[19] EBA ANNUAL REPORT

EUROPEAN BLOOD ALLIANCE 2019

Safe blood for Europe

DEVELOPING AND MAINTAINING
AN EFFICIENT AND STRONG COLLABORATION
AMONGST EUROPEAN BLOOD AND TISSUE
AND CELL SERVICES

FOREWORD

We look back on 2019 with great pride. The European Blood Alliance (EBA) had a very good year, which makes us feel confident that we can pursue and have a significant impact on the advancement of the science and knowledge in the blood banking field: to help patients, protect donors, and supply safe quality products.

Philippe Vandekerckhove
EBA President

To name just a few of our achievements: this year, we were successful in setting-up a new office in Brussels; holding a public meeting in the European Parliament; sharing our views for future EU legislation on blood at a high level European Commission meeting; holding a workshop on the use of O negative; and contributing to the upcoming EDQM Blood guide.

Our ambition is threefold: to safeguard donor health and wellbeing; protect and improve patient care and the blood supply; and improve the performance of European Blood Establishments. Sharing its expertise, EBA supports its members in providing high quality service. As I end my mandate as President of the EBA, I am happy to see that EBA is delivering on its promises and I am confident that my successors are at the helm of a robust and sound association.

In this report you will find a wealth of information about how, in 2019, we went about creating an environment in Europe that is conducive to improving quality blood supply as well as providing our members with crucial information and facilitating exchange of knowledge and skills between them.

The European political landscape changed in 2019: European Union citizens voted for new Members of the European Parliament (MEPs) altering the traditional balance between right and left. The UK has exited the European Union leaving uncertainty about the future relations in the field of health between the UK and the Union. The European Commission concluded its evaluation of the EU Blood Directives and we can expect for the coming years, robust negotiations on what should be the next regulatory framework for the EU blood sector.

It is a time when Blood Establishments across Europe must particularly show unity and solidarity, to help deliver the best legislation for their field of work, ensuring that patients and donors are provided with the best service, care and protection. The same goes for facing and reacting to sudden disease outbreaks as we have witnessed in December in China, with the COVID19 and the SARS-Cov-2 viruses. Our EU advocacy, Emerging Infectious Disease Monitor (EID M), Contingency planning working groups and other ad hoc sets of EBA internal expertise are instrumental in delivering the most appropriate support and response to both the EU and national authorities.

EBA also strives to keep its international presence, despite the fact that the Alliance of Blood Operators (ABO) changed its governance and does not now allow associations of BEs to remain members. EBA kept the dialogue going with ABO's leadership, recommending a partnership between the two entities to replace membership. Representatives from Australia, Canada and the US are still part of our EID M meetings and EBA leadership attended international events on behalf of the association.

Finally, EBA remains firm on advocating and supporting voluntary-non-remunerated blood and blood components donations (VNRD), despite growing pressure from the plasma industry to allow some form of compensation or remuneration. The debates at EU level on the need to increase plasma collection will trigger arguments to attempt to alter our views on VNRD; EBA needs to be prepared to counter-argue, based on evidence and recommendations for the future course of action, with donors' protection as our main focus.

In conclusion, I wish the EBA new President, Pierre Tiberghien all the best in his mandate and I am confident that under his leadership, together with the rest of the Executive Board, the association will continue to be successful in both advancing our knowledge in the Blood Sector and management of Blood Establishments, and to support EBA's members in their practice. I will be happy to continue interacting with EBA members, as Immediate Past-President and co-representative for Belgium.

Warm regards,

Philippe Vandekerckhove

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EBA's mission is to:

1

Contribute to the availability, quality, safety and cost-effectiveness of the blood and tissue supply for the citizens of Europe by developing and maintaining efficient and strong collaboration amongst European blood, cells and tissue services

2

Increase public and professional awareness of voluntary and non-remunerated donation of blood and blood components as an indispensable therapeutic means of helping patients

3

Assist European blood establishments to continuously improve their performance, based on scientific and ethical principles for the benefit of patients

EBA strives towards this mission by assisting our members to improve performance through collaboration, to engage in regulatory affairs to promote best practice and to facilitate information collection and knowledge exchange.

EBA’s core values are:

1

Donor safety

Core value statement: EBA members take good care of donors and actively take measures to avoid harm to them.

Explanation: Donors represent a unique source and EBA members have to ensure the continuity of their gift. This can happen only if EBA members take good care of them through being aware of harm that may be caused in the context of donation, donation frequency and taking measures to avoid it. EBA and EBA members are open and transparent and take action to improve where possible donor safety. This could mean e.g. explaining deferral rules to donors and being open in the rationale behind any policy – evidence based.

2

Patient Care

Core value statement: Through safe and sustainable supply of blood components, EBA members contribute to the patient's care.

Explanation: Patient care is the ultimate goal of transfusion medicine: safe and adequate blood supply contributes to a well-functioning professional healthcare system. All actions that EBA members take, should therefore as a first priority aim to improve patient's care.

3

Excellence through evidence

Core value statement: EBA members are striving towards excellence by being innovative, adopting state-of-the-art processes and practices and implementing actions through evidence-based methods. Positions taken by EBA are based on evidence thereby avoiding bias in conclusions. Explanation: EBA Members constantly monitor whether the set targets for excellence are still relevant and update them from time to time. They implement actions to ensure that the set targets are reached and encourage continuous learning. Excellence in blood products supply chain cannot be characterised merely by high productivity and quality. It means right, evidence based, decisions to contribute to a well-functioning professional healthcare system. When EBA uses the term 'Evidence based', it is used in the strict sense of the Cochrane Collaboration.

4

Information sharing

Core value statement: EBA shares information to support evidence based decision making and performance improvement of services in blood, tissues and cells.

Explanation: EBA and EBA Members share information within the membership and when agreed, with regulators and other stakeholders with the goal of improving patient and donor care in Europe. Sharing information and collaborative activities leverage the economies of scale. The collateral benefits outweigh the time and manpower invested in joint activities. EBA respects the members' decision on the use of the disclosed information.

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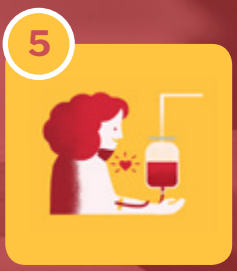


Voluntary, Non-Remunerate Blood Donation(VNRD)

Core value statement: EBA and EBA members are committed to voluntary non-remunerated donations (VNRD) for sustainable blood, tissues and cells supply for the benefit of donor and patient safety.

Explanation: To protect donors' and patients' safety, transactions of human bodily materials should comply with the well acknowledged four principles of biomedical ethics: autonomy, non-maleficence, beneficence and justice. Protection of donor's dignity, involving the prohibition of making the human body and its parts as such a source of financial gain, has been strongly encouraged by the Council of Europe Oviedo Convention.

WORKING GROUPS

EBA has several Working Groups which support EBA's mission to share knowledge and deliver evidence-based information. Working groups communicate the outputs of their work with all EBA members and help shape the basis of EBA's positions and recommendations.

A Emerging Infectious Disease (EID) Monitor

Since 2010, the EID Monitor network has emitted recommendations for members, but also influenced the recommendations and decisions elaborated by the ECDC and finalised and issued by the European Commission (EC).

The objectives of the working group are:

• To organise appropriate information exchange between the EID Monitor members on the emerging infectious agents and diseases.
• To discuss, elaborate and disseminate to members recommendations on blood safety measures to cope with the risks of EIDs.

• To discuss, elaborate and promote at European institutions level (eg ECDC, EC, EMA, CD-P-TS/EDQM) the adoption of recommendations / guidance / legislation on blood safety measures to cope with the risks of EIDs.

Through its monthly teleconference and regular information exchange, the Emerging Infectious Disease (EID) Monitor continued to watch emerging infectious diseases and exchange information about blood safety measures in the area of EBA and Alliance of Blood Operator* membership. On average 19 EID Monitor (EIDM) members participated in each telecon in 2019. The prompt circulation of the telecons' minutes ensured a quick spread of information and recommendations to EBA and ABO members. The following topics were particularly important this year.

*side note on ABO: The Alliance of Blood Operators (ABO) is a network of not-for-profit blood operators with voluntary non-remunerated blood donor bases. Its members are America's Blood Centers, American Red Cross, Australian Red Cross, Lifeblood, Vitalant, Canadian Blood Services, European Blood Alliance (up until July 2019) and NHS Blood and Transplant.

West Nile virus (WNV)

The seasonal WNV transmission of 2019 was mild. The number of cases this year is much lower than in 2018, but comparable with previous European seasons. For 2019, 453 human cases were reported on the European continent (2015: 125; 2016:272; 2017: 258; 2018: 1,955). The first cases were reported in Greece and Romania in July and the last WNV case was reported in Italy in mid-November. Most human infections occurred mainly in known endemic WNV areas, but transmission to humans was also observed in Eastern Germany (where also numerous WNV infected horses and birds were found) and one human WNV case was found in Slovakia. Although the season was relatively mild, the spreading of WNV to new areas to Northern European regions, confirms further spread across Europe. These developments not only impact the safety of blood products in affected regions, but also the blood supply of non-affected countries because of increased donor deferral. A switch to WNV Nucleic Acid Testing (NAT) is an alternative strategy enabling the acceptance of those donors returning from travelling in WNV affected areas.

The trigger for applying blood safety measures for WNV (WNV NAT or donor deferral), based on confirmed human WNV infections, remained unchanged. Although there is the discussion as to whether the notifications of equine cases should be used as a complementary trigger for blood safety measures, a study by the European Centre for Disease Prevention and Control (ECDC) found no correlation between human and equine data. There was no evidence that equine cases increased the likelihood of human cases. Infections among equines only raises awareness of virus circulation for public health and for triggering enhanced surveillance.

It is known that WNV NAT is also reactive with other arboviruses such the Japanese encephalitis virus, St Louis encephalitis virus, Murray Valley encephalitis virus, Usutu virus and Kunjin virus. In 2018 this was observed for Usutu virus in Europe. This year, large outbreaks of dead birds due to Usutu virus outbreak were not reported in Europe, suggesting a seasonal pattern with years of low circulation like WNV.

In a meeting organised by the ECDC, EIDM contributed to the evaluation of the safety of blood supply during WNV outbreaks in Europe by summarizing the preventive strategies applied. This resulted in a publication of the paper West Nile and Usutu virus infections and challenges to blood safety in the European Union (Emerg Infect Dis. 2019 Jun;25(6):1050-1057).

Other vector-borne viruses

Zika virus

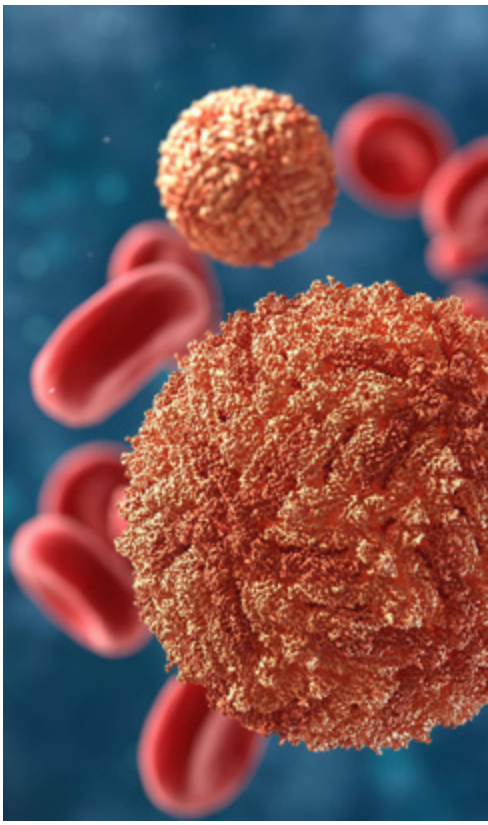
Sustained transmission of Zika virus occurred in various countries worldwide, although at a lower frequency compared to previous years. The WHO publishes the Zika virus situation at a global level. As a precautionary principle, the ECDC recommends a deferral of 28 days after returning from a Zika virus affected area, and 28 days after sexual contact with a man diagnosed with Zika virus infection in the three months preceding sexual contact, or with a woman in the eight weeks preceding the sexual contact. It is up to the MS to decide how to address sexual risks: they should perform their own risk assessment and decide the deferral rule for sexual risks.

A total of three autochthonous Zika virus cases were found in France. These are the first cases of autochthonous vector-borne Zika virus infections ever documented in Europe. After the report of the first case, two additional cases were retrospectively identified. All these cases experienced clinical symptoms in the period of early-mid August. The primary index case (imported case) was not identified. The identification of this small cluster confirms vector-borne transmission (by Aedes albopictus), but a large outbreak did not occur. For this year there was no risk for blood safety.

Dengue virus

Autochthonous dengue virus transmission was found in Spain and France. After a case of dengue was detected in Barcelona at the end of September, it was decided by the Catalan health authorities to conduct a study of the possible penetration of the dengue virus in Catalonia. Between 1 October till 1 December 2019 approximately 46,000 donors were screened by NAT in a pool of 16 samples. No positive samples were detected. New patients with dengue have not been detected in Catalan hospitals or in the rest of Spain. In France, a few cases were observed in the areas of Rhône and Alpes Maritimes. The dengue cases in these regions did not lead to large outbreaks.

Additionally, one probable sexual transmission of dengue through MSM has been observed. Transmission through a sexual route has not been reported before. One man acquired the infection during travel (Cuba) and very likely infected his male sexual partner. The infections of both men were diagnosed by PCR and the viral sequences were identical. The investigation of other sources did not confirm another route of infection (mosquito-borne). Sexual transmission is a potential, but apparently rare mode of transmission for dengue.

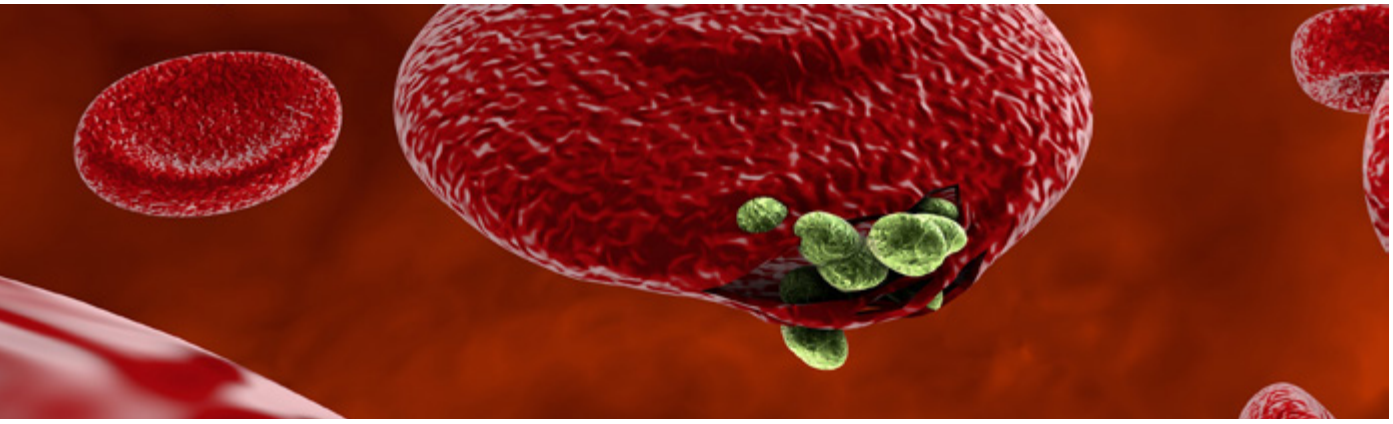


Chikungunya virus

The virus is largely spreading in the Americas, especially in Brazil.
No autochthonous cases have been reported in Europe.

Malaria

A few isolated local malaria transmissions have been observed in Greece, illustrating the risk of sporadic malaria transmission in the South of Europe and the risk of reintroduction due to migrants or travellers from malaria endemic countries to Europe and the favourable climate for mosquitoes in Mediterranean countries. The risk for outbreaks and the risk for blood safety in Europe is considered very low.



A European perspective on emerging infections

In 2017, a research group from Sanquin received the EBA grant to develop an integrated tool, based on European Upfront Risk Assessment Tool (EUFRAT). The objectives of the tool are to estimate the risk of transfusion transmitted emerging infections for the whole of Europe. Data (numbers of donations and products) of European blood banks and data of European travellers are integrated in this tool. The result is displayed in an Excel spreadsheet, where only a minimum of input parameters is additionally required. By adding the reported number of infections in the country/ countries, the proportion of unobserved cases and the specific disease characteristics of the pathogen, the risk for the European blood supply can easily be calculated. The tool is prepared for vector-borne viral infections. The virus specific data of WNV, Chikungunya and Zika virus is already included in the tool.

A training (webinar) for all EBA and EBA EID Monitor members was organised on 3 May 2019. The manual and spreadsheet of the tool can be found on the EBA website[1] .

Survey concerning archive samples

Finland prepared a survey regarding the policy for collection and storing of archive samples from blood donations. Investigation of archive samples in a lookback situation is hardly needed since the introduction of (ID) NAT screening. A total of 15 answers from 14 European countries and 9 answers outside Europe (Australia (1), Canada (1) and USA (7)) were received. Two countries did not perform NAT testing, but one of them (Malta) introduced NAT screening later during the year. For most countries it is not a regulatory requirement to have a storage of archive samples. Archive samples are collected in 86% of European countries and stored for at least two years (up to 30 years or indefinitely).

Arguments to maintain archive samples besides those for (sero)converted donors comprise specific research questions relating to the purpose of maintenance of blood safety regarding emerging infectious diseases such as hepatitis E or Usutu virus, and for other transfusion transmitted infections tested by serology only, such as malaria or Chagas disease or untested pathogens. The cost effectiveness of maintenance of an archive, the local epidemiology of pathogens and the ability and availability for thorough evaluation of donor's post donation are also important considerations.

[1]https://europeanbloodalliance.eu/a-european-perspective-on-emerging-infections-and-blood-safety/

Pre-exposure prophylaxis (PrEP) for HIV

Blood banks are concerned about the increasing availability of pre-exposure prophylaxis (PrEP) in the prevention of HIV infection. The recent developments of PrEP were monitored closely. Because PrEP is very effective, PrEP is more widely used and encouraged by the Health authorities. Breakthrough infections under PrEP, if compliant with usage, are rare. PrEP in HIV infected persons can result in a late or even absent seroconversion and viral suppression.

HIV infection in donors using PrEP, post-exposure prophylaxis (PEP) or on antiretroviral treatment (ART) to control a current HIV infection (where usage is not disclosed) can be missed in donation screening, even by ID NAT. Blood products derived from these donors may still be infectious. Due to reduced use of protective measures such as condoms, there is an increased risk for other sexually transmitted infections.

Research reveals that antiretroviral drugs are found in blood donors; however, the question as to how to exclude donors using antiretroviral (therapeutic) drugs has not been established. This can be done by donor education and encouragement to them to self-defer, listing the names of antiretroviral drugs on the medication list and/or asking a specific question for antiretroviral drugs. In July 2019 a survey was launched among EID Monitor members to get a better overall view of interventions and considerations by blood banks.

In a questionnaire dealing with PrEP, 19 answers from 17 countries were received. The identified risk groups using PrEP are:

1) Medium to high risk MSM and transgenders (main group);

2) Heterosexuals with high risk, as having a HIV infected partner;

3) Intravenous drug users;

4) Sex workers;

5) multiple sexual partners. There is no consensus as to the best practice for identification of PrEP in blood donors.

Most countries (16 of the 17) do ask specifically about MSM contacts. The appropriate deferral period is not well known, because the seroconversion time after PrEP is not established. The development of new PrEP (depot) medication could result in even more uncertainty. The deferral period is mainly bound to the MSM deferral period or other high risks for HIV. The range of deferral period varies from three months to life-time restriction. For reasons other than high risk sexual behaviour, an individual risk assessment could be considered to decide on deferral or permitting donation. The greatest concern, however, is the risk perception and compliance for declaring PrEP medication.

B Benchmarking Working Group (BMG)

The EBA Benchmarking Working Group has the following as objectives:

1. To create and maintain an EBA Scorecard of key performance measures and definitions, identifying good practices by EBA members across the blood supply chain, in the areas of efficiency, sufficiency and safety.

2. To utilise the data collected to support operational development, and performance improvement in participating EBA member services.

3. To hold regular symposia and workshops designed to tease out the key success factors that underpin the activities of the best performers in each area.

4. To access expert opinion in areas like LEAN from both within and outside the blood industry.

5. To adopt training in LEAN as a primary objective of the Benchmarking Group, and to support the LEAN training of staff in participating EBA members, with a view to encouraging them to join the EBA Flying Squad.

6. To arrange "Flying Squad" visits to requesting EBA members, to help them implement the BMG's recommendations for performance improvement.

7. To extend the benchmarking brief to cells and tissues, and to support the EBA Tissues and Cells Working Group.

8. To utilise the informal network of Scorecard representatives to share and grow knowledge between EBA members;

9. To align EBA BMG activities with those of other benchmarking networks (APBN, ABO) with a view to growing the knowledge base further, and identifying good practices outside Europe.

10. To organise regular consultations with EBA Board Members on BMG outcomes, and present conclusions at Board Meetings

11. To professionalise communications to EBA members, to help members to implement performance improvement, with the support of the EBA Secretariat.

1. Benchmarking exercise

Yearly, the EBA Benchmarking working group circulates a scorecard for EBA Members to fill in. Some notable outcomes of 2019 survey were as follows:

18 countries (vs 20 last year)

Survey respondents serve a population of c286 million (c56% of total EU)

9.0 million red cell issues = -1.1% reduction. Previous year was -2.0%

Million platelet issues = 2.2% increase. Previous year was -0.3%

"Unlike last year, with declines in most blood services, this year issues of red cells increased for seven blood services and decreased for eleven".

2. Benchmarking Workshops

2.1. Spring workshop on 0neg management

In May 2019, in Nice, France, the Benchmarking WG organised a workshop on 0neg management. The event was hosted by EFS and was attended by 35 participants from 12 different blood establishment organizations / countries.

In preparation for the workshop, the Benchmarking WG circulated a survey and the results were presented at the workshop. The agenda comprised the following presentations:

1. 0neg Donor management: Examples of successful recruitment and retention strategies to increase the O neg donor base

2. Use of O neg in mass casualty incidents: how to prepare for them and learn from experiences (lessons learned from attacks in Nice)

3. O neg Demand Management: Where does the O neg blood go in hospitals? What can we learn from that and how we can support hospitals for a more appropriate use of O neg valuable units?

4. Increasing demand for O neg from new trends: How changes in population and hospitals landscape are further increasing the demand for O neg and how blood services are managing the impact on those trends?

Following the sharing of experiences of different Blood Establishment across Europe, a number of lessons were learned, summarised below:

1. Low percentage 0neg erythrocytes are transfused to 0neg patients: high 0neg usage might be a stock management issue, instead of a real demand issue.

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2. Partner with hospitals to reduce 0neg usage:

• Inform hospitals about their performance on 0neg usage and raise their awareness

• Inform hospitals on costs of expiry and raise their awareness.

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3. 0neg usage to cover Ro: issue in France and UK. Future risk for other countries.

• How to recruit Ro donors: cultural barriers, multi-cultural staff, lower Hb for some ethnic groups, use role models, ambassadors from targeted communities, genotyping to select Ro donors

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4. 0neg donor recruitment/retainment- the workshop conclusions highlighted the important role of

• Community influencers, social media by ambassadors, donor-recruits-donor

• Donation sessions at university: test blood type in the morning and ask (0neg) donors to donate on the same day in the afternoon

• The recruitment of blood donors amongst stem cell donors

• An appointment system with favourable slots open for 0neg donors and the use of big data to analyse preference

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5. Mass attack

• Number of units to be transfused is low compared to the available stock; so stock levels are not the issue

• Be prepared for hectic uncontrolled situation

• Risk of losing full traceability of blood products

• Regularly check emergency plan. Check correctness of telephone numbers and email accounts.

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6. 0neg platelet usage varies because of differences in transfusion guidelines

• Harmonize guidelines on platelet transfusion policy

• ABO identical is not needed

• Some countries have very high demand for Aneg

2.2. Autumn workshop on inventory management

In October 2019 in Dublin, Ireland, the Benchmarking WG organised a second workshop on inventory management. The workshop was hosted by the Irish Blood Transfusion Service (IBTS) and was attended by 40 European Supply Chain / Logistics / Operation / Medical officers and experts from 15 countries.

The workshop programme comprised thirteen presentation over three main sessions:

1. Stock Management: How blood services are managing the ever changing and fluctuating demand trends for blood and blood components

2. Stock Management initiatives with blood service partners

3. How some countries face uniquely different stock management challenges?

The WG presented the results of a pre-Workshop questionnaire (answered by 14 Countries in total based on 5 main stock control themes, 42 questions).

Following the presentations, one of the lessons learned was that the operating environment and funding model of all the organisations varied greatly. This had a direct impact on two issues in particular: information technology investment, and visibility of stock across the entire blood component user network. It was also observed that the information technology systems and access and vision of hospital stock levels varied markedly between blood establishments and countries: some countries have full visibility and others absolutely none.

There was a generally held view that undoubtedly there are great opportunities for all blood establishments to learn from each other. A summary report on the Workshop was produced by the IBTS hosts and it was delivered to the BMG and to EBA Office, available for EBA Members on EBAse.

C Data Privacy Officers (DPO) working group: "the right to be forgotten"

The EBA DPO/Privacy working group was formed in early 2018 in response to the new Europe wide data protection legislation, the General Data Protection Regulation (GDPR) EU 679/2016 coming into force in May of that year. One of the aims of the group is to conduct research, provide opinions, guidance, and ultimately, position papers in relation to data protection topics insofar as they apply to blood transfusion.

In June 2019, the group released a paper on the "right to be forgotten". The aim of the paper is to provide guidance on how to interpret this right in the blood transfusion context, under data protection legislation. Specifically, the paper relates to blood components, tissues and cells, including from cord blood and bone marrow. While organs are outside the remit of the group and the EBA, it is acknowledged that there are many points of similarity both in terms of the governing legislation and its objectives; for example, the question of traceability. Much of the guidance provided here could, therefore, be of some use in that context also.

The group proposed a joint approach on a number of topics related to the right to be forgotten, in particular, where a donor cannot be forgotten (start of donor journey); where a donor can be forgotten (end of donor interaction with BE); the impact of national legislation, and the limitations of the analysis.

The paper is posted on EBA website (open access): https://europeanbloodalliance.eu/activities/working-groups

D Medical devices ad-hoc working group

Starting in May 2019, the EBA secretariat conducted, with four of its members, a reflection on whether laboratory information systems (LIMS) and blood establishment computer systems (BECS) could be considered Medical Devices or/and In Vitro Devices, under the new EU legislation. After consulting with the European Commission, MedTech, the trade association representing manufacturers, and on reading the EC's guidance, we concluded that the qualification as MD or IVD is governed by the "medical intent/purpose" of the device or piece of device.

The decision on such qualification is made on a case-by-case basis.

Several conditions are to be met to be a MD:

1. Intended purpose of the device **as described by the manufacturer**

2. Software that is processing, analysing, creating or modifying medical information may be qualified as MD if the creation or modification of that information is **for a medical purpose**

3. An accessory of a MD falls under the scope of the MD regulation – a software MD may be intended to be used alone or in combination with another device

4. A software that is driving or influencing the use of a MD is covered by the MD regulation, either as part/component of a device, or as an accessory for a MD

5. If the software performs an action on data, or performs an action beyond storage, archival, communication, simple search then it may be a MD software – **if the action is for the benefit of an individual patient**

Based on the above, and the information provided in the European Commission Guidelines on the classification of MDs, and on "modules" part of a MD, the group could conclude that most LIMS and BECS would not qualify as MD software in themselves.

The EC's guidelines are posted on EBA's website [insert path]

E DEHP working group

Formed in 2018, the EBA working group on DEHP tasks are to follow and respond to changes in European legislation on the use of DEHP (Bis(2-ethylhexyl) phthalate (di-2-ethylhexyl phthalate, diethylhexyl phthalate) a plasticiser found in blood collecting systems since 1955. Following a modification of the REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances) regulation, after 2023 the use of DEHP will no longer be the object of an exemption. To address this major change in the transfusion sector, the EBA working group on DEHP did the following:

• Answered a consultation by SCHEER, the EU Scientific Committee on Health, Environmental and Emerging Risks on "Preliminary guidelines on benefit-risk assessment of phthalates" in April. The EBA shared several comments, one of which highlighted the fact that donors' exposition to DEHP by means of aphaeresis was not included in the guideline. The EBA comments were adopted in the final SCHEER guidelines.

• Started to collaborate with manufacturers to help with the validation of new DEHP-free blood collecting systems; this validation included the whole transfusion chain, including manufacturers, blood establishments and clinical application.

• At the meeting of the EU competent authorities and DG SANTE on 19 June 2019, presented its perspective and opinion on the transition to DEHP-free blood collecting system. EBA supported the transition to DEHP-free blood collecting system and indicated the steps needed to transfer to DEHP-free blood and maintain the safety and continuity of blood supply. EBA wrote a position paper regarding the transition to DEHP-free blood collecting systems that will be used in further collaboration with stakeholders such as manufacturers, clinical users and the European Commission.

RESEARCH GRANTS

Every year, the EBA allocates financial support for EBA members' research projects in the form of a maximum grant of 50,000 Euro. Members send applications for a research grant and the EBA scientific committee evaluates them in a collaborative manner, before awarding the funds.

In 2019 two research projects were ongoing:

Grantee: Belgian Red Cross-Flanders, Centre for Evidence-Based Practice (CEBaP)

• **Title:** Towards evidence-based Patient Blood Management: systematic reviews to scientifically underpin the management of preoperative anaemia.

• **Project period:** 1 January 2019- 31 January 2021.

• **Project description:** The aim of this project is to evaluate and publish the current evidence regarding the safety, effectiveness and cost-effectiveness of using ESA and/or iron supplementation in patients undergoing a planned major orthopaedic or cardiac surgery. The evidence-based conclusions of this project will inform researchers, medical personnel and patients whether the use of ESAs and/or iron therapy is safe and cost-effective in a preoperative setting. The publications will also serve as a supportive evidence-based source to the recommendations that were formulated during the first International Consensus Conference on Patient Blood Management (ICC-PBM, 24-25 April 2018, Frankfurt, Germany).

• **Project progress in 2019:**

Methods

In close collaboration with an external expert panel (four content experts and one methodologist) four PICO questions were developed: (defining Population, Intervention, Comparator, Outcomes) regarding the effectiveness of iron monotherapy (PICO 1); the effectiveness of ESA+iron therapy (PICO 2); the adverse events of iron and/or ESA therapy (PICO 3); and the cost-effectiveness of iron and/or ESA therapy (PICO 4); all in patients with preoperative anaemia undergoing elective surgery. Systematic reviews to answer these four PICO questions will be conducted as follows:

1) screening potentially relevant publications, protocols and trial registries from six databases (PubMed, Embase, Cochrane Library, Transfusion Evidence Library, Wed of Science and Centre for Reviews and Dissemination database) and two registers (ClinicalTrials.Gov and International Clinical Trials Registry Platform), by two reviewers independently (February 2019 – June 2019),

2) extracting the characteristics concerning study design, study population, (co-)interventions versus comparison and the outcomes of interest (July 2019 – September 2019),

3) extracting information of the effect estimates and conducting a narrative- or meta-synthesis (for each outcome per PICO question) in addition to a quality assessment of the included studies (by the GRADE approach) (October 2019 – December 2019),

4) discuss the key results (synthesis) with the expert panel, formulate conclusions and prepare and publish four peer-reviewed publications in a scientific journal (January 2020 – December 2020).

Belgian Red Cross

Grantee: Finnish Red Cross Blood Service

• **Title:** Prediction and impact of personalised donation intervals.

• **Project period:** 1 July 2019 – 1 July 2020

• **Project description:**

The deferral of donors due to low haemoglobin (Hb) is demotivating to donors, can be a sign of developing anaemia, and incurs costs for blood establishments. The aim of this project is to use available iron status, blood count, whole genome genotyping, donation visit and demographic data to assess the predictive value of such features with standard machine learning and deep learning tools and to build predictors for donor recuperation from donation. Furthermore, with access to a wealth of historical donation data and current operational blood establishment data, we can simulate the financial and blood supply effects of implementing such predictors.

• **Project progress in 2019:**

The project was launched on the 10th of May 2019 with a collaborative visit of Prof Emanuele Di Angelantonio and his team from NHS Blood and Transplant (NHSBT) to the Finnish Red Cross Blood Service to discuss common modelling approaches and details of available data set.

Based on the data available at FRCBS and at NHSBT it was concluded that the team at NHSBT will concentrate on logistic prediction of deferral while FRCBS aims for probabilistic prediction of days to next donation event. Further collaboration meetings were held in July and October.

During 2019, a state-of-the-art probabilistic mixed model for prediction for Hb-value of donor when she returns for the next donation has been implemented at FRCBS. The model forms the bases of predicting the likelihood of deferral if a donor returns after some number of days. The model is based purely on donation history data i.e. donation visit times, finger prick Hb-measurements, age and sex of donor. The model predicts Hb well above the deferral limits; however, below the deferral limit the model's performance is not sufficient for practical implementation.

During 2020, we will add further data i.e. ferritin, blood count, genotyping, weight, height and smoking and estimate their capability to improve the model. Furthermore, we will release the actual code and a container i.e. a self-standing software package that contains all the necessary elements to run the prediction models developed in the project. To estimate the economic effects of prediction of personalised donation intervals the focus is on estimating how a good model would be needed in order to create beneficial economic, supply or health benefits. The major question of the project, therefore, is whether the additional data will improve modelling to a level that would give practical benefits and, if not, how we can estimate how far we are from that kind of a level.

Finnish Red Cross
Blood Service

Awarded grant
2019 – 2020 implementation

Grantee: Sanquin

• **Title:** Ferritin measurement IN Donors – donor Population LongitUdinal Study: FIND +

• **Project period:** 1 January 2020 – 1 January 2021

• **Project description:**

Frequent whole blood donors often have low iron stores, potentially leading to donor deferral and iron deficiency-related symptoms. International consensus on an appropriate policy for iron monitoring is lacking. Detailed information on individual donor ferritin trajectories may help to tailor iron monitoring and deferral strategies.

To be able to investigate ferritin trajectories, ferritin levels of 300 new whole blood donors will be measured from stored (lookback) samples from each donation over a two-year period. Donors will be included if stored samples from 2-10 donations are available.

Variation in ferritin level trajectories will be investigated using a growth mixture model which assumes that each donor belongs to one of several subgroups with specific longitudinal traits. These subgroups include donors with similar ferritin level trajectories.

Furthermore, we will investigate differences in demographic characteristics of donors with different ferritin trajectories to be able to identify whole blood donors who have a higher risk of developing iron deficiency. Subgroup analyses will be performed to investigate differences in ferritin level trajectories between male and female donors.

The combination of demographic characteristics of donors and ferritin levels at pre-donation screening or the first whole blood donation can be used to predict ferritin trajectories, which may be updated by newly measured ferritin levels from subsequent whole blood donations. The association between different ferritin trajectories and the probability of low-haemoglobin deferral will be investigated using Kaplan-Meier analysis by comparing the different ferritin trajectories with respect to the number of donations until the first low-haemoglobin deferral. This is of practical importance as this will help blood collection centres identify donors with fast declining ferritin and haemoglobin levels and tailor their donation intervals to prevent iron deficiency and donor deferral.

The probability that a donor belongs to a particular ferritin trajectory will increase as new information on ferritin levels becomes available, resulting in better predictions of a donor's ferritin trajectory. With the growth mixture model, we can calculate the likelihood that donors were assigned to the correct ferritin trajectory at each new ferritin measurement. This provides information on the number of ferritin measurements that should be performed at minimum to have a sufficiently high probability to assign donors to a ferritin trajectory. This information will provide guidance for decisions regarding donation intervals and the optimal ferritin measurement strategy.

Sanquin

EU legislation and advocacy

A EBA round-table discussion in the European Parliament

The first EBA European Parliament roundtable took place on 22nd of January in Brussels. The event was hosted by Ms. Grossetête, of the EPP party (European People's Party, Christian centrum-right) and Mr. Balas of the Socialists & Democrats and moderated by EBA's Executive Director, Catherine Hartmann.

The meeting was organised to raise awareness of the challenges of a sustainable blood supply in Europe and was aimed at EU health stakeholders, Members of European Parliament (MEP), European Commission representatives and Member States health attachés. More than 90 people attended the meeting. This number was larger than expected, demonstrating a strong interest in the subject matter, probably due in part to a desire to continue the reflection on the Blood Directives, after the European Commission concluded its consultation in 2018. A Commission report was expected at the end of December or beginning of January but was released in October. The EBA debate also served as a platform of discussion, to maintain the momentum after the EC evaluation of the Blood Directives.

Importance of voluntary non-remunerated donation: MEP Grossetête (pictured right) opened the meeting noting the importance of voluntary non-remunerated donation (VNRD -for all body parts), underlining the need to maintain solidarity among citizens. She recalled the European Parliament debates from the end of the 1990s when the first Blood Directives were adopted and explained that winning on the principle of VNRD was already difficult at the time and should not be challenged for the potential upcoming revision of the texts. The first session dealt with the question on whether blood is a "good". MEP Guillaume Balas, lawyer Samuel Valcke and Professor Tamara Hervey explained how conflicting European directives and articles, in particular, on medicinal products legislation led to putting the subject into the hands of the European Court of Justice. The legal options were explained to the roundtable attendees.

Rare blood Groups: The second session was on rare blood groups and on how to secure a robust donor base for these groups. Speakers Lisa Klinkenberg and Khadija Kerissi emphasized the need for donors of all heritages, to make up a good donor base that would be able to cater to the needs of the multicultural population. Based on research they had led, they presented techniques on how to attract new donors to match the needs and retain them.

Patient example: They were followed by Georgios Kakou Constantinou, a thalassemia patient who presented his own story of a person who needs regular blood transfusion. A great example and testimony of what being chronically ill with a rare disease means, Mr Constantinou helped understand the importance of a constant and safe supply of red blood cells, which he needs to keep him alive.

Voluntary Unpaid Donations: The last session was on Voluntary Unpaid Donations. Alice Simonetti, from FIODs praised the solidarity aspects of the lifesaving gift of the voluntary, anonymous and non-remunerated donors. Cees Smit, a lifelong plasma products user noted that, thanks to medical progress, haemophilia patients now have a life expectancy similar to that of non-patients. He urged governments to increase domestic plasma collections as Europe is now dependent on US paid plasma and he reminded the gathering as to how in the past this has led to unfortunate transfusion transmitted infections.

Summary: Philippe Vandekerckhove closed the meeting emphasizing the importance of donors for the whole supply chain of blood and blood products. The donors, he noted, are the least elastic economic part of that chain, as they cannot be "turned on and off" readily. Therefore, it is important he noted, not to scale up or down collections at the spur of the moment, but to ensure solid planning and policy for blood supply and the support of the donors.

B Meetings with DG SANTE

DG SANTE is the European Commission Health and Food safety Directorate. A new Director General, Ms Anne Bucher (French), was nominated at its helm at the end of 2018.

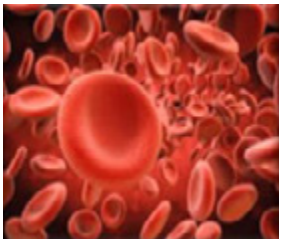
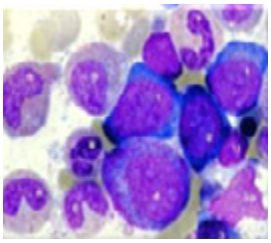
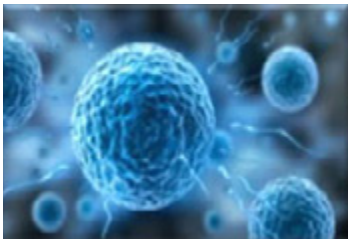
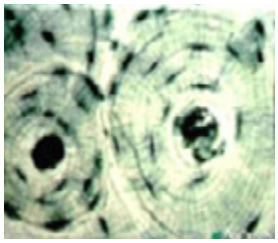
On the 17th of January, Philippe Vandekerckhove EBA President and Catherine Hartmann met with Ms Bucher as an introductory meeting, since she was new to the field (health in general and blood in particular). EBA had requested this meeting and it was the first health association Ms. Bucher was meeting in her new role. Philippe and Catherine briefly presented EBA together with the main issues blood sector is facing, and the shortfalls of the EU blood Directives, supporting its stance by graphs and figures shared by Philippe. He highlighted the challenges of self-sufficiency, of VNRD and the internal market rules, providing examples from e.g. Belgium. He explained the difference use of plasma rules by both blood and medicinal products legislations. She carefully listened, asked some questions in particular in relation with un-paid donation, donor bases, considering blood as a service, and on what the EU Directives have positively brought to the sector. Ms. Bucher seemed to have appreciated our discussion and understood the challenges.

EBA also presented the "Impact of DEHP ban on blood collecting systems" and the "EBA research priorities" at a meeting of the Competent Authorities and the European Commission in June 2019, in Brussels.

EBA also spoke at the EU stakeholders conference on the evaluation of the EU legislation on blood, tissues and cells in October (see below).

C DG SANTE conference on the evaluation of the BTC evaluation

The European Commission concluded its evaluation of the BTC directives (started in 2017) with a stakeholders' conference held in Brussels on the 28th of October. It followed the publication of a report published on its website. The main elements of the report were presented at the start of the conference and were opening each of the 5 sessions. The event was held to collect views and suggestions for future legislation concerning the BTC field.

The main key messages from the conference were:

Panel 1

"The challenge of keeping legislation up-to-date in a dynamic sector with changing risks"

The President of EBA Philippe Vandekerckhove was the first panellist and highlighted the following five points:

The Directives are not adapted to the present state of the science and knowledge – as the evaluation results asserted

• The technical aspects of the Directives should be removed from future texts and replaced by a binding reference to the Council of Europe Guide to preparation, use and quality assurance of blood component (the Guide)

• The scope of future legislation should continue including collection and testing of human blood and blood components, whatever their intended purpose, but should also include products that were not regulated at the time of the Directives, such as serum eye-drops platelet rich plasma

• Public health must continue being the legal basis of future blood and blood components legislation; there should not be a parallel system for plasma

• The principle of VNRD should be reinforced

This was supported by other panellists from the European Association for Tissue and Cell Banking, the European Society for Blood and Marrow Transplant and the European Eye Bank Association who underlined among others the following:

• We should not over-regulate – a position which is in line with Philippe's point 2

• We need to standardise donor criteria across all Member States

• We need to recognise the principle of sustainability as the basis of public health systems

During the conversation that followed, participants mentioned the lack of robust data, and asserted the need for more evidence of the quality of ATMPs, for further collaboration across the field, and the importance of risk assessments.

Philippe made an additional comment during the conversation on the level of plasma collected in the past in the EU and the reasons why we are now so dependent on US plasma, as an unintended consequence of internal market rules.

View Panel one video: https://webcast.ec.europa.eu/conference-on-the-evaluation-of-the-eu-legislation-on-blood-tissues-and-cells-panel-1

Panel 2

"The challenge of ensuring that all EU citizens affected by the BTC chain are protected

(This panel did not only focus on donors but also on offspring from donated gametes)

The session started with a presentation from Alice Simonetti from FIODS who highlighted the importance of education, VNRD, and sustainability of the systems. Like EBA, FIODS advocates for national long-term strategies for blood and blood components donation, as a public ethical and strategic service.

The European Society for Human Reproduction and Embryology then spoke about assisted reproduction and the need to protect the donor and offsprings, including when there is cross-border donations.

The European Plasma Association (EPA) followed underlining 3 main priorities: patient access to PDMPs, donor protection and the need for future policy to be based on scientific basis and data.

Panel 3

"The Challenge of providing appropriate and robust oversight"

Experts from national authorities, EDQM and BTC establishments raised questions regarding the appropriateness and robustness of oversight and inspection, and the lack of harmonisation across the EU. They suggested a system similar to that implemented with the EMA (mutual inspections).

EBA was represented in this panel through its participation in the CoReSoHO (Common Representation of Substances of Human Origin) and highlighted the need for legislation to support better classification (T&C vs medicines) via the following:

- Incorporate expert technical input on classification decisions
- Include assessment of impact on access to care and self-sufficiency
- Improve inspections
- Increase mutual recognition
- Harmonise donor criteria

Many highlighted the need to move to risk-based inspection planning and the value of inter-Member State work on oversight, inspection and vigilance.

Panel 4

"The Challenge of keeping pace with innovation in BTC for patient benefit"

One of the key points was some lack of clarity at « borderlines » with other frameworks for BTC that are used to manufacture medicinal products or medical devices.

It was recommended that the BTC directives should support the CAs by defining criteria for the new BTC products compared to non-BTC products (ATMP, combined devices) and better consistency of classification between Member States and internationally. Legislation needs to be flexible enough to accommodate rapidly with evolving science and technology.

Panel 5:

"The challenge of achieving sufficiency and a sustainable supply to meet patient need"

This panel identified the main problem: reliance on US for sufficient plasma for the manufacture of plasma-derived medicinal products. Johann Prevot, representing the patient's groups IPOPI/PLUS made clear that patients want more products and better access to the latter. He highlighted the following:

"Development of guidelines, policy & legislation should be based on FACTS & SCIENCE & experience (not ideology)", underlining that this group does not believe in the absence of payment of plasma donors. Johann Prevost added that we should "Encourage the co-existence of public & private plasma collection to face the needed investments and benefit from existent knowledge and experience". He concluded his presentation by stating that we should be ready to equally encourage compensated plasma donations as VU blood and plasma donations.

PPTA said the same about compensation: the need to collect more plasma and recommended that dedicated plasma collection (plasmapheresis) programmes and outreach campaigns towards plasma donors be established in ALL EU Member States.

Following the conference, EBA shared a press release with its members and stakeholders and thanked the DG SANTE SoHO team for the event.

More information on the DG SANTE's website: https://ec.europa.eu/health/blood_tissues_organs/events/ev_20191028_en

D EBA advocacy toolbox

The EBA secretariat made available to EBA members though its intranet, EBAse, an Advocacy Toolbox, including template documents, explanations about EU institutions and the legislative process, lists of contacts, such as Members of the European Parliament (MEPs) per country, Health Attachés and references to the EU set of legal texts on Blood. This is accessible to all members and serves as key resource for the EBA EU Directives working group.

E DG Research consultation on future priorities

European Commission Directorate General for Research consulted stakeholders on the priorities for research (any field) over the next seven years, as the EU is drafting its next multi-annual financial framework. The European Parliament and the Council (the co-legislators) have provisionally agreed on the Horizon Europe -- the name of the research programme -- legislative package. Based on the agreement, a Strategic Plan will put forward the "targeted impacts for the investment in research and innovation" and the priorities for the first four years of implementation of Horizon Europe.

EBA answered the consultation which was divided into specific targets and subjects with the following priorities, in relation with the set targets:

- Horizon Europe should support research on the importance of blood transfusion in the case of haemorrhage at birth, in order to reduce maternal mortality.

- To help protect blood donors' health and enhance knowledge on potential health effect of blood donations, a European register for donor vigilance should be supported by Horizon Europe, with a view to allowing long-term follow up of donors and the collection and use of big data.

- With European chemical and medical devices legislation making it compulsory to halt the use of endocrine disruptors, it will be essential for Horizon Europe to facilitate research in alternatives to DEHP.

- Horizon Europe will need to mobilise researchers to fully investigate the impact of climate change on health and on infectious diseases since climate change is facilitating the spread of insects as well as insect borne diseases in temperate zones. Blood establishments monitor emerging infectious diseases (e.g. dengue, west Nile virus, zika) in blood, and hence participate in disease vigilance.

- Horizon Europe must coordinate further research in gene editing and the development of cost-effective new technologies and treatments, including those based on blood products, to critically improve outcomes of medical interventions and to provide modern high-quality healthcare. Medicinal products derived from human donations of blood and plasma play a critical role in health care and are fundamental for achieving universal health coverage. Safe blood contributes to saving millions of lives every year, dramatically improving the life expectancy and quality of life of patients suffering from a wide spectrum of inherited and acquired conditions such as cancer and blood diseases congenital (e.g. sickle cell) and life-threatening conditions (bleeding and immune diseases) and supporting complex medical and surgical procedures. Horizon Europe should favour research to promote evidence based intervention to reduce donor complications, to evaluate clinical efficacy of various transfusion strategies, and to promote linkage between donor, product and recipient data to improve therapeutic efficacy. Gene editing techniques are advancing and their application for human conditions requiring ongoing transfusion support is being actively trialled in a clinical setting (e.g. haemophilia b, beta thalassemia). This area of gene editing has potential to disrupt demand for blood and tissue products and would greatly benefit from international cooperation through the European research programme. Gene editing techniques have the potential to reduce transfusion requirements for some patient groups impacting red cell demand, and plasma for fractionation.

- To support "Ensuring access to innovative, sustainable and high-quality healthcare in the EU", Horizon Europe should commit funds for investigations on rare blood types and patients with rare blood types' access to treatment, as migration and movement of populations have brought into the EU patients with blood types rarely matched in the Caucasian population.

- To secure equitable access to healthcare, Horizon Europe must also invest in researching strategies and mechanisms to ensure blood and blood products (including labile blood components and plasma-derived medicinal products) availability, to achieve self-sufficiency in blood and blood products based on voluntary non-remunerated blood donation.

F Brexit stakeholders' group

EBA is part of an informal group of European health organisations reflecting on the potential impact of BREXIT both in the UK and in the EU27. Under the leadership of the NHS Confederation Brussels office and HOPE, the European association of hospitals, the group advocates for maintaining close links between the Union and the UK in the field of scientific research, access to healthcare by British citizens in the EU27 and vice-versa, smooth movement of goods and services in relation to health. In 2019, the EBA Executive Director attended three meetings of the group.

G GAPP Joint Action

The European Joint Action is aiming at facilitating the development of a common and optimal approach to assess and authorize preparation processes in blood and tissues establishments (BEs and TEs), adapting requirements as prescribed by Article 29 of Directive 2002/98/EC and Article 28 of Directive 2004/23/EC.

GAPP objectives are:

• Increasing consistency and efficacy of competent authority regulatory activities through harmonization of EU-level tools for authorization procedures for preparation processes at blood and tissues establishments.

• Developing a concept model for a European knowledge-sharing platform that can support competent authorities in the assessment and evaluation of novel preparation processes of products

• Developing an international network of experts that can support competent authorities in the assessment and evaluation of preparation processes of products, trained by the Joint Action

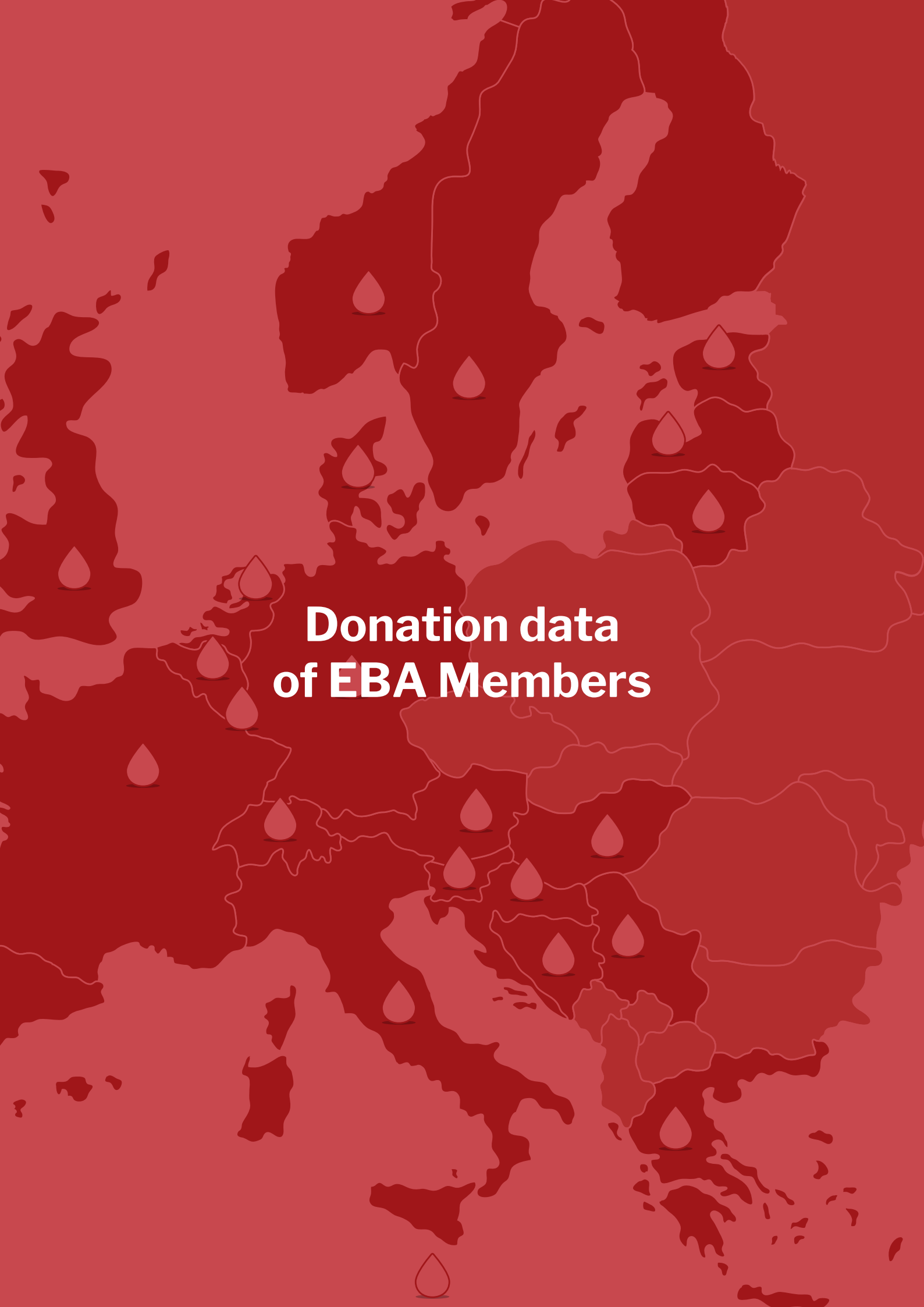
The Joint Action started in 2018 and will end in 2021. EBA is involved as a consulting partner in work package (WP) 7 (assessing the quality and safety of donor testing, microbial inactivation and sterilisation steps) and WP 8 (evaluation of existing clinical data). The EBA joined the meetings of WP7 and WP8 and contributed to the items that were related to blood transfusion. Various deliverables are drafted and the EBA will continue as a consulting partner to finalise the deliverables.

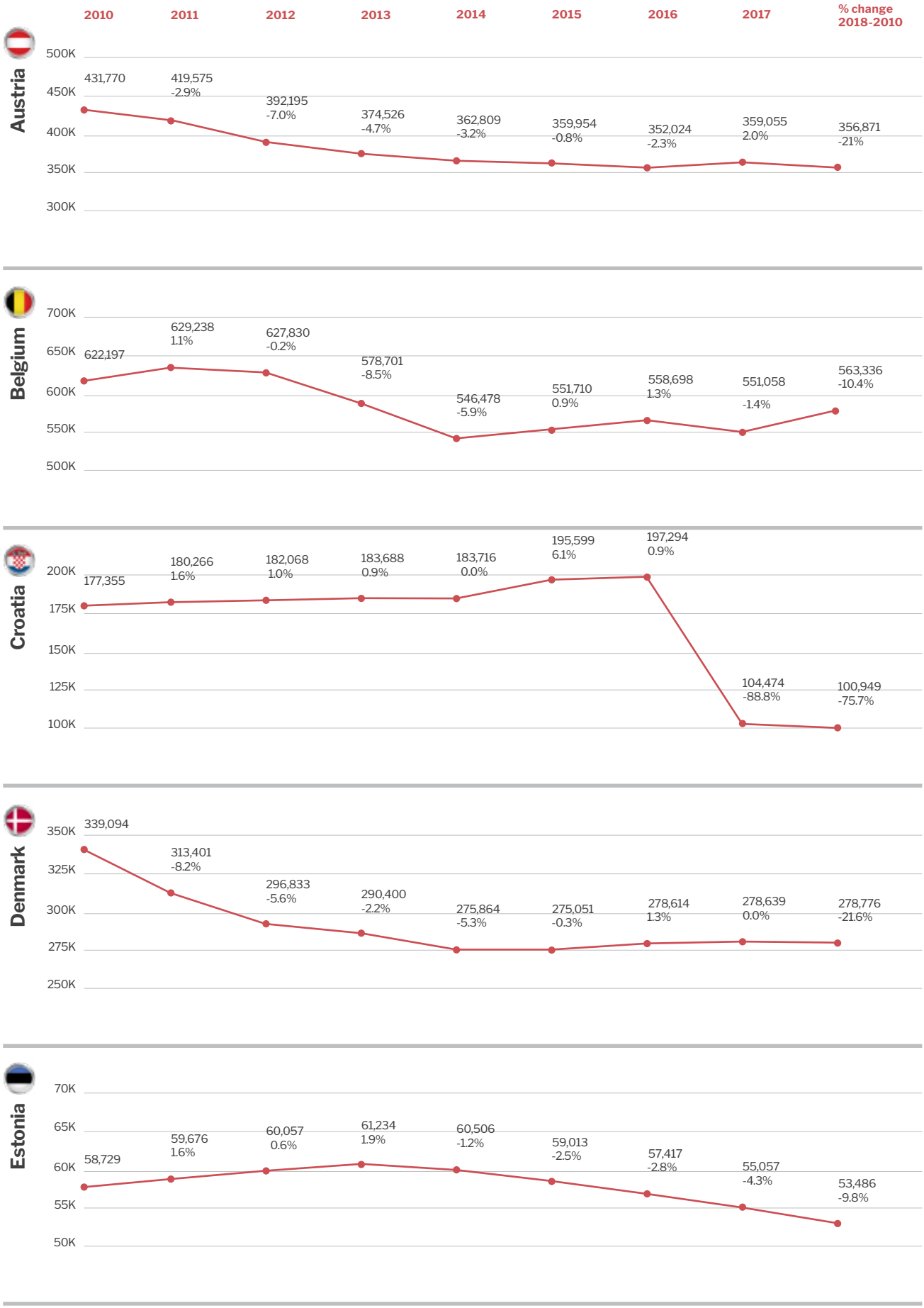
H Transpose Project

Main activities of TRANSPOSE in 2019

TRANSPOSE is a European Commission co-funded project, focusing on opportunities to further improve the collection of safe and sufficient SoHO as well as to ensure donor safety. The project started in 2017 and comprises seven work packages, including four substantive, interrelated work packages. The initiative involves many European partners, experts and healthcare professionals working in the transplantation and transfusion field, dedicated researchers, and key stakeholders such as the European Blood Alliance (also member of advisory board) and the International Federation of Blood Donor Organisations.

In 2019, the work package teams headed by Sanquin Blood Supply Foundation (the Netherlands), the Italian National Blood Centre (Italy), the Établissement Français du Sang (France), the University of Cambridge (United Kingdom), the Copenhagen University Hospital (Denmark) and the University of Hamburg (Germany) led the project to its final stage of completing the deliverables, including a thorough review of the current donor selection and donor protection practices in Europe; a novel risk assessment method for policy decision-making purposes; proposals of donor selection criteria which reflect both the evidence from the scientific literature; the opinion of professionals working in the SoHO field; and a standardized donor health questionnaire with SoHO specific modules.


Donation data
of EBA Members


2010
2011
2012
2013
2014
2015
2016
2017
% change 2018-2010
Austria
500K
450K
400K
350K
300K
431,770
419,575 -2.9%
392,195 -7.0%
374,526 -4.7%
362,809 -3.2%
359,954 -0.8%
352,024 -2.3%
359,055 2.0%
356,871 -21%
Belgium
700K
650K
600K
550K
500K
622,197
629,238 1.1%
627,830 -0.2%
578,701 -8.5%
546,478 -5.9%
551,710 0.9%
558,698 1.3%
551,058 -1.4%
563,336 -10.4%
Croatia
200K
175K
150K
125K
100K
177,355
180,266 1.6%
182,068 1.0%
183,688 0.9%
183,716 0.0%
195,599 6.1%
197,294 0.9%
104,474 -88.8%
100,949 -75.7%
Denmark
350K
325K
300K
275K
250K
339,094
313,401 -8.2%
296,833 -5.6%
290,400 -2.2%
275,864 -5.3%
275,051 -0.3%
278,614 1.3%
278,639 0.0%
278,776 -21.6%
Estonia
70K
65K
60K
55K
50K
58,729
59,676 1.6%
60,057 0.6%
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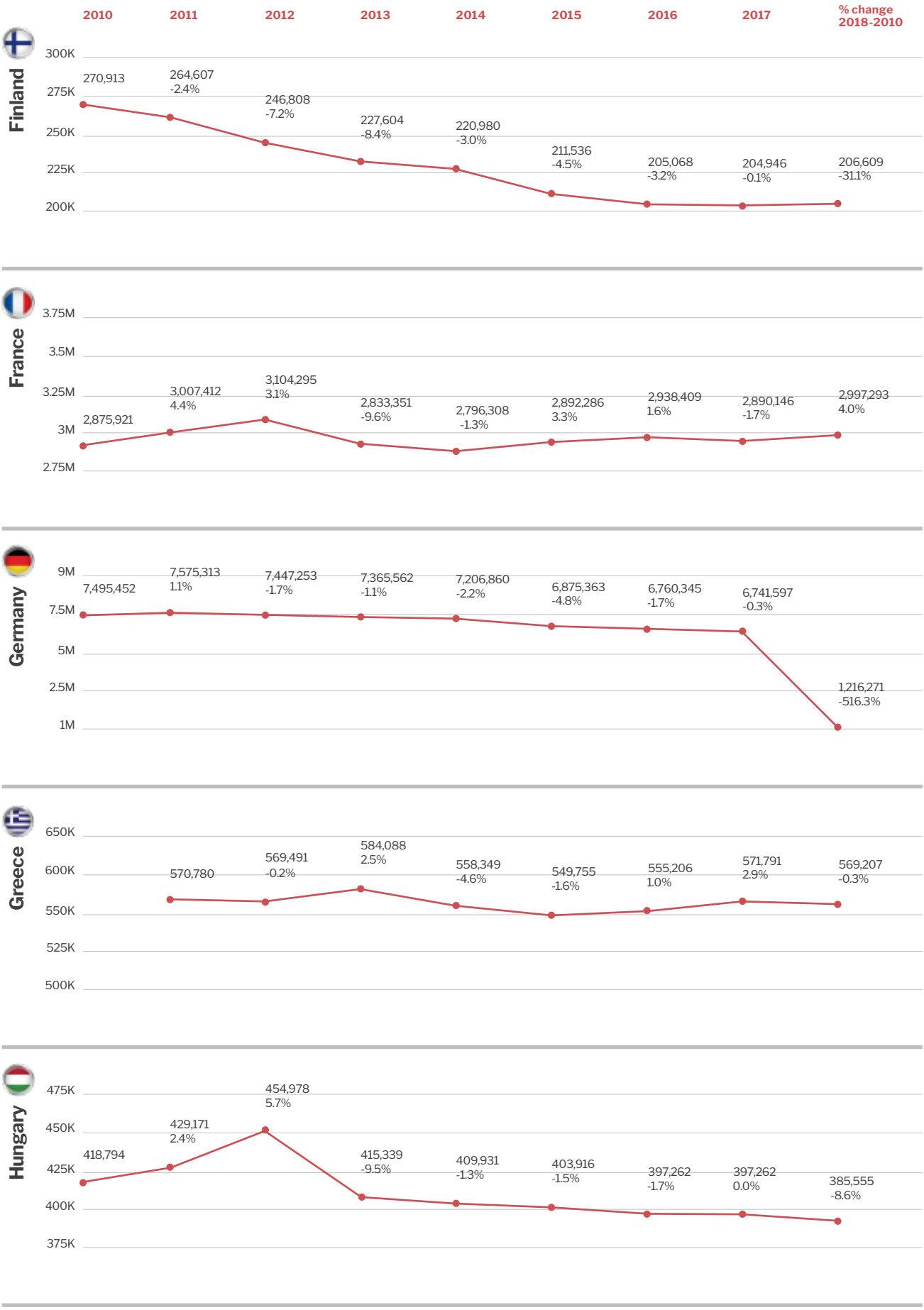
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% change 2018-2010
Finland
300K
275K
250K
225K
200K
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246,808 -7.2%
227,604 -8.4%
220,980 -3.0%
211,536 -4.5%
205,068 -3.2%
204,946 -0.1%
206,609 -31.1%
France
3.75M
3.5M
3.25M
3M
2.75M
2,875,921
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3,104,295 3.1%
2,833,351 -9.6%
2,796,308 -1.3%
2,892,286 3.3%
2,938,409 1.6%
2,890,146 -1.7%
2,997,293 4.0%
Germany
9M
7.5M
5M
2.5M
1M
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7,575,313 1.1%
7,447,253 -1.7%
7,365,562 -1.1%
7,206,860 -2.2%
6,875,363 -4.8%
6,760,345 -1.7%
6,741,597 -0.3%
1,216,271 -516.3%
Greece
650K
600K
550K
525K
500K
570,780
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558,349 -4.6%
549,755 -1.6%
555,206 1.0%
571,791 2.9%
569,207 -0.3%
Hungary
475K
450K
425K
400K
375K
418,794
429,171 2.4%
454,978 5.7%
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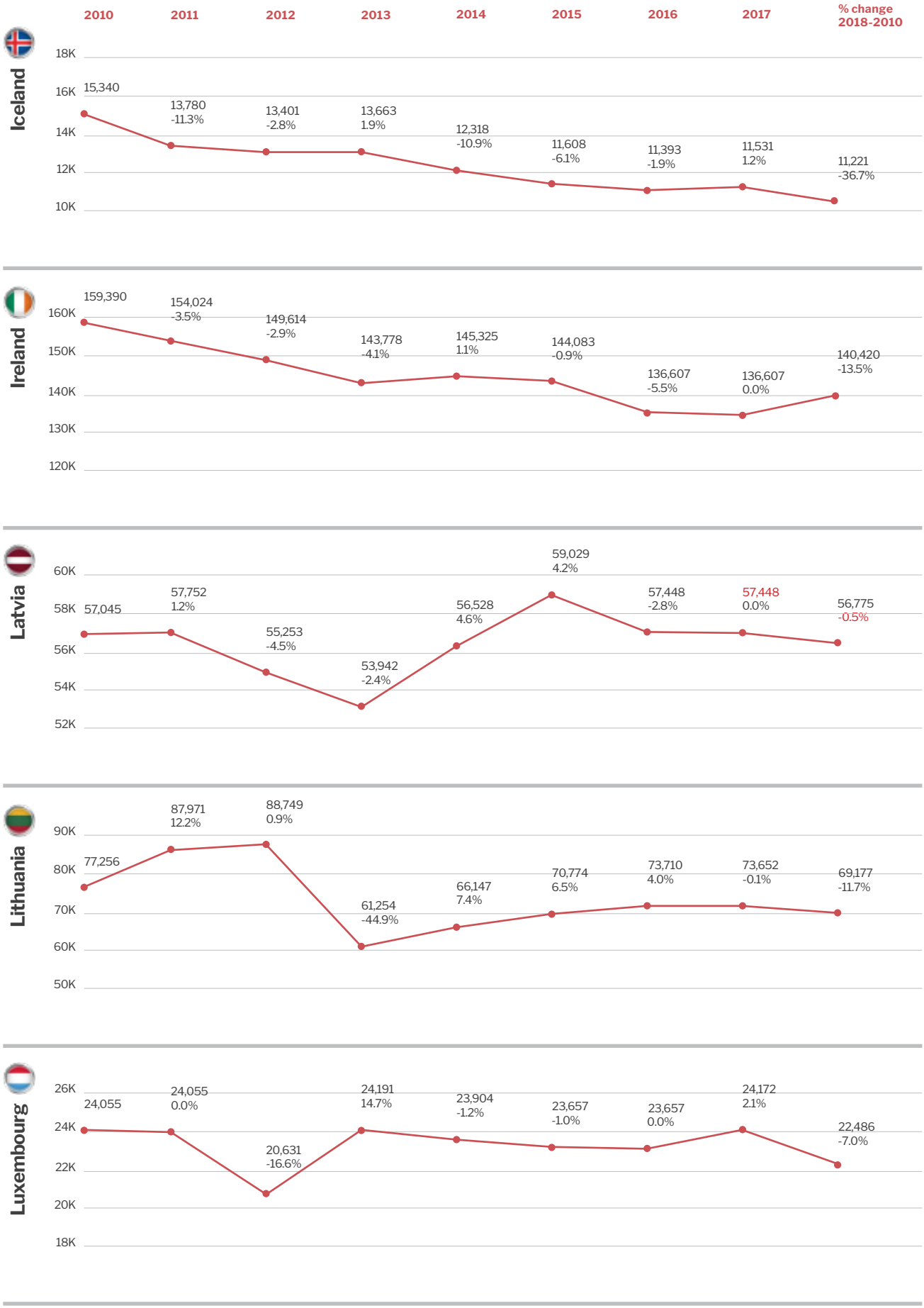
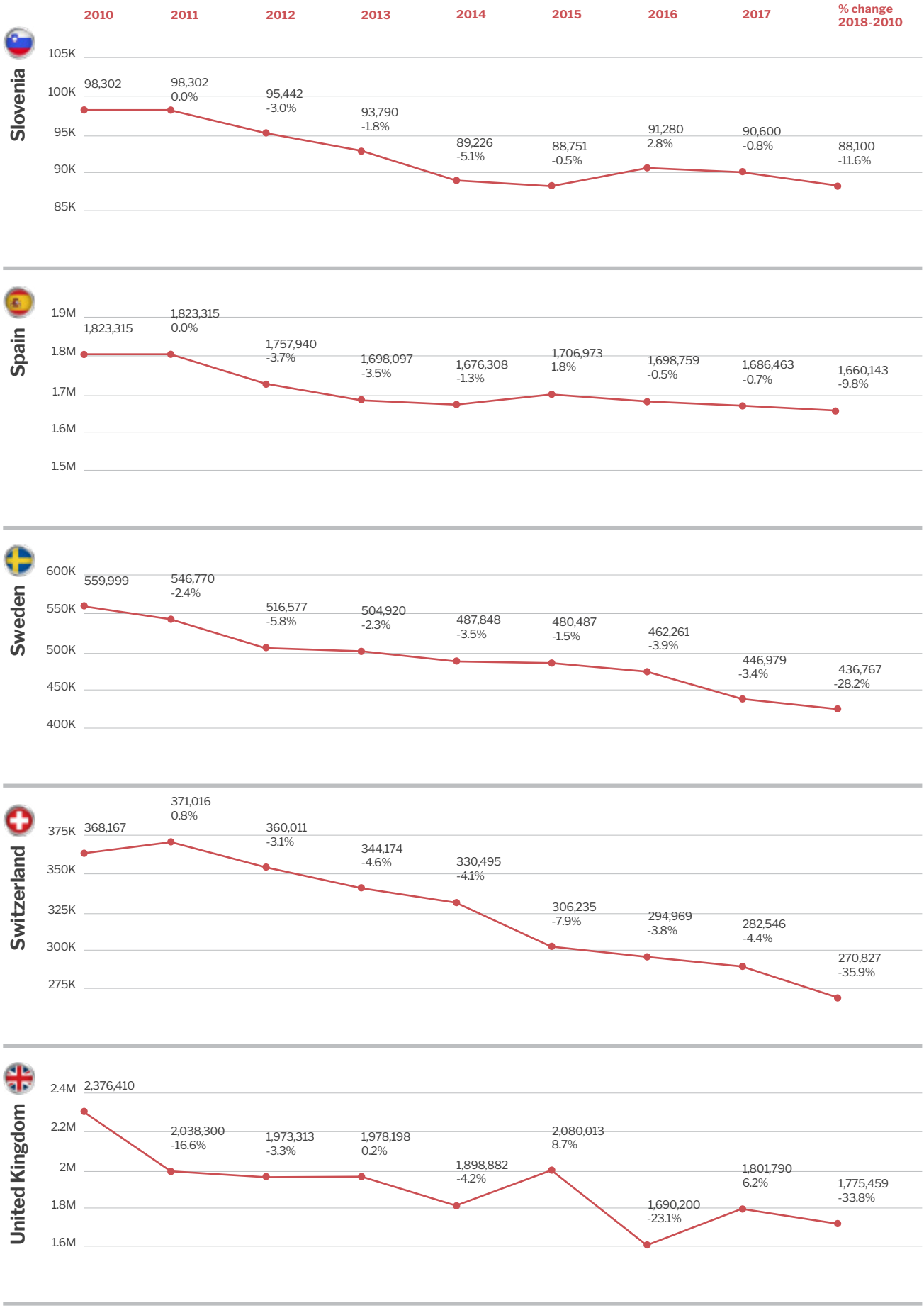
385,555 -8.6%



[1] Latvia - no data for 2017 received

[2] Serbia - %change 2015-2018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2016
2017
% change 2018-2010
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100K
95K
90K
85K
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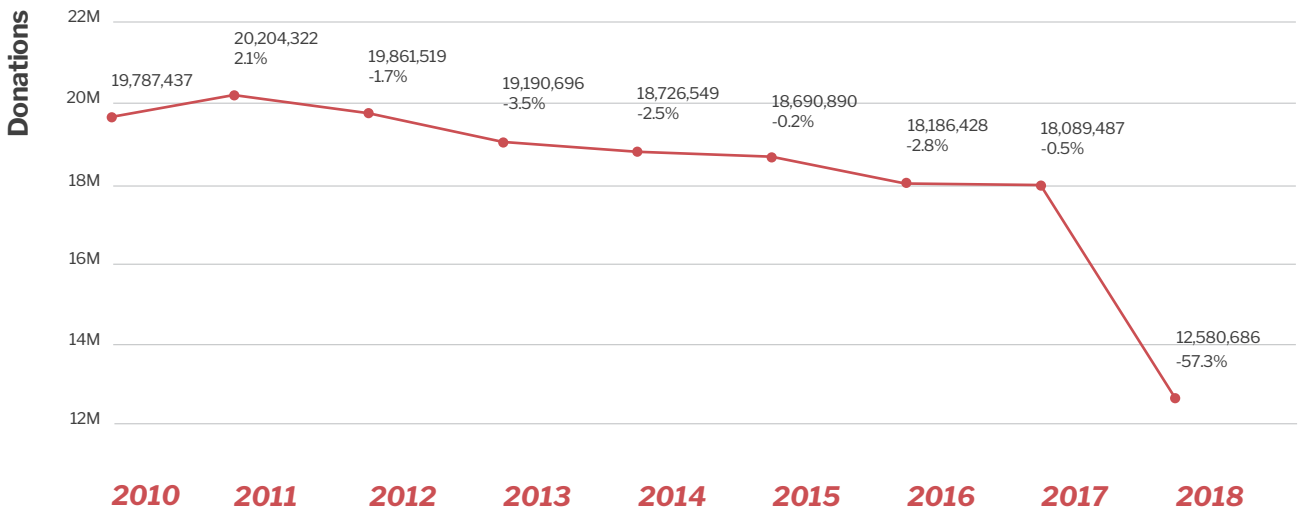
98,302 0.0%
95,442 -3.0%
93,790 -1.8%
89,226 -5.1%
88,751 -0.5%
91,280 2.8%
90,600 -0.8%
88,100 -11.6%
Spain
1.9M
1.8M
1.7M
1.6M
1.5M
1,823,315
1,823,315 0.0%
1,757,940 -3.7%
1,698,097 -3.5%
1,676,308 -1.3%
1,706,973 1.8%
1,698,759 -0.5%
1,686,463 -0.7%
1,660,143 -9.8%
Sweden
600K
550K
500K
450K
400K
559,999
546,770 -2.4%
516,577 -5.8%
504,920 -2.3%
487,848 -3.5%
480,487 -1.5%
462,261 -3.9%
446,979 -3.4%
436,767 -28.2%
Switzerland
375K
350K
325K
300K
275K
368,167
371,016 0.8%
360,011 -3.1%
344,174 -4.6%
330,495 -4.1%
306,235 -7.9%
294,969 -3.8%
282,546 -4.4%
270,827 -35.9%
United Kingdom
2.4M
2.2M
2M
1.8M
1.6M
2,376,410
2,038,300 -16.6%
1,973,313 -3.3%
1,978,198 0.2%
1,898,882 -4.2%
2,080,013 8.7%
1,690,200 -23.1%
1,801,790 6.2%
1,775,459 -33.8%

Total (members only)

Year	Donation	Change
2010	19,787,437	
2011	20,204,322	
2012	19,861,519	2.1%
2013	19,190,696	-1.7%
2014	18,726,549	-3.5%
2015	18,690,890	-2.5%
2016	18,186,428	-0.2%
2017	18,089,487	-2.8%
2018	12,580,686	-0.5%
Total		**-57.3%**



INTERNATIONAL COLLABORATION

A Review of EDQM Blood Guide

In 2019 a draft version of the 20th edition of the EDQM blood guide was released for consultation and the EBA was invited to review. The EBA provided comprehensive comments, either for clarification or to express another opinion. One of the most important EBA comments was related to the proposed change of the maximum frequency of aphaeresis from 33 to 60 per year. EBA highlighted that this doubling of the maximal allowed volume of donated plasma per year is not the best way to ensure donor safety and increase plasma collection.

B Memorandum of Understanding with FIODS

EBA and the International Federation of Blood Donor Organisations (FIODS) have a long history of on-going collaboration and maintain a continuing dialogue in an informal manner. To reinforce the relation, the two parties decided to sign a Memorandum of Understanding (MoU) in March, in Rome. The MoU states that the two organisations keep each other informed of their respective initiatives when relevant to the other party, who would systematically be invited to take part in the activity undertaken on application. EBA and FIODS have also agreed to co-sign public statements when they share the same point of view, to meet at least once a year, and to join efforts in EU advocacy if opinions are aligned. EBA attended FIODS' "Blood donation in the third millennium, ethics, society, education, donor associations" workshop in Rome in October.

C Cooperation with the ABO

At the beginning of 2019, the Alliance of Blood Operators (ABO) decided to change its membership structure, allowing only individual blood establishments to be part of the Alliance. The American Blood Centres (ABC) and EBA being both association of blood establishments were, therefore, invited to renew collaboration in a different manner with the ABO.

EBA put forward a partnership offer which has been favourably reviewed by ABO. A formal agreement between EBA and ABO is forthcoming. In the meantime, experts from Australia, Canada and the USA remained part of the EBA Emerging Infections Disease Monitor (EID M) working group and the contact was maintained with key blood establishments at global level for best practice sharing.

EBA Consultations 2019

EBA encourages and facilitates collaboration within Europe and supports the Blood Establishment Members which want to circulate a survey within the EBA network. This service enables Member Organisations to contact EBA with a survey or request for information. EBA will then send a message to its Members to ask for responses by a specific date. After the deadline, EBA will send a report with the collated answers received to all respondents and all EBA Board Representatives. The final report is for internal use only, not to be distributed outside of EBA.

Survey Number	Survey Requested By	Survey Title	Members surveyed	No of replies
S1901	ABO	KE minority/ethnic donors and phenotyped and genotyped product	EBA Board	12
S1902	ABO/LT	Quick queries: 1. manufacturing/testing equipment | 2. national coordination of blood and organs	EBA Board	16
S1903	ABO/NHSBT	KE demand forecast accuracy	EBA Board	6
S1904	NHBTS	KE: Agitator Equipment Endorsements	EBA Board	8
S1905	ABO	Whole blood pack preparation for centrifugation	EBA Board	13
S1906	Donor Studies SIG	Needle related events and transfusion-transmissible infections	WG Donor Studies SIG	/
S1907	ABO	Deep dive overview and methodology	EBA Board	6
S1908	ABO	Collection facilities - floor and equipment plans, innovative design features, consumables and waste management	EBA Board	2
S1909	NHBTS	Plasma for Fractionation	WG Plasma Collection	3
S1910	EFS	HEV Screening in blood donors	EBA Board	16
S1911	NHBTS/ABO	ABO KE: User experience of blood collection equipment	EBA Board	9
S1912	Scottish National Blood Transfusion Service	Importing of Tissue and Cells	EBA Board	4
S1913	ABO	ABO KE: Luggage labels or alternate identification systems for 'special' components (due 17th July 2019)	EBA Board	12

Survey Number	Survey Requested By	Survey Title	Members surveyed	No of replies
S1914	Scottish National Blood Transfusion Service	ABO KE: Donor Award Structure	EBA Board	10
S1915	EBA	Domaine Manual	EBA Board	12
S1916	ABO	ABO Deep Dive Staff health and safety data	EBA BMG WG	/
S1917	Sanquin	ABO KE: social and environmental responsibility (CSR)	EBA Board	11
S1918	Sanquin	EBA Plasma WG 2019 questionnaire	AT, BE, HR, DK, EE, FR, GR, HU, IS, IR, LV, LT, Lux, MT, PT, SL, CH	9
S1919	Scottish National Blood Transfusion Service	Tissues and Cells Donor Testing Requirements	EBA Board	7
S1920	Sanquin	Annual Permission Donors over 65 years	EBA Board	16
S1921	Welsh Blood Service	Mobile Donation Units	EBA Board	9
S1922	Sanquin	ACD-A Bags	EBA Board	11
S1923	SNBTS	Self-Serve Refreshments DMcN	EBA Board+ABO	17
S1924	Swiss Red Cross	Labeling RBC products after the first determination of RH-KEL donor antigens	EBA Board	18
S1925	EFS	Donor thanks message	EBA Board	19
S1926	Finnish Red Cross	Apheresis devices and IgA deficient plasma	EBA Board	18

EBA ADMINISTRATION

A New staff

After having supported the EBA secretariat for more than 10 years, Willemijn Kramer, Communications and Administrations Officer said goodbye in April to EBA as she chose not to move to Brussels. After presenting the main results of her MBA on Lean Management at the April Board meeting, an MBA that EBA co-sponsored, Willemijn handed over her tasks and responsibilities to Rodica Popa, who was recruited in Brussels to take over both the administrative and financial tasks, as well as project management.

EBA secretariat was also supported part-time by Marleen Ruarus, from Sanquin, during the transition period – EBA thanks them warmly for their invaluable help.

EBA published a job advertisement and description and Rodica Popa was appointed EBA Administration and Projects Officer.

Peter van den Burg, MD, PhD joined EBA from Sanquin where he works part time as EBA Medical Director in February. Peter was very familiar with EBA as he led its Education and Training working group.

B Office move

The decision to move the EBA office from Amsterdam to Brussels was made in 2018 and based on the agreement reflected in the EBA new strategic plan to develop further EBA advocacy activities, especially in the context of a potential review of the European Blood Directive. EBA wishes to assert its key position as an expert and stakeholder towards European institutions and to be able to swiftly answer questions and requests for expertise from inter alia DG SANTE.

The Executive also considered enhanced networking with other Health representatives' opportunities which, together with more immediate access to the European Commission and other regulatory institutions, will improve delivery of the EBA strategy, at lower cost, through increased cooperation with health partners.

New address since mid-April 2019

European Blood Alliance, C/0 BLSI
Clos Chapelle aux Champs 30
B- 1200 Bruxelles, Belgium
Office 717

C Financial data

Balance sheet

Assets

Tangible fixed assets	31 December 2019	31 December 2018
Inventory	€6.937	€8.217
	€6.937	€8.217
Current assets		
Amount to be received	€944	€1.014
Warrant fee	€1.960	€-
Prepaid costs	€3.095	€202
Accounts receivable	€-	€47.531
	€5.999	€48.747
Liquidities		
Rabobank .542	€102.986	€198.164
Rabobank .620	€180.022	€180.000
Rabobank .338	€407.711	€406.718
	€690.719	€784.882
Total	**€703.655**	**€841.846**

Balance sheet

Liabilities

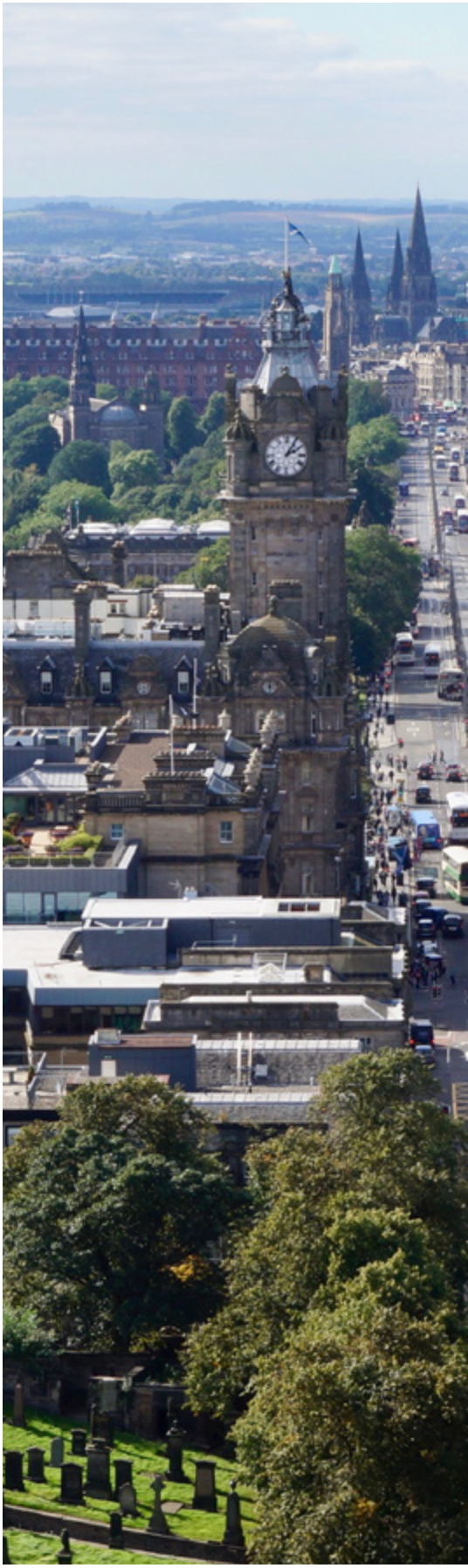
Capital	31 December 2019	31 December 2018
Accumulated result	€682.440	€692.263
	€682.440	€692.263
Current liabilities		
Pre-invoiced amounts	€-	€13.748
Accounts payable	€21.215	€133.835
To be invoiced	€-	€2.000
	€21.215	€149.583
Total	**€703.655**	**€841.846**

State of income and expenses

Income	2019	2018
Membership fees	€357.300	€398.806
Interest bank account	€944	€1.014
CPI income	€13.748	€93.656
Revenue Int. Consensus Conference	€-	€95.930
Charged costs Heart Valve project	€-	€930-
	€371.992	€588.476
Expenses		
Personnel costs	€210.013	€244.744
Depreciation	€5.242	€17.261
Meetings and workshops etc.	€6.747	€138.352
Travelling etc.	€20.862	€22.743
Office costs fixed	€15.813	€11.787
Office costs variable	€21.183	€60.114
Other costs	€101.955	€77.118
	€381.815	€572.119
Total result	**€9.823-**	**€16.357**

CPI income	€13.748	€93.656
CPI expenses	€-	€35.028-
Result CPI	€13.748	€58.628
Result Association activities	€23.571-	€42.271-
Balance	**€9.823-**	**€16.357**

EBA GOVERNANCE



A Change of statutes

During the October 2018 Board meeting in Vilnius, EBA decided to change its statutes so that the Executive term of office would be 4 years instead of 3, and to allow the Executive members the possibility to remain an Executive member up to 12 years (renew mandate twice). Additionally, with the move of the EBA office, it proved necessary to add an article allowing the EBA to have an office in another country than its official seat.

Members voted and approved these two changes in April this year, in Edinburg. The following changes were adopted:

"The Alliance may have its office in a foreign country" is added to article 1, paragraph 4

Article 6, paragraph 7 has been altered and now reads as follows:

7. a. The term of office for the members of the Executive Board is four years with the possibility of being re-elected twice.

7.b. The total maximum term of office is twelve years for all members of the

B Executive and Board meetings

EBA Board Spring Meeting

On 11 and 12 April 2019, the 43rd EBA Board Meeting was kindly hosted by the Scottish National Blood Transfusion Service in Edinburgh.

On April 11th the day started with an extraordinary EBA Board Meeting on changing the EBA Statutes. The Board approved adding an article stipulating that the Alliance can have the office in a foreign country. Also, the Board approved changing the term of Office Executive members from 3 to 4 years, with a maximum term of 12 years.

During the ordinary Board Meeting, the Board was presented with information on the topic "adapting to changes" with examples from Welsh Blood Service on Building the Supply Chain and from Sanquin on Plasma Collection – changes in donor behaviour. The second day had an in-depth session on Donor's right to be forgotten with presentations on the DPO Working Group work and paper one.

EBA Board autumn Meeting

On October 3rd and 4th 2019, the 44th EBA Board Meeting was hosted by the Austrian Red Cross in Vienna, Austria. Two in-depth sessions were presented -- one on whole blood transfusion with an example from Norway. Another in-depth was on ICT challenges in the blood establishments where EBA members from Finland, Belgium and UK shared their experiences with ICT systems.

EBA Executive Meetings

Throughout 2019, the Executive Board had eight meetings – three face to face and five teleconferences.

ABOUT EBA

The European Blood Alliance (EBA) is an association of not for profit Blood Establishments within the European Union or European Free Trade Association.

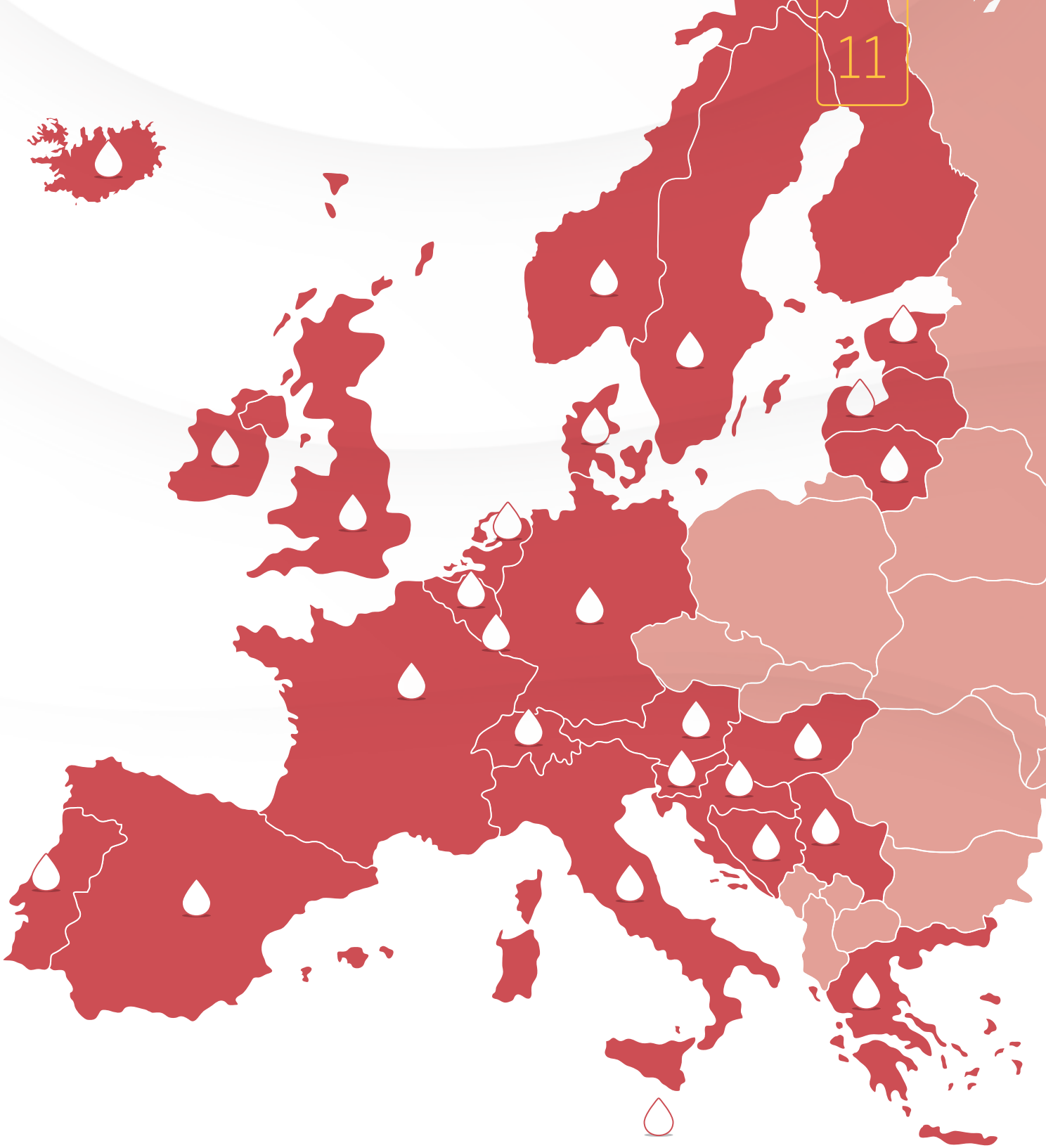
Its statutes are available on EBA's website www.europeanbloodalliance.eu/about-EBA

Creation

It was created in 1998 with nine members: Belgium, United Kingdom, Finland, France, Ireland, Luxembourg, the Netherlands, Portugal and Scotland.

Current membership

EBA now has 26 EU members and two observers:
Serbia and America's Blood Centers.



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Lithuania
Luxembourg
Malta
Netherlands
Norway
Portugal
Serbia
Slovenia
Spain
Sweden
Switzerland
United Kingdom

Executive Board (2019)

The EBA Executive Board consists of the following members:

Philippe Vandekerckhove, President – Belgian Red Cross - Flanders

Pierre Tiberghien – Établissement Français du Sang (France) – Vice-President

Rudolf Schwabe – Swiss Transfusion – Treasurer

Martti Syrjälä – Finnish Red Cross - Secretary

Daphne Thijssen-Timmer – Sanquin Blood Supply (the Netherlands)

Polonca Mali – Blood Transfusion Centre of Slovenia

EBA Staff

Catherine Hartmann – Executive Director

Peter van den Burg – Medical Director

Rodica Popa – Administration and Projects Officer – since April

Willemijn Kramer- Communications and Administrations Officer – until April

Marleen Ruarus – Administrative officer - until April

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ANNUAL REPORT

2019

Hyperlinks

All hyperlinks in this document can be accessed through the digital version of the Annual Report: **europeanbloodalliance.eu/downloads/eba-annual-reports**

Thank you

A big thank you to all EBA members who helped compile this Annual Report.

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