolf Schwabe**



**Jørgen Georgsen**



**Andy Kelly**

the latter was then elected as Executive member, Markus Jarnig (Austrian Red Cross Blood Transfusion Services) was appointed at the October Board meeting to replace him. The effective start of the Committee took place in early 2015.

Kari Aranko was director of Research and Cell Therapy Services at the Finnish Red Cross Blood Service (FRCBS), and has over 20 years of experience at senior management positions. In the beginning of his career he served over 5 years as a medical officer at the competent drug regulatory authority in Finland. After that he worked for national and multinational pharmaceutical and biotech companies gaining experience in managing international operations. Since 2007 he has been holding senior management positions at the FRCBS, covering e.g. research and development, Finnish Stem Cell Registry, Cord Blood Bank, Advanced Cell Therapy Centre, laboratory services to hospitals, as well as plasma and pharmaceutical distribution business. He was a temporary CEO of FRCBS from September 2010 until August 2011. His research and development activities are reflected in over 50 publications, about 100 study reports, and successful submissions of several new drug and marketing authorization applications. In addition he has had a pharmaceutical facility constructed and managed IPR portfolio of over 30 patent families. He has also several years of experience as a member of Board of Directors both in public and private sector.

# FINANCIAL REPORT

## BALANCE SHEET

### Assets

#### 31 December 2014

**Tangible fixed assets** € 1,892

Equipment

### Current Assets

Amounts to be received € 5,486

Prepaid costs € 681

Accounts receivable € 37,390

### Liquidities

Rabobank € 817,492

**Total** € 867,495

## State of income and expenses 2014

### Income

Membership Fees € 390,500

Interest bank account € 5,486

EU Grant € 9,471

€ 405,457

### Expenses

Personnel costs € 246,769

Depreciation € 762

Meetings and workshops € 2,354

Travelling etc. € 26,231

Office costs fixed € 3,596

Office costs variable € 18,690

Other costs € 26,376

€ 324,778

**Balance** € 80,679