ABOUT EBA

THE EUROPEAN BLOOD ALLIANCE (EBA) IS AN ASSOCIATION OF NON-PROFIT BLOOD ESTABLISHMENTS (BE), 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 PRESIDENTS

During the year 2013, one of the most important outcomes for the European Blood Alliance (EBA) was the elaboration and adoption of a new strategy for the period 2014 – 2018. The four strategic objectives were defined as follows.

◆ Safe and secure self-sufficiency from voluntary non-remunerated donors (VNRD)
◆ Performance improvement through collaboration
◆ Support to national and European authorities to promote best practice
◆ Information exchange and dissemination

The presentation of this annual report - the first one for EBA - reflects each of the EBA strategic objectives. To facilitate the implementation of the defined strategy, actions with tangible and measurable outcomes have been gathered in a yearly action plan. We are pleased to note that for 2013, 90% of the action plans attributed to the EBA Staff have been realised. Through the work achieved by the EBA working groups, and experience sharing with internal consultations, many practical ways of continuous improvement have been made available to the members, benefiting first patients and donors and second cost-effectiveness (important in the current times of economic constraints).

Furthermore, EBA was proactive in working with international institutions. For instance, influencing the in vitro diagnostic (IVD) future EU Regulation at the EU Commission and the EU Parliament, completing the blood supply management project with the Council of Europe and initiating a more active collaboration with the World Health Organization.

We warmly thank all EBA member employees who have contributed to the work realised and to all our Volunteer Non-remunerated Donors who make safe transfusion available for patients.

Jeroen de Wit
EBA President 2008-2013

Philippe Vandekerckhove
EBA President 2014 – 2016
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.

Four strategic pillars are derived from this mission:

- **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 2013.

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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 SANGUINIS¹, 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 2013 COMPRISED 25 MEMBERS.

SAFE AND SECURE SELF-SUFFICIENCY FROM VNRD

1.1 BLOOD SUPPLY MANAGEMENT (BSM) IMPROVED
Blood Supply Management is defined as “a series of processes and procedures that ensures the availability of safe blood components for patients requiring transfusions.” At the core of each Blood establishment’s practice is ensuring the efficacy of the primary process from donor to patient. Up to 2013, the EBA Executive Director chaired the Council of Europe (CoE) Working Group on Blood Supply Management. To help improve the management of the blood supply chain in blood establishments, this group devised tools of assessment and improvement. This method was validated in different settings and countries. The questionnaire and method for BSM that was developed there was promoted and disseminated through CoE and international Society of Blood Transfusion (ISBT) websites, 4 articles in ISBT Science Series (June) and 6 articles in Transfusion Today (December). These tools are available on the Council of Europe website:
www.edqm.eu/en/healthcare-news-44.html

In March 2013, the Executive Director facilitated meetings in Tallinn, Estonia to assess Blood Supply Management and devise ways of improvement. These meetings gathered clinicians, blood establishment experts and Ministry of Health officials. This was an example of the capacity of the EBA to assist individual members in specific core topics.

1.2 PROFESSIONAL AND EFFECTIVE DONOR MANAGEMENT
In 2010, the DONor MAnagement IN Europe (DOMAINE) project
was completed with the publication of the *Donor Management Manual* and the organization of the first international training course. In 2013, the **DOMAINE** principles were further promoted through a second training course in Dublin, 24-25 September 2013, gathering experts from 25 countries with extensive experience: “Five modules (donor management process, database management, marketing and communication, collection operations management and donor safety), enthusiastic participants, interactive learning methods and excellent networking opportunities” is how the **DOMAINE** Training Programme was described by Project Coordinator, Elze Wagenmans. Assessment of the training course by participants produced very positive feedback.

**MiMi Project**

For the first time, EBA initiated a research project on **Donor Missing Minorities**. The missing minorities are representing a growing concern particularly with immigrants inducing specific transfusion needs. As an example, donations from donors from sub-Saharan Africa or the Caribbean could be required to treat patients with sickle cell anemia, needing regular red blood cell transfusions.

The project conducted in Estonia and the Netherlands showed that minority groups are now under represented in the donor populations throughout Europe. It provided guidance to assess and address these concerns.

1.3 **MANAGEMENT OF EMERGING INFECTIOUS DISEASES MASTERCED**

The EID monitor is a network of experts in epidemiology of infectious diseases within Blood Establishments who, on a monthly basis, share information on infectious diseases that could impact blood product safety. This network gathers experts from Europe (EBA) and also from beyond: Australia, Canada, USA. In 2013, information sharing about risk assessment and blood safety measures was again facilitated by the EID Monitor at national, EU and international levels. Examples of successful interventions were the West Nile Virus (WNV) outbreaks, Malaria in Greece and the pre-qualification of new donors.

The EID-Monitor participated in two meetings on malaria organised by the European Centre for Disease Control (ECDC) to discuss measures to be taken to ensure safety when an area in Europe is affected by autochthonous malaria, as recently observed again in Greece. In these meetings the group agreed upon definitions for affected areas and how and when to screen donors with malaria tests. Measures should follow a risk assessment and be proportional to the number of cases, the nature of the cases, the spread of cases and the affected population.

The WNV season ended on 30 November 2013. During the WNV season weekly WNV maps were published by ECDC and discussed by the members of the EID-monitor, so countries were able to adjust their blood safety measures (e.g. donor deferral or WNV Nucleic Acid Testing – NAT – of travelers returning from an affected area). Following a case of HIV transmission reported in Austria, the European Commission (EC) requested ECDC to investigate the potential value of pre-qualification of new donors. This procedure would mean that new donor candidates would come through a full donor selection process (pre-donation interview and laboratory testing – before being invited, when the donor selection criteria are fulfilled – for a first time donation. As compared to the most current situation in Europe (donor selection and first time donation in one collection session instead of two), this measure could contribute to reducing the risk of transmitting diseases through transfusion. For this, a meeting has been planned in Rome with contribution of ECDC and EBA EID Monitor, in early 2014. The decision to create a WG to further explore this topic was made at the end of that meeting.

1.4 **USE OF BLOOD COMPONENTS AND PLASMA DERIVATIVES OPTIMISED**

Optimising the use of blood components has led to further developing patient-centered evidence based transfusion strategies, the so-called **Patient Blood Management (PBM)**, representing a re-emergence of transfusion medicine principles. The growing importance of PBM has led the European Commission to launch a call for
tender to develop European Guidelines on PBM. With the strong support of its members, EBA gathered an international group of experts to prepare and submit a proposal. Unfortunately, the European Agency for Health and Consumers did not grant the tender to the EBA Consortium. However, strong motivation from the EBA consortium members led to the decision to move the project forward from its own funds. This project called Patient Blood Management in Europe (PaBloE) has been effectively launched in 2014.

Plasma Derived Medical Products (PDMP)
Based on the successful outcomes of the Blood Supply Management Working Group, EBA proposed to the Council of Europe that it create another working group on Plasma Supply Management, with the objective to assess and develop self-sufficiency in plasma from voluntary non remunerated donors and PDMP in Europe. This initiative was agreed in principle but postponed until 2014.

1.5 SELF-SUFFICIENCY FROM VNRD ASSESSED AND IMPROVED
As presented in the EBA Book because of patient safety, security and continuity of the blood supply and because of ethical reasons (dignity, autonomy, justice) EBA strongly promotes Voluntary Non-Remunerated (blood) Donations. EBA published an article in a peer-reviewed journal presenting renewed considerations on ethical values for blood and plasma donations and donors. These considerations are intended to obtain better understanding and acceptance by all the stakeholders involved: donors, blood establishments, plasma collectors, prescribers, health care providers, health authorities and policy makers. VNRD is, according to many international institutions (as WHO, Council of Europe, ISBT, IFRC, EBA), the best way to ensure a safe and sustainable blood and plasma supply for patients and a safe and sustainable donor population. These considerations have been discussed in a WHO-EBA meeting, chaired by the WHO Assistant Director-General for Health Systems and Innovation. The conclusion was that WHO would like to work with EBA to further discuss possible ways forward, as proposed by EBA, to further develop self-sufficiency from VNRD. These considerations were presented during a high-level Policy-makers Forum on Achieving Self-sufficiency in Safe Blood and Blood Products, based on VNRD, organised by the World Health Organization (WHO) in October in Rome, Italy. EBA was invited to participate in this forum, with representatives of many countries in the world and other international organisations. Fruitful discussions led to the drafting of a new WHO resolution on self-sufficiency of blood products from VNRD (still ongoing). It also led WHO to create a core working group on self-sufficiency of blood products from VNRD, in which EBA was invited to participate.


‘VOLUNTARY NON-RENUMERATED DONATIONS IS THE BEST WAY TO ENSURE A SAFE AND SUSTAINABLE BLOOD AND PLASMA SUPPLY FOR PATIENTS’
2.1 PERFORMANCE IMPROVEMENT

Following from its mission, performance improvement is a direct goal of EBA and its members. A Master Class on Performance Improvement was held on May 31st. A group of about 50 participants from all over the world dived deep into how to improve performance at a blood establishment. The physical outcome of this Master Class is a document linking the presentations, videos and summaries all into one Desktop Poster.

The EBA Flying Squad is a small group of members’ employees who are specialized in Lean management and who help other members (at the cost only of travel and accommodation) to improve performance in their blood service. In 2013, the Flying Squad visited three countries: Austria, Ireland and Portugal. The follow-up visits after one year all showed significant improvements in efficiency from the action plans set up after the visits. Most of the measures of the action plans dealt with simple organizational changes to streamline the process; for example, in donor collections sessions, multi-skilled staff appeared as accessible and very effective, instead of being restricted to one task.

In spring, a Benchmarking exercise on donor safety practices was held at Établissement Français du Sang (EFS) with EBA Executive Director as facilitator and experts from four other countries. The workshop facilitated a presentation of EFS practices on means to prevent donor reactions (e.g. fainting); means to cure/manage donor with adverse reactions; and donor vigilance (reports on donor adverse reactions). The outcomes were mutual lessons with improvement measures for both EFS for some points needing improvement at EFS and other EBA members for other points for which EFS practices were identi-
fied as good practices that could be implemented in other BEs. For instance, EFS will make available to other members the necessary training and qualification programs and procedures for collection staff. This benchmarking work was presented at the International hemovigilance seminar in early 2014 and experts welcomed this exercise and its outcomes as a very practical means to raise donor and also patient safety in conjunction with hemovigilance.

With an increasing number of EBA Members engaging in the manufacturing of tissues and cells, the benchmarking activities extended to Tissues and Cells. The first scorecard showed a wide range of activities by the members, which will be worked on in the coming years.

2.2 JOINT PROCUREMENT

Based on two surveys held the previous year, the decision was made in 2013 to develop an EBA Grouped Purchasing Organisation (GPO) with the objective of saving money for members, improving quality of medical devices used by the members, and generating finance for EBA’s funding and activities.

In previous years, an EBA pilot GPO, hosted by NHSBT, had successfully tendered for blood bags with common European specifications, the “Eurobloodpack”. The transfer of this project leader to Australia sparked the decision to hire an EBA Collaborative Procurement manager. The potential savings, based on Eurobloodpack experience, should help to secure the required funding. Based on this, within a few years, the organisation of the GPO should be cost neutral to the EBA with members able to join contracts if they wish.

2.3 RISK BASED DECISION MAKING / COST-EFFECTIVENESS OF NEW MEASURES

EBA has in 2013 actively participated in the ABO WG on Risk Based Decision Making (RBDM). Phase I (April 2013 to March 2014) of the RBDM was devoted to developing a draft framework that will be used as a catalyst for consultation with key stakeholders in Phase II (beginning April 2014).

The project covers four pillars (fig 1):

◆ **The Risk Framework Committee**, which has as its goal an integrated, internationally applicable RBDM framework focused on optimal patient outcomes and donor safety

◆ **The Health Economics Committee**, focusing on creating a consistent methodology and tools to ascertain the cost and impact of proposed interventions in the context of the blood system and health care

◆ **The Web Portal Committee** will develop a web-based database to permit organisations to share data and work collaboratively on blood safety risk management models

◆ **The Stakeholder Engagement Committee** will devise a mechanism to guide blood operators in the appropriate engagement of stakeholders in RBDM.

Besides EBA members being active in the four Working Groups, EBA also contributed to this project in kind,
through the time of an expert from the University of Utrecht, who has been active in the Health Economics subgroup.

2.4 HARMONISED TRANSFUSION MEDICINE TRAINING AND QUALIFICATION IN THE EU

Sanquin Blood Supply (the Netherlands), EBA and other European partners applied for a grant in the Erasmus Life Long Learning projects. In the summer of 2013, EU money has been granted to the DoHeCa project. The goal of DoHeCa is to build a distance-learning curriculum for professionals in Donor Health Care. A new element in this curriculum is that it’s focused on all donors donating ‘substances of human origin’, in both living and deceased donors. This collaboration in the fields of blood, cells, tissues and organ donation will improve donor care, for the donors, the professionals, and their institutions.

DoHeCa is a European project and will have a global interest through the collaboration with ISBT, American Association of Blood Banks (AABB), WHO and other international organisations. EBA will play an active role in the curriculum about basic donor health care and the dissemination of the project outcomes. The project will last for three years and the curriculum will continue to be available after the end of the project.

‘DONOR HEALTH CARE IS PROTECTING THE DONOR AND PROTECTING THE SAFETY AND EFFICACY OF THE BODY MATERIAL, TAKING SOCIETAL AND ETHICAL FRAMEWORKS INTO ACCOUNT’
3.1 MD – IVD RECAST
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 recital making obligatory that any IVD manufactured by blood establishments be CE-marked. This potential threat (patient harmed by lack of specific tests) led EBA to propose a new wording authorizing niche IVDs produced 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 a new version of the Regulation first by the ENVI (Environment-Food –Health) committee of the European Parliament and then 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 began after this successful outcome.

3.2 BLOOD EU DIRECTIVES EVALUATED IN THE PERSPECTIVE OF THEIR REVISION
Although the EC stated that there would not be a revision process before 2014 and the appointment of the new EU Parliament (July 2014) and Commission (October 2014), it seemed logical to expect the revision process to be launched by the end of 2014. In this perspective, EBA has decided to launch two Working Groups to prepare an EBA position, one on the revision of Directive 2004/33/EC concerning donor selection, and the other to prepare a position about the three other blood directives.

3.3 MANAGED REGULATORY CONVERGENCE (fig 2):
Following the death of an apheresis donor in 2009, 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. An international meeting gathering all these stakeholders in 2011 has moved forward 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 has been approved by all concerned suppliers and EBA. The process of establishing and adopting ISO-standards for apheresis connectors progressed up to the first phase (of three) with the help of the industry and ISO-sub committees. The full standardization process is expected to be completed by the end of 2015.

3.4 STANDARD SETTING ROLE FOR THE COUNCIL OF EUROPE BLOOD GUIDE

EBA addressed comments on a new chapter of the Council of Europe Blood guide on quality assurance. Despite the finalisation of this chapter, DG SANCO has decided not to accord it legal status comparable to the one on the Pharmacopeia, before the end of the mandate of the Commission. This chapter will be made accessible on the Council of Europe website, but it cannot be considered as binding.

Figure 2: Spike port connector and luer connector requiring different movements and action by user
4.1 INTERNAL COMMUNICATION AND MEMBERS’ SATISFACTION

Since August 2013, EBA has its own Newsletter, providing members with updated news on EBA activities and what is ongoing for blood establishments’ current affairs. In 2013 seven Newsletters were sent out with the following items:

- Many items on the progress of the Medical Devices EU Directive change
- Six requests for member consultations on various subjects
- Nine articles on publications from other organisations such as WHO, Council of Europe and FDA
- 22 articles on news generated by EBA, like updates on working groups, outcomes of meetings and use of social media in blood establishments.

In November 2012, the EBA conducted a Satisfaction Survey. At the board meeting in Copenhagen in spring 2013, the members were presented with the outcomes of this Survey. During the year, the EBA Staff took several measures to improve points from members’ suggestions through the survey. As a result of this, several items were identified:

- The Coordinating Committee of Working Group Chairs (CoCo committee) was installed, with the objective of coordinating the work group activities and strengthening the relationship EBA executive members and the Board has with its Working Groups. The first meeting of this committee took place in Dublin in September. It was followed by a joint meeting between the group and the EBA Executive members to discuss the ongoing projects of each working group and prepare decisions requested from the Board.
• The structure of the board meetings was revised, with more time allocated for discussion, shorter times for presentations, and in depth sessions dedicated to subjects relevant to Board members. The new formula was implemented at the Dublin Board Meeting with the Missing Minorities project and the possible tender for Patient Blood Management by the EC.

• To improve recognition of EBA, the EBA Logo was reviewed, with a view to making it more contemporary. The colour red was retained. The new logo was agreed in December 2013 and implemented in 2014.

4.2 MEMBER CONSULTATIONS
To help members to share their experiences and expertise from daily life, members can request a consultation. The requester of such a consultation 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 2013, when 15 consultations circulated amongst members.

For instance, Latvia asked EBAs help to explore the use of Albumin and Immunoglobulins and the Plasma self sufficiency in Europe. As usual, at the EBA Board meeting in Dublin on 27 September, the outcomes of the consultation were presented to the members. Other consultations were on HB levels in donors, costs of refreshments for donors and in which capacities Blood Establishments made partnerships with other organisations.

4.3 LEVERAGING INFLUENCE OF EBA ON POLICY AND DECISION MAKERS DEVELOPED

4.3.1 EBA Book
EBA took the initiative for involved stakeholders and decision makers in EBA member's countries and European Institutions to gather the state of the art on blood transfusion chain and tissues and cells manufacturing and distribution. This book was published as: Blood, tissues and cells from human origin: the European Blood Alliance Perspective. It was published in hard copy, pdf and as an ePub and can be downloaded through this link.

4.3.2 European Commission
The Executive Director was invited to participate in the two annual DG Sanco-National competent authorities meetings in Brussels. This provided an opportunity to discuss the following items:

• The report on an HIV transmission in Austria, involving a test seeker (meaning a donor willing to be tested for the result not primarily for donation) led EBA to be involved in the creation of a European Working Group to investigate the potential value of new donor pre-qualification testing. This means that new donors would undergo donor selection, including testing, before being invited for a first donation.

• The EBA presentation of possible risks for patients from the draft IVD-regulation proposed by the EC, was acknowledged by DG SANCO and they encouraged EBA and national competent authorities to act
at the European Parliament and Council levels to correct the text on this point. Action from EBA has been strengthened by this encouragement.

• Following an EBA presentation on the questionnaire for the regular EC Survey on Voluntary Unpaid Donations, DG SANCO encouraged EBA to submit proposals for modifications. Most of the proposals have been integrated in the version used for the third survey (launched in 2014).

4.3.3 European Parliament

EBA actions relating to IVD regulation proved to be successful (see above).

4.3.4 Other organisations

The Executive Director was invited to attend and speak at the following meetings:

• ISBT (international Society of Blood Transfusion) Meeting: Academic session and parallel session on Blood Supply Management
• SFTS (French society of Blood Transfusion), EBA communication on Patient Blood Management
• PLUS (Plasma Users Coalition): participation in the fourth Consensus Conference
• EuBIS (European Blood Inspection System); training course in Dublin.
• DOMAINE (Donor Management in Europe: training course in Dublin.
• WHO (World Health Organization) meeting on self-sufficiency in safe blood and blood components, followed by participation in the WHO core group on this topic
• Abbott Global Transfusion Safety meeting, as scientific chair
• CD-P-TS meeting of the Council of Europe to promote the creation of a working group on Plasma Supply Management

4.3.5 EBA publications in 2013:


## BALANCE SHEET

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