ANNUAL REPORT 2015

EUROPEAN HAEMOPHILIA CONSORTIUM

EHC
european haemophilia consortium

ACRONYMS

CEO – Chief Executive Officer
CoE – Council of Europe
DEC – Data and Economics Committee
EAHAD – European Association for Haemophilia and Allied Disorders
EDQM – European Directorate for the Quality of Medicines and Healthcare
EHC – European Haemophilia Consortium
EHCCC – European Haemophilia Comprehensive Care Centre
EHL – Extended Half-Life
EHTC – European Haemophilia Treatment Centre
EIN – European Inhibitor Network
EMA – European Medicines Agency
EPF – European Patients'Forum
EU – European Union
EUHANET – European Haemophilia Network
EUHASS – European Haemophilia Safety Surveillance
EURORDIS – European Rare Diseases Organisation
F – Factor
HCV – Hepatitis C virus
HTA – Health Technology Assessment
ISPOR – International Society for Pharmacoeconomics and Outcome Research
IWG – Inhibitor Working Group
MAG – Medical Advisory Group
MEP – Member of the European Parliament
NMO – National Member Organisation
PWI – People with haemophilia and Inhibitors
SC – Steering Committee
UK – United Kingdom
WFH – World Federation of Hemophilia
VWD – von Willebrand Disease

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EHC

european haemophilia consortium

About the European Haemophilia Consortium

The European Haemophilia Consortium (EHC) is a non-profit, non-government organisation that works to improve the quality of life of people with congenital bleeding disorders such as haemophilia, von Willebrand Disease (VWD) and other rare bleeding disorders in Europe.

Mission Statement

The EHC was established in 1989 with the mission to:

- Improve diagnostic and treatment facilities,
- Ensure adequate supply of – and access to – safe factor concentrates,
- Promote patients' rights and raise ethical issues,
- Follow and influence developments in European health policy,
- Monitor the status of haemophilia care in member countries,
- Stimulate research in all fields related to haemophilia and rare bleeding disorders.

Members

The EHC has 45 National Member Organisations (NMOs) from 27 EU Member States[1], including all acceding countries as well as most of the Council of Europe (CoE) Member States.

The EHC represents patients with congenital bleeding disorders such as haemophilia A and B, VWD and other rare bleeding disorders. It is estimated that approximately 90,000 people in Europe are affected by these conditions.

▷ **Albania**
Shoqatës Shqiptare
të Hemofilikëve

▷ **Armenia**
Armenian Association
of Hemophiliacs

▷ **Austria**
Österreichischen Hämophilie
Gesellschaft (ÖHG)
www.bluter.at

▷ **Azerbaijan**
Hemofiliyalı Xəstələrin Respublika Assosiasiyası
www.hemophilia.az

▷ **Cyprus**
Παγκύπρια Οργάνωση
Αιμορροφιλικών (Π.Ο.Α.)
www.poh.org.cy

▷ **Czech Republic**
Český svaz hemofiliků
www.hemofilici.cz

▷ **Denmark**
Blødderforening
www.bloderforeningen.dk

▷ **Estonia**
Eesti Hemofiliauhing
www.hemofiilia.ee

▷ **Hungary**
Magyar Hemofília Egyesület
www.mhe.hu

▷ **Iceland**
Blæðarafélag Íslands
www.hemophilia.is

▷ **Ireland**
Irish Haemophilia Society
www.haemophilia.ie

▷ **Israel**
היליפומה ילוחל התומע – הלע
www.hemophilia.org.il

▷ **Macedonia**
Hemolog
www.hemolog.org

▷ **Moldava**
Ассоциации Гемофилии
Молдовы
www.hemophilia.ucoz.ru

▷ **Montenegro**
Montenegrin Association
for Hemophilia

▷ **Netherlands**
Nederlandse Vereniging van
Hemofilie-Patiënten (NVHP)
www.nvhp.nl

▷ **Serbia**
Udruženje hemofiličara Srbije
www.hemofilija.org.rs

▷ **Slovak Republic**
Slovenské hemofilické
združenie
www.shz.sk

▷ **Slovenia**
Društvo hemofilikov Slovenije
www.drustvo-hemofilikov.si/

▷ **Spain**
Federación Española
de Hemofilia (FEDHEMO)
www.hemofilia.com

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[1] Malta is no longer a NMO

Belarus
Белорусская Ассоциация
Больных Гемофилией
www.belabg.org

Belgium
AHVH – Hemofilievereniging –
Association de l'Hémophilie
www.ahvh.be

Bosnia and Herzegovina
Udruženje Hemofiličara
Bosne i Hercegovine
www.uhbh.org.ba

Bulgaria
Българска Асоциация
по Хемофилия
www.hemo-bg.org

Croatia
Društvo hemofiličara Hrvatske
www.dhh.hr

Finland
Suomen Hemofiliayhdistys
(SHY)
www.hemofilia.fi

France
Association Française
des Hémophiles (AFH)
www.afh.asso.fr

Georgia
Georgian Association
of Hemophilia and Donorship
www.gahd.org.ge

Germany
Deutsche Hämophilie
Gesellschaft
www.dhg.de

Greece
Σύλλογος Προστασίας
Ελλήνων Αιμορροφιλικών
(ΣΠΕΑ)
http://hemophiliasociety.gr

Italy
Federazione delle Associazioni
Emofilici (Fedemo)
www.fedemo.it

Kyrgyz Republic
Kyrgyz Haemophilia Society
"Community of handicapped –
haemophiliacs"
http://hemophilia.go.kg

Latvia
Latvijas Hemofilija Biedrība
www.hemofilija.lv

Lithuania
Lietuvos Hemofiljos Associja
www.hemofilija.lt

Luxembourg
Association Luxembourgeoise
des Hémophiles
www.alh.lu

Norway
Foreningen for blødere
i Norge (FBIN)
www.fbin.no

Poland
Polskie Stowarzyszenie
Chorych na Hemofilię
www.hemofilia.of.pl

Portugal
APH – Associação Portuguesa
de Hemofilia e de outras Coagulopatias Congénitas
www.aphemofilia.pt

Romania
Asociația Română de Hemofilie
(ARH)
www.hemofilic.ro

Russian Federation
Всероссийского общества
гемофилии
www.hemophilia.ru

Sweden
Förbundet Blödarsjuka
i Sverige
www.fbis.se

Switzerland
Schweizerische
Hämophilie-Gesellschaft
www.shg.ch

Turkey
Türkiye Hemofili Derneği
www.turkhemoder.org

Ukraine
Всеукраїнське товариство
Гемофілії
www.hemophilia.org.ua

United Kingdom
The Haemophilia Society
www.haemophilia.org.uk

Message from the President and Chief Executive Officer (CEO)

Brian O'Mahony & Amanda Bok

Some endings and many new beginnings marked the year for the EHC as we continued in 2015 on our trajectory of growth – in budget, staffing and programming.

The EHC ended 2015 in solid and healthy financial standing, as we achieved a 60 per cent growth in income from 2014 to 2015 (and this following on from a 73 per cent growth in income in the preceding 2013-2014 period), thereby allowing us not only to expand our staffing base but also to introduce new activities and programmes, as well as to add towards a healthy operational reserve and work to ensure the organisation's longer-term sustainability (see pg 53).

In 2015 the EHC introduced two ambitious new areas of work: a multi-faceted, multi-annual programme for people with haemophilia and inhibitors (PWI) and their families/caregivers called the European Inhibitor Network (EIN – see pg 29) and an annual Leadership Conference designed to bring established NMO leaders, youth and staff together on an annual basis to exchange best practices, strengthen networks and align voices as necessary (see pg 25). With regard to the EIN, Kristine Jansone joined the EHC in early summer to manage and lead the programme as its full-time programme officer.

In 2015 the EHC also worked closely together with the European Association for Haemophilia and Allied Disorders (EAHAD) and the World Federation of Hemophilia (WFH) on a specific advocacy/training project in two Baltic countries (see pg 36). In line with this, Aislin Ryan joined the EHC as well as EAHAD in the early new year and provided support to both organisations in a joint-role.

The year saw some important areas of work rounding off. These include the completion of the three-year Economics and Health Technology Assessment (HTA) workshop cycle (these workshops were held in Eastern, Central and Western Europe from 2013-2015; with the last one being held in St Petersburg in September – see pg 18) as well as the foreseen end of the European Commission's three-year co-funding for work on the European Haemophilia Network (EUHANET) project. That project resulted in 116 haemophilia centres being certified by the end of 2015 as either European Haemophilia Treatment Centres (EHTC) or European Haemophilia Comprehensive Care Centres (EHCC). Despite their official 'end' both of the above areas of work will continue – the economics workshops entered a new thematic cycle for the next three years (Tenders and Procurement) and both EHC and EAHAD are committed to continuing the EUHANET work.

The remaining areas of EHC work were implemented with great success; these included the EHC Youth Leadership workshop held in Rome in July (see pg 27), the New Technologies workshop held in London in November (see pg 19), the long-standing Round Tables held in March, June and November in Brussels (see pgs 16, 24 and 17), the World Haemophilia Day event held in April in Dublin (see pg 23) and the annual conference held in Belgrade in October (see pg 20).

Most notably, a main focus of the EHC's advocacy efforts in 2015 was on Tenders and Procurement as the EHC completed and published the survey results in *Haemophilia* and as a monograph (see pg 23) and strongly advocated for the official and formal inclusion of patient representatives and clinicians in national tender and procurement processes – work that will be on-going for a number of years. A separate survey was also conducted in 2015, namely on access to novel hepatitis C (HCV) treatment products – also work that will be on-going in subsequent years.

2015 was another successful year and not just in the above-outlined areas of work, budget- and staff growth, but also in our broad community- and network-building, in our ability to advance our advocacy efforts using our own patient-collected data and evidence, and in our strong collaborations with key volunteers who give much of their valuable time and energy (see pg 45-50) and who help us keep the EHC's work reflective of and in line with the spirit of our European community.

Brian o Mahony

Brian O'Mahony
President

Amanda Bok
CEO

EHC 2015 activities at a glance

HIGHLIGHTS FROM THE YEAR:

- Annual Conference in Belgrade, Serbia
- World Haemophilia Day event on the results of the survey on the tender and procurement of coagulation factor concentrates in 38 countries
- Pilot Leadership Conference
- Re-elected Mr Brian O'Mahony as President
- Added two staff members to its team
- Started a European Inhibitor Network Programme
- Organised joint advocacy visit in the Baltic region with the WFH and EAHAD
- Continued EUHANET project

MEDICAL AND SCIENTIFIC UPDATE ON:

- Inhibitors in haemophilia A
- Mild and moderate haemophilia
- New technologies in haemophilia care
- Rare bleeding disorders
- Women and bleeding disorders
- Complications in haemophilia

TRAINING AND BEST PRACTICES IN:

- Economics and HTA
- NMO management, strategic planning and funding
- Patient involvement in tenders and procurement of treatment products
- Engagement of women in the bleeding disorders community
- Engagement of patients with inhibitors
- Engagement of young volunteers

DATA COLLECTION ON:

- The state of haemophilia care in Europe
- Access to HCV treatment

FEBRUARY

Round Table on Inhibitors in Haemophilia A

APRIL

World Haemophilia Day event

JUNE

Round Table on Tenders and Procurement

JULY

Youth Leadership workshop

SEPTEMBER

Workshop on Economics and HTA

OCTOBER

Annual Conference
Pilot Leadership Conference
Conference workshop on Inhibitors
Conference workshop on women in the bleeding disorders community

NOVEMBER

Round Table on Mild and Moderate Haemophilia
Workshop on New Technologies in Haemophilia Care

Activity Report

In 2015 the EHC continued to carry out activities in line with its 2014-2017 Strategic Plan objectives, which seek to:

1. Support and empower NMOs,
2. Promote access to optimal treatment and comprehensive care for people with congenital bleeding disorders in Europe,
3. Ensure constructive engagement with key stakeholders,
4. Increase its influence on the European policy-making environment,
5. Ensure the good governance and sustainability of the organisation.

These strategic objectives maintain the spirit of the original EHC mission while also taking into account the changing environment in which the EHC operates.

SUPPORT AND EMPOWER NMOs

The EHC was founded by European haemophilia patient organisations (now its NMOs) to serve them both at a national and European level. As such, supporting and empowering NMOs is the EHC's core strategic objective.

This is why the EHC tries to continuously keep its members informed about policy and legislative developments, concepts of health economics and HTA and their practical application for access to haemophilia treatment, new scientific and medical developments, and best practices from its members and other patient communities.

The EHC also collects data annually to assess the state of access to haemophilia treatment care and related areas to develop advocacy materials for its members.

Communication materials

The EHC communicates with its members through different media.

WEBSITE

- Revamped in 2014 and launched in 2015
- Contains information on EHC, its events and activities
- Had over 15,000 visits in 2015

NEWSLETTER

- Published three times a year
- Features EHC news, NMO updates and current issues in haemophilia and other bleeding disorders

QUARTERLY REPORT

- Published four times a year
- Available to NMOs only
- Covers relevant EU and national policy and legislative updates in the area of health care

FACEBOOK PAGE

- Used for rapid dissemination of EHC news, event updates and event pictures
- Used to highlight NMO activities
- Doubled its number of *likes* in 2015 (to over 600 likes)

YOUTUBE PAGE

- Used to disseminate EHC advocacy videos and EHC Annual Conference scientific sessions webcasts

EVENTS REPORTS

- Produced following Round Tables to report on presentations and event discussions

Education and training

Besides its Annual Scientific Conference, the EHC organises each year several events to provide its members with the latest available scientific and medical information on haemophilia and other rare bleeding disorders. In 2015 the EHC organised stand-alone events on topics such as inhibitor development, health economics, new technologies in haemophilia care and mild and moderate haemophilia. In the section here below is a brief description of each event.

ROUND TABLE OF STAKEHOLDERS ON 'INHIBITORS IN HAEMOPHILIA A'

March 2015 - Brussels, Belgium

Inhibitors remain one of the main challenges of haemophilia treatment. Some 30 per cent of people with severe haemophilia A receiving either on demand or prophylactic treatment are likely to develop an inhibitor. Having an inhibitor means that traditional treatment no longer offers protection against bleeds (one of the main causes of disability and sometimes death in people with haemophilia) and patients will have to resort to much more expensive treatments such as bypassing agents and immune tolerance induction. Inhibitor treatment is unfortunately often unavailable in resource-limited countries in Europe resulting in PWI loss of quality of life.

The Round Table of Stakeholders on 'Inhibitors in haemophilia A' gathered patients, scientific and medical experts and regulators to present the latest evidence on inhibitor development and to share best practices.

Topics covered during the event included:

- Inhibitor incidence with plasma-derived versus recombinant factor (F) VIII treatment,
- Inhibitor incidence with second versus third generation coagulation (F) VIII treatment,
- Data from the European Haemophilia Safety Surveillance (EUHASS) programme,
- Statistical analysis of inhibitor data in previously untreated patients,
- Epidemiological risk assessment,
- Patients' role in reporting treatment's side-effects.

The event concluded that additional studies and scientific evidence were needed to determine inhibitor development risks and causes. The EHC wishes to thank Members of the European Parliament (MEPs) Dr Paul Rübig (Austria) and Mr Heinz Becker (Austria) for supporting this event.

ROUND TABLE OF STAKEHOLDERS ON ‘MILD AND MODERATE HAEMOPHILIA’

November 2015 – Brussels, Belgium

Haemophilia is categorised into three severities: mild, moderate and severe. Severe haemophilia means that a person has less than one per cent coagulation FVIII or IX in his or her system, leaving them very vulnerable to bleeds, which severely damages joints and puts an individual at risk of disability and death. People with severe haemophilia tend to receive more appropriate medical care and access to therapies. This is despite the fact that people with mild and moderate haemophilia represent the vast majority of patients.

In this Round Table of Stakeholders, speakers, who included both medical and scientific experts as well as patients’ representatives, introduced the audience to mild and moderate haemophilia and gave an overview of the issues faced by this patient population both from a clinical point of view but also in relation to patient engagement within NMOs.

Topics covered during the event included:

- Introduction to mild and moderate haemophilia,
- Patients’ experiences with inhibitor development,
- Needs assessment with mild and moderate haemophilia,
- Immunological and clinical evidence for inhibitor development in mild and moderate haemophilia,
- Safe practice of sports.

The EHC wishes to thank MEP Mrs Mady Delvaux-Stehres (Luxembourg - pictured on the right in the image) for chairing and supporting this event.

EHC WORKSHOP ON ‘ECONOMICS AND HEALTH TECHNOLOGY ASSESSMENTS’

September 2015 – St Petersburg, Russian Federation

In 2015, the EHC held its third and final workshop in a series of three workshops to train members of EHC NMOs on basic concepts of health economics and HTA so that they can take a more active role with regard to access to medicines in their respective countries.

The event was held in English with live Russian interpretation and was aimed at EHC NMOs from outside the EU. Twelve participants from six[2] countries gathered for two days for a mix of lectures and practical exercises.

This workshop was made possible thanks to an educational grant from Pfizer.

WORKSHOP ON ‘NEW TECHNOLOGIES IN HAEMOPHILIA CARE’

November 2015 – London, United Kingdom

Despite being a rare disease, the haemophilia community can rely on an advanced community of medical and other experts invested in better understanding and tackling the disorder. The same is valid for the pharmaceutical industry invested in developing new technologies (treatments) to improve the quality of life of patients with haemophilia and other rare bleeding disorders. Furthermore this is an exciting time for the rare bleeding disorders community as many new treatments with promises of considerably improving the quality of life of patients with haemophilia and also PWI are under development and it is hoped that they will soon reach European patients. These new technologies include treatments such as extended half-life (EHL) coagulation factor concentrates, gene therapy, biosimilars and bi-specific antibodies.

In 2015 the EHC held the second edition of its workshop on New Technologies in Haemophilia Care, which was attended by over 50 participants including patient representatives and medical experts from 14[3] European countries as well as Canada and the United States. The primary objective of this workshop was to inform patients about the science behind these new medical technologies and their potential impact on the daily lives of patients. Additionally, the workshop also looked at the economics of these new treatments and how they may be evaluated, compared to existing technologies, when they reach European markets.

Topics covered in this workshop included:

- Clinical trial update for EHL coagulation factor concentrates,
- Laboratory monitoring of EHL coagulation factor concentrates,
- Experience with EHL products in the real world,
- Update on novel therapies: gene therapy, biosimilars and AT3 therapy,
- Variation in payment models: tenders and procurement.

This workshop was made possible thanks to educational grants from Sobi and Baxalta

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[2] Armenia, Azerbaijan, Kyrgyzstan, Moldova, Russia and Ukraine.

[3] Austria, Belgium, Finland, Germany, Iceland, Ireland, Italy, the Netherlands, Norway, Portugal, Slovakia, Switzerland, Turkey and the UK.

ANNUAL SCIENTIFIC CONFERENCE

October 2015 – Belgrade, Serbia

Each year the EHC organises a scientific conference to bring together the European bleeding disorders community and to provide participants with an update on the scientific and medical developments of the past year. In 2015 the EHC held, together with Udruženje hemofiličara Srbije, the EHC Serbian NMO, its 28th Conference in Belgrade. The one and half day event attracted over 300 delegates from 40 European countries as well as Canada and the United States.

The conference sessions focused on:

- The state of haemophilia care in Serbia,
- Gene therapy,
- Women and bleeding disorders,
- Complications in haemophilia,
- Updates on EHL coagulation factor-concentrates.

The conference was held in English with simultaneous Russian interpretation.

The EHC wishes to thank Udruženje hemofiličara Srbije for hosting this conference and all volunteers who contributed to the success of this event.


EHC
EHC

Data collection and sharing of best practices

Since its inception the EHC has been a platform for patients to share and gather information about haemophilia care and best practices in health care and NMO management from countries all over Europe.

Data collection is one of the key activities of the EHC as it is the bedrock on which the EHC develops stronger advocacy material. Each year the EHC surveys its own members on a topic related to haemophilia care and NMO management, analyses the data and generally publishes the article in a scientific journal such as *Haemophilia*.

The EHC also organises events aimed exclusively at its membership to share best practices regarding the management of NMOs and how to engage with particular populations within the NMO such as youth, women and PWI.

TENDERS AND PROCUREMENT: EHC SURVEY OF 38 COUNTRIES

In 2014 the EHC surveyed its members on the practices regarding the purchase of coagulation factor concentrates and other treatments in their own countries. The survey was published in 2015 in *Haemophilia*[4], and showed that countries where patients and healthcare professionals were officially involved in the procurement process had better access to treatment at more sustainable costs for the healthcare system. These results demonstrated the importance of involving patients and healthcare professionals in the decision-making process regarding the organisation of healthcare, something that is strongly advocated by the EHC.

To disseminate the survey results, the EHC organised two events to present the survey findings.

The EHC wishes to thank Mr Declan Noone and Dr Lucia Prihodova for their work towards the EHC survey on tenders and procurement.

WORLD HAEMOPHILIA DAY EVENT 'EHC TENDERS AND PROCUREMENT: SURVEY OF 38 COUNTRIES'

April 2015 – Dublin, Ireland

In April 2015 the EHC organised an event in Dublin to mark World Haemophilia Day and to present the preliminary findings from the survey of 38 EHC members on how tenders and procurement are organised. The event was attended by some 50 participants representing patients, physicians and industry.

Topics covered during the event included:

- EHC tenders and procurement survey,
- Outcomes of clinician and patient involvement,
- Patient involvement in Serbia,
- UK tender process,
- European commission procurement directive.

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[4] O'Mahony, B. et al. Survey of coagulation factor concentrates tender and procedures in 38 European countries. Haemophilia, 21 no.4 (2015):436-43.

ROUND TABLE OF STAKEHOLDERS ON ‘TENDERS AND PROCUREMENT OF COAGULATION FACTOR CONCENTRATES: A EUROPEAN SURVEY OF 38 COUNTRIES’

June 2015 – Brussels, Belgium

Following the World Haemophilia Day event, the EHC organised a second event to present the findings of the survey on ‘Tenders and procurement,’ in more detail. This was because the article containing the findings of the survey was still in press at the time of the World Haemophilia Day event and therefore detailed information could not be disclosed.

The June Round Table of Stakeholders provided participants with much more detailed information regarding the survey and its findings. Again the event was attended by some 50 participants including patients, physicians, regulators and industry.

Topics covered during the event included:

- Results of the EHC survey on tenders and procurement,
- Product selection and economic aspects,
- Clinical involvement in the UK tender process,
- Clinical involvement in alternative processes,
- Patient involvement in the Portuguese tender process,
- Impact of non-involvement of patient organisations,
- Directive 2014/24/EU on public procurement,
- Procurement of longer acting factor concentrates.

The EHC wishes to thank Dr Paul Rübig (Austria - pictured in the image in the left low corner), MEP for supporting the event.

SURVEY ON THE STATE OF HAEMOPHILIA CARE

In 2015 the EHC surveyed its members about the state of haemophilia care in Europe. Survey questions looked at both access to treatment and access to healthcare services as well as the state of patient registries and national haemophilia councils.

The survey is expected to be published in 2016 and is a direct follow-up of the 2012 and 2009 surveys, which will give all European stakeholders in haemophilia a good idea of how haemophilia care is progressing in Europe.

PILOT LEADERSHIP CONFERENCE

October 2015 – Belgrade, Serbia

The EHC Pilot Leadership Conference was created to provide European NMOs with a space in which to meet and exchange information on best practices and ask for advice and support on ongoing national issues. In the past years there had been a growing number of requests from EHC NMOs to create a forum where NMOs could meet, discuss ongoing issues and share best practices. In 2015, ahead of the EHC Annual Conference, the EHC held its Pilot Leadership Conference. The two-day event gathered over 70 participants representing established leaders, youth representatives and staff members from EHC NMOs to exchange on topics such as NMO governance and strategic planning, fundraising, financing, tenders and procurement.During the subsequent 2015 meeting of the EHC's General Assembly, NMOs fully endorsed this new concept and voted unanimously to hold this meeting annually as a stand-alone event.

This Pilot Leadership Conference was made possible thanks to educational grants from Baxalta, Pfizer and Sobi.

EHC YOUTH LEADERSHIP WORKSHOP AND COMMITTEE

The EHC believes that it is important to prepare the leaders of tomorrow so that the European bleeding disorders community can continue to be well represented by competent volunteers who understand the complex economic and political environment in which the NMOs operate. For this reason the EHC launched the 'Youth Leadership workshops' to bring together young volunteers and to provide training on the operational environment of patient organisations and on how to be a more effective volunteer within NMOs.

In July 2015 the EHC held its second Youth Leadership workshop in Rome, Italy, where 15 participants from 12[5] countries met for a two-day event to learn more about how to engage and retain volunteers, engage with their NMOs, engage in external communications and strategic planning.

At the end of 2015 the EHC formalised its Youth Committee (see pg 48) and welcomed three new members. Ms Aleksandra Ilijn (Serbian NMO), Mr Ivan Sebest (Slovakian NMO) and Mr Thomas Sannié (French NMO) joined existing members Mr Michael van der Linde (Dutch NMO and chair of the committee), Ms Olivia Romero-Lux (EHC Steering Committee member) and Ms Traci Marshall-Dowling (EHC Steering Committee member). The role of the EHC Youth Committee is to develop the programme of the EHC Youth Leadership workshop and to advise the EHC Steering Committee (SC) on youth related strategies and activities. The work of the Youth Committee is supported by EHC staff members Ms Amanda Bok and Ms Kristine Jansone.

The EHC wishes to thank all members of its Youth Committee for their time and contribution to EHC youth-related activities. The EHC Youth Leadership workshop was made possible thanks to educational grants from Novo Nordisk and Baxalta.

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[5] Azerbaijan, Bulgaria, Hungary, Ireland, Italy, the Netherlands, Poland, Romania, Serbia, Slovakia, Turkey and the UK.

CONFERENCE WORKSHOP ON WOMEN IN THE BLEEDING DISORDERS COMMUNITY

October 2015 – Belgrade, Serbia

It is a common perception that bleeding disorders (and in particular haemophilia) affect more men than women. Nonetheless, the European rare bleeding disorders community sees a great number of very active female volunteers involved in both EHC and NMOs activities. These women can be either patients or carriers or share their lives with someone affected by a bleeding disorder (such as mothers, daughters, sisters or partners). This is why EHC members felt there was a need to organise an event to bring together all of these women to discuss common issues and to exchange on activities that are organised specifically for women at NMO level.

In 2015 during its Annual Scientific Conference the EHC held a parallel workshop on 'Women in the European bleeding disorder community.' The workshop was developed by Mrs Yannick Collé (French NMO), Mrs Christina Burgess (UK NMO), Mrs Helene Døscher (Norwegian NMO) and Ms Evelyn Grimberg (Dutch NMO). The one and half-hour workshop brought together 40 participants (primarily patient representatives but also some physicians and industry representatives) to discuss what the role of women is in the bleeding disorders community and what is done at NMO level for these women.

The EHC wishes to give particular thanks to Mrs Yannick Collé and the French NMO Women's Committee for conceiving and leading this workshop.

EHC INHIBITOR NETWORK

As mentioned in page 16, inhibitors are one of the biggest side-effects of current haemophilia treatment, leaving those affected by them with no protection from bleeds and more susceptible to disability and death. Inhibitor development can have dire consequences on both the physical and psychosocial life of those impacted by them as well as their families. As a result this group of patients can feel more isolated and marginalised than other patients with rare bleeding disorders due to potential reduced mobility, frequent hospital visits and the constant threat of debilitating bleeds.

The EHC decided that more should be done for this group of patients and in 2015 it started to lay the foundation for a European Inhibitor Network (EIN) that would bring together PWI and their families from EHC membership.

In July 2015 a survey to map current activities of EHC NMOs for PWI was opened. This was followed in September by a survey open to all PWI and their families to assess the needs of those impacted by inhibitors. The survey was available in nine languages (English, French, Spanish, Russian, German, Dutch, Italian, Latvian and Romanian). In the beginning of October the EHC launched a call for members for its Inhibitor Working Group (IWG).

During the EHC Annual Scientific Conference the EHC held a parallel conference workshop regarding the programme element of the EIN and preliminary results of the needs' assessment survey were presented together with the mapping exercise of NMO activities for PWI. Participants during the meeting made concrete suggestions on the scope and the organisation of the EIN.

In November a preliminary meeting was held with members from the EHC membership and Medical Advisory Group (MAG) to develop an action plan for the roll out of the EIN.

At the end of 2015 permanent members of the IWG were selected by the EHC SC. The EHC was delighted to welcome:

- Mr Miguel Crato (Portuguese NMO), Mr Carl Fredrik Gustafsson (Swedish NMO) and Mr Mirko Jokic (Serbian NMO) as representatives of PWI,
- Mrs Elisabeth Olesen (Danish NMO) as representative of caretakers of PWI,
- Dr Hannele Kareranta (Finnish NMO) as representative of professional caregivers,
- Dr Oleksandra Stasyshin (Ukrainian NMO) as representative of health care specialists caring for PWI,
- Mrs Christina Burgess (UK NMO) as ex-officio member,
- Dr Radoslaw Kaczmarek and Mr Brian O'Mahony as representatives of the EHC SC,
- Prof Paul Giangrande and Prof Flora Peyvandi as representatives of the EHC MAG,
- Ms Amanda Bok and Ms Kristine Jansone as support staff.

The EIN was made possible thanks to an educational grant from Baxalta.

NMO liaison

In 2014 the EHC started a programme to allocate to each Steering Committee (SC) member (with the exception of the President and the ex-officio members such as the EHC CEO and the WFH President nine NMOs so that each EHC member can have direct contacts with the EHC SC. In return, SC Members can give and receive information about current affairs in NMOs and provide an update to NMOs about SC decisions.

Jordan Nedevski *Vice-President Finance*	**Radoslaw Kaczmarek** *SC Member*	**Olivia Romero Lux** *SC Member*	**Giuseppe Mazza** *SC Member*	**Traci Marshall Dowling** *SC Member*
Armenia	Czech Republic	Austria	Albania	Denmark
Azerbaijan	Estonia	Belgium	Bosnia-Herzegovina	Finland
Belarus	Hungary	France	Croatia	Iceland
Bulgaria	Latvia	Germany	Cyprus	Ireland
Georgia	Lithuania	Luxembourg	Greece	Israel
Kyrgyzstan	Moldova	Portugal	Italy	Netherlands
Russia	Poland	Slovenia	Macedonia	Norway
Turkey	Romania	Spain	Montenegro	Sweden
Ukraine	Slovakia	Switzerland	Serbia	UK


AQUA LUNA
Bloedverwanten
European Haemophilia Consortium
NVHP

EUHANET

Improving the care of European citizens with inherited bleeding disorders.

Download information leaflet here

Download lay version of final project report here

Haemophilia Central Website

The Haemophilia Central website has been set up to provide information about Haemophilia.

Haemophilia Central website (opens up in new window)

Certification of European Haemophilia Centres

Certification of European Haemophilia Centres.

European Haemophilia Centres Map (opens up in new window)

PROMOTE ACCESS TO TREATMENT AND COMPREHENSIVE CARE

As part of its strategic objectives, the EHC engages in projects and activities that promote access to treatment and comprehensive care for people with bleeding disorders

EUHANET

The European Haemophilia Network (EUHANET) is a project that established a network of haemophilia centres to work together to improve the care of European people with rare bleeding disorders. The project was funded in part by the European Commission via its Executive Agency for Health and Consumers and in part by the pharmaceutical industry.

The EUHANET project has four components:

The certification of European haemophilia treatment centres

This project aims at certifying haemophilia centres in EHCCC, offering a more comprehensive range of healthcare services and emergency services for people with rare bleeding disorders, and EHTC (still specialised centres but with a more limited offer of healthcare and emergency services) so that patients know what type of services they can expect when visiting a haemophilia treatment centre.

The European Haemophilia Safety Surveillance (EUHASS)

EUHASS is a pharmacovigilance project through which haemophilia treatment centres can report adverse events with treatment. This is important for physicians and researchers to better evaluate and ensure the safety of treatment products and to further research into bleeding disorders.

The Rare Bleeding Disorders Database

This is an international collaborating network that has developed a web database designed to prospectively collect clinical and laboratory data of patients with coagulation factor deficiencies in order to evaluate prevalence, bleeding frequency and management as well as consumption of treatment products and related complications.

The Haemophilia Central website

This is a public website designed to provide comprehensive information for patients and healthcare professionals on rare bleeding disorders.

In 2015 the EHC sat on the EUHANET Steering Committee and made active contributions to the development of these projects.

Council of Europe resolution on principles concerning haemophilia therapies

In April 2015 the Council of Europe (CoE) adopted a historic resolution on principles concerning haemophilia therapies (resolution CM(2015)3).

The resolution outlines six principles that should be followed by European countries with regard to haemophilia care. The resolution is a direct follow-up on the work carried by the Wildbad Kreuth initiative, an event organised by the University of Munich, the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the CoE in 2013 to establish the optimal use of coagulation factor concentrates in Europe. This event brought together medical, regulatory and industry experts as well as patient representatives (including representatives from the EHC) to develop a set of recommendations for the optimal treatment of patients with haemophilia in Europe.

The recommendations cover various topics including organisation of care, minimum level of FVIII consumption, the importance of safety and effectiveness of haemophilia treatment, prophylaxis for children and adults, prophylaxis with bypassing agents for PWI and the use of single coagulation factor concentrates for patients with rare bleeding disorders.

In 2015 the EHC updated its advocacy video on the Wild Bad Kreuth recommendations to disseminate the CoE resolution.

PRINCIPLES

1. To optimise the organisation of haemophilia care, a system should be established in each Member State to allow the implementation of a multidisciplinary approach for the treatment and care of patients (for example by setting up an advisory body including representatives of the relevant clinicians, national haemophilia bodies, patients' organisations, the health ministry, the paying authority, blood establishments and the regulatory authorities or by setting up centres of excellence);

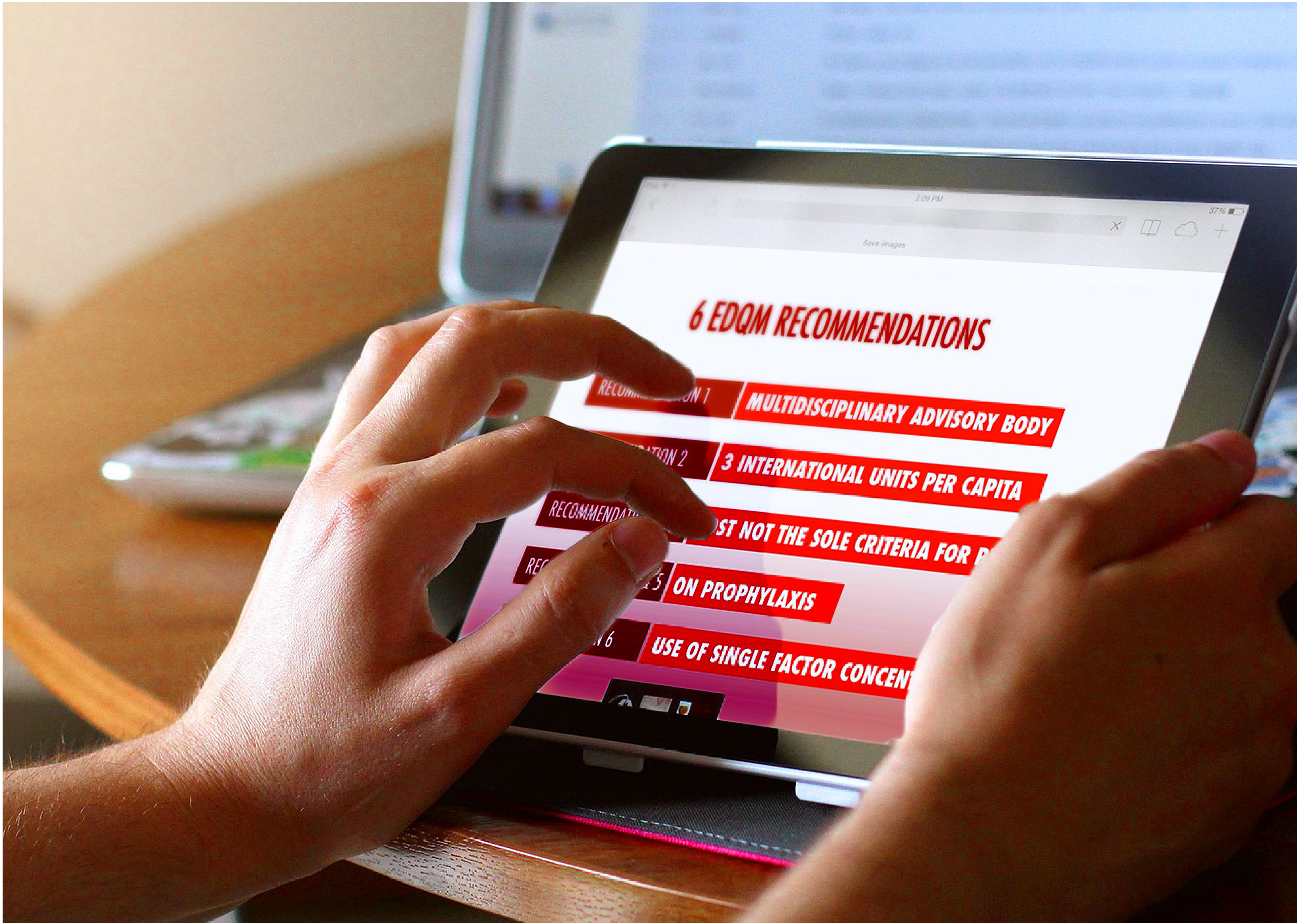
2. In each Member State, the coagulation F VIII utilisation level should be at least three International Units (I.U.) per capita;

3. Decisions on whether to use a new or an alternative product should be based on evidence of safety and effectiveness and not solely on cost;

4. The evidence of the effectiveness of different treatment regimens should be strengthened. Prophylaxis is currently recognised as the optimum therapy for children with severe haemophilia. Ongoing prophylaxis for adults should be provided, when required based on a clinical decision by the clinician in consultation with the patient;

5. Prophylactic treatment with bypassing agents should be offered to haemophiliac children who have developed inhibitors and in whom immune tolerance induction therapy has failed or was unsuitable;

6. Single coagulation factor concentrates should be used as therapy wherever possible in patients with rare bleeding disorders.



6 EDQM RECOMMENDATIONS

RECOMM ON 1 — MULTIDISCIPLINARY ADVISORY BODY

ATION 2 — 3 INTERNATIONAL UNITS PER CAPITA

RECOMMENDAT — ST NOT THE SOLE CRITERIA FOR

REC & 5 — ON PROPHYLAXIS

N 6 — USE OF SINGLE FACTOR CONCEN

EHC-EAHAD-WFH joint visit in the Baltic region

October 2015

In October 2015 patients and healthcare professionals joined forces to hold a joint visit to Estonia and Latvia to provide support and training local patient organisations and healthcare professionals. The delegation also conducted meetings with government representatives to advocate for better access to treatment. Representatives from the EHC, WFH and the EAHAD attended the four-day visit to meet their local counterparts, assess patients' needs and provide support to local patients' advocacy projects.

This was the first time that all of these organisations held a joint visit to a region.

ENSURE CONSTRUCTIVE ENGAGEMENT WITH KEY STAKEHOLDERS

The EHC operates in a complex environment where many other stakeholders such as patient organisations and professional societies, carry out parallel actions that have an impact on haemophilia, rare bleeding disorders and the EHC activities generally. As only one piece of a larger puzzle, the EHC works closely with key partner organisations, medical and professional societies, to ensure collaboration and alignment.

Patient Organisations

WORLD FEDERATION OF HEMOPHILIA (WFH)

The EHC and the WFH share the same NMOs and, as a result, they work closely together. In 2015, the EHC and the WFH worked together to organise a joint advocacy visit to the Baltic region (see pg 36). Additionally, the President of the WFH sits as ex-officio member on the EHC SC and in turn the EHC President or his/her designee is invited annually to attend the WFH board meeting. This is to ensure that both organisations work organically and do not duplicate activities. Furthermore both organisations stay regularly in close contact, attending each other's conferences and coordinating joint positions at European and international levels when necessary and appropriate.

EUROPEAN PATIENTS' FORUM (EPF)

EPF is an umbrella organisation representing chronic and lifelong conditions across Europe. In 2015, the EHC continued to take active part in their work on access to healthcare and interfaced on EPF projects at European and national levels.

PLATFORM FOR PLASMA USERS (PLUS)

PLUS, the Platform of Plasma Protein Users, is formed by EHC, Alpha-1 Global, GBS/CIDP Foundation International, HAEI, WFH, APLUS and the International Patient Organisation for Primary Immunodeficiency (IPOPI). PLUS meets every year to discuss pressing topics concerning plasma products and their impact on patients' health. The 2015 meeting was held in March in Rome and focused on the European legislation on blood and blood products and on the developments at the World Health Assembly regarding a Decision on "Blood and other medical products of human origin," which was also discussed at the World Health Organization (WHO) Executive Board earlier in 2015. The PLUS Steering Committee elections were held during the meeting with Brian O'Mahony (EHC), Johan Prévot (IPOPI) and Henrik Boysen (HAEI) were elected.

EURORDIS

The EHC is a long-standing member of the European Rare Disease Organisation (EURODIS), an international organisation representing over 600 patients groups active in the area of rare diseases. In 2015, the EHC was an active participant of EURORDIS' Rare Disease Day activities and EURORDIS' members' meeting. The EHC also worked closely with EURORDIS within the European Commission's Expert Group for Rare Diseases.

Medical and professional societies

EUROPEAN ASSOCIATION FOR HAEMOPHILIA AND ALLIED DISORDERS (EAHAD)

EAHAD is an organisation representing healthcare professionals working in the area of haemophilia and other bleeding disorders. The EHC and EAHAD share a Memorandum of Understanding (MoU), which formally sets the terms in which both organisations interact. The EHC and EAHAD speak at each other's conferences and have formal meetings twice a year. Additionally they often consult each other with regards to the development of position statements, surveys and any other relevant documents. In 2015 the EHC and EAHAD hired a shared project consultant, Ms Aislin Ryan, to coordinate the joint advocacy visit to the Baltic region.

INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOME RESEARCH (ISPOR)

ISPOR is an international multidisciplinary professional membership society that advances the policy, science and practice of pharmacoeconomics (health economics) and outcome research. In 2015 ISPOR organised its Annual European Conference and held a Patient Round Table to discuss current state of patient involvement in HTA processes. Mr Declan Noone, Chair of the EHC Data and Economics Committee, attended and presented at this event.

INCREASE INFLUENCE ON THE POLICY-MAKING ENVIRONMENT

Intricate and complex, the European policy-making environment is a layered arena of multiple decision-making bodies and diverse experts, all of whom need to understand the specificities of both haemophilia and other rare bleeding disorders in order to ensure that informed and appropriate decisions are made that will affect the lives of people with these conditions in Europe.

Informal MEP group ‘Friends of Haemophilia’

The European Parliament is an important player in developing European legislation and policies and as such they represent the voice of the people. For many years the EHC has been reaching out to MEPs to provide information about bleeding disorders and the needs of those living with these conditions. In 2014, the EHC developed a small informal group of MEPs ‘Friends of haemophilia,’ chaired by Mrs Nessa Childers (Ireland) and composed of Dr Paul Rübig (Austria), Dr Miroslav Mikolášik (Slovakia), Dr Cristian Bușoi (Romania). In 2015, the EHC continued to reach out to MEPs and ensured that all of its Round Tables of Stakeholders were supported by MEPs. In particular the EHC wishes to thank Mr Heinz Becker (Austria) and Dr Paul Rübig and their offices for the support of the Round Table of Stakeholders on Inhibitors in Haemophilia A; Dr Paul Rübig and his office for his support for the Round Table of Stakeholders on ‘Tenders and Procurement’ and Mrs Mady Delvaux-Stehres (Luxembourg) and her office for her support for the Round Table of Stakeholders on ‘Mild and moderate haemophilia.’

The EHC also met with other MEPs to discuss its work and advocacy efforts.

European Commission expert group on rare diseases

The EHC is one of the patient organisations representing patients' interests within the European Commission expert group on rare diseases. This committee works together with various stakeholders such as regulators, Member State representatives, European Commission officials and others to develop policies and to support people with rare diseases and to support the work of the European Commission and the Member States in this regard.

European Directorate for the Quality of Medicines and Healthcare (EDQM)

The EDQM, a Directorate of the Council of Europe, is responsible for protecting public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. It is one of the main partners of the Wildbad Kreuth initiatives and the EHC works with them closely on the development and promotion of standards and recommendations.

European Medicines Agency

The EHC is one of the patient organisations recognised by the European Medicines Agency (EMA) and in 2015 EHC representatives took part in various events and workshops organised by the EMA. In addition, Dr Günter Auerswald continues to sit on the EMA Paediatric Committee as a representative on behalf of the EHC.

ENSURE GOOD GOVERNANCE AND SUSTAINABILITY

The EHC maintains open and transparent relations with all stakeholders, including pharmaceutical companies, payers and regulators. The EHC is an eligible patient organisation associated with the EMA and is also on the Transparency Register of the European Parliament. The EHC receives, amongst others, financial support from the pharmaceutical industry in accordance to a strict policy that is published on its website. All EHC staff, consultants, elected and non-elected volunteers as well as members of the MAG have to adhere to a code of conduct and declare conflicts of interest. The EHC continually seeks to explore opportunities to diversify its sources of funding.

Sound and transparent financial policies and procedures

As the staff and activities of the EHC grow, it must ensure sound and transparent financial management to ensure good governance and sustainability. To this end the EHC has in place strict policies and procedures ensuring robust checks and balances between staff and volunteers on all payment approvals and transfers. The EHC works with an external accounting firm and reports cash flow to the SC on a quarterly basis. The EHC annual accounts are submitted to an external audit, which is made public and published at the end of this report and which is also submitted to key partners such as the EMA.

Maintain neutral and transparent corporate sponsorship policy

Much of the EHC's work is made possible by generous support from its corporate partners. In order to ensure ethical and transparent relationships, the EHC accepts corporate funding in strict compliance with its 'Policy on Financial Support from Corporate Sponsors,' which is published on the EHC's website, and which outlines the terms and conditions relating to such funding, including that the EHC shall exercise full independence, accountability and transparency.

Adhere to clear and ethical codes of conduct

In order to ensure the clear and ethical behaviour of all staff and volunteers, the EHC requires everyone who collaborates with the organisation (paid or unpaid) to complete and sign codes of conduct as well as declaration of interest forms.

Ensure constructive ongoing partnership and engagement between the EHC SC and the MAG

As complementary bodies in the governance and strategic work of the organisation, the EHC takes care to ensure a constructive and ongoing dialogue between the elected members of the Steering Committee – composed of patients or their family members – and appointed MAG members – composed of clinicians. To this end, each body has a dedicated Terms of Reference and has joint meetings to ensure maximum dialogue, mutual engagement and alignment on key issues.

Ensure adequate staff and financial resources to implement the strategic plan

In 2015 the EHC continued to expand its activities and focus and to support its growing work hired both an Inhibitor Programme Officer as well as an EHC-EAHAD Project Consultant.

Build up a minimum of six-month operational reserve

In 2015 the EHC continued to build its operational reserve and reached a one-year operational reserve in order to weather possible future funding cuts without damaging the work and activities of the organisation in the short term.

Develop and implement clear plan for diversification of funding

In 2015 the EHC continued to look at opportunities to diversify its income to continue to ensure the independence and long term sustainability of the EHC as a patient organisation.

Structure and governance

Steering Committee

In 2015 the General Assembly re-elected Mr Brian O'Mahony as President for a four-year term. The EHC SC also co-opted Mr Michael van der Linde, Chair of the EHC Youth Committee, as SC Member. The SC is composed of:

- Brian O'Mahony, EHC President, Irish NMO
- Jordan Nedevski, EHC Vice-President Finance, Bulgarian NMO
- Radoslaw Kaczmarek, EHC SC Member, Polish NMO
- Traci Marshall Dowling, EHC SC Member, Irish NMO
- Giuseppe Mazza, EHC SC Member, Italian NMO
- Olivia Romero-Lux, EHC SC Member, French NMO
- Michael van der Linde, co-opted SC Member, Dutch NMO
- Alain Weill, Ex-Officio, WFH President
- Amanda Bok, Ex-Officio, EHC CEO

Medical Advisory Group (MAG)

Established in 2009 the MAG provides high-level medical and scientific support to the SC and the EHC staff. It is composed of European medical and scientific experts in haemophilia and other congenital bleeding disorders. The MAG is composed of:

- Prof Paul Giangrande (Chairperson), Oxford University
- Prof Angelika Batorova, Medical Director of the National Haemophilia Centre and the Haemostasis and Thrombosis Unit, University Hospital, Bratislava
- Prof Michael Makris, Honorary Consultant Haematologist, Sheffield Teaching Hospitals, NHS Trust
- Prof Flora Peyvandi, Director of the Department of Internal Medicine, RCCS Maggiore Hospital, University of Milan

EHC Committees

DATA AND ECONOMICS COMMITTEE

The Data and Economics Committee (DEC) was created to support the EHC's work in the area of health economics and HTA. In 2015 Prof Frist Rosendaal from Leiden University joined the DEC. In addition Ms Aislin Ryan, EAHAD-EHC Project Consultant also joined the committee. The DEC is composed of:

Chair – Declan Noone	Irish NMO
Amanda Bok	EHC CEO
Mariëtte Driessens	Dutch NMO
Michael Makris	MAG member / University of Sheffield
Giuseppe Mazza	SC member / Italian NMO
Jamie O'Hara	UK NMO
Brian O'Mahony	EHC President / Irish NMO
Frits Rosendaal	Leiden University
Aislin Ryan	EHC staff
Laura Savini	EHC staff
Uwe Schlenkrich	German NMO
Keith Tolley	Tolley Health Economics

YOUTH COMMITTEE

The EHC Youth Committee develops the programme of the EHC Youth Leadership workshop and provides advice to the SC on youth-related matters. In 2015, the EHC welcomed three new members to its Youth Committee: Mr Thomas Sannié from the French NMO, Ms Aleksandra Ilijn from the Serbian NMO and Mr Ivan Sebest from the Slovakian NMO. In addition Ms Kristine Jansone, EHC Inhibitor Officer, also joined the committee and started supporting its work. Mr Federico Ruiz-Garcia from the Spanish NMO left the Youth Committee in 2015. The EHC wishes to thank Mr Federico Ruiz-Garcia for his work and contributions to the EHC Youth Committee.

The EHC Youth Committee is composed of:

Chair – Michael van der Linde	Dutch NMO
Amanda Bok	EHC CEO
Aleksandra Ilijn	Serbian NMO
Kristine Jansone	EHC staff
Olivia Romero Lux	EHC SC Member / French NMO
Thomas Sannié	French NMO
Laura Savini	EHC staff
Ivan Sebest	Slovakian NMO
Traci Marshall-Dowling	Irish NMO

INHIBITOR WORKING GROUP

The EHC created in 2015 an Inhibitor Working Group (IWG) to support the planning, development and creation of the European Inhibitor Network. The EHC IWG is composed of:

Chair - Paul Giangrande	EHC MAG Chair/ Oxford University
Amanda Bok	EHC CEO
Christina Burgess	UK NMO
Miguel Crato	Portuguese NMO
Carl Fredrik Gustafsson	Swedish NMO
Kristine Jansone	EHC staff
Mirko Jokic	Serbian NMO
Hannele Kareranta	Finnish NMO
Radoslaw Kaczmarek	EHC SC Member/ Polish NMO
Brian O'Mahony	EHC President/ Irish NMO
Elisabeth Olesen	Danish NMO
Flora Peyvandi	EHC MAG Member/ University of Milan
Oleksandra Stasyshin	Ukrainian NMO

NEWSLETTER EDITORIAL COMMITTEE

The Newsletter Editorial Committee supports the EHC with the conception, planning, content and production of the EHC newsletter. In 2015, Ms Aislin Ryan, EAHAD-EHC project consultant joined the committee to provide support to its activities.

In addition the EHC wishes to thank all NMOs and external contributors who submitted material for publication in the newsletter.

The Newsletter Editorial Committee is composed of:

Amanda Bok	EHC CEO
Jo Eerens	EHC staff
Radoslaw Kaczmarek	SC Member/ Polish NMO
Olivia Romero-Lux	SC member / French NMO
Aislin Ryan	EHC staff
Laura Savini	EHC staff

EHC NEWSLETTER
MAY 2016
www.ehc.eu

Volunteers

With the exception of the EHC staff and consultants, unpaid volunteers carry out all of the other above-mentioned roles and responsibilities. These individuals work extremely hard to help advance the EHC's activities and we thank them most sincerely for their time, dedication, patience and passion!

In addition to the volunteers named above, we also express our thanks to those individuals who provided ad hoc support to the EHC in 2015:

- Katja Kirchkevitch for her Russian translation of website and other material
- Steffen Hartwig for his IT support
- Lucia Prihodova for her work on the EHC survey

The EHC also wishes to thank all speakers, facilitators and chairs of the EHC Round Tables, workshops, the Annual Conference and the Pilot Leadership Conference.

The EHC would also like to extend its thanks to the local volunteers that ensure a smooth running of its Annual Conference by helping delegates to find their way around as well as the nurses who manned the treatment room.

Staff

Over the past few years the EHC grew in scope and activities, which required additional staff to support volunteers and projects. In 2015 two new staff members joined the EHC.

The EHC office is based in Brussels and has a small team composed of:

- Amanda Bok, EHC CEO
- Jo Eerens, EHC Office Manager
- Kristine Jansone, EHC Inhibitor Programme Officer
- Aislin Ryan, EAHAD-EHC Project Consultant
- Laura Savini, EHC Communications and Public Policy Officer

Service Providers

The EHC would like to thank the Conference Organisers for their help in the logistical organisation of the EHC events; Toast for their help with visual and print communication tools; RPP Group for their support of our EU-level work; BDO for their accounting services; Stéphane Rosier, our external auditor; Ethical Properties for making it possible for NGOs to be in the European Quarter; Luka Pilipovic and Adrien Moorman for visually documenting our events and last but not least Mrs Olga Miniuk and Mrs Julia Krivkina for their tireless work and dedication towards ensuring our Russian speaking members can fully participate in our conferences and workshops.

Financial Report

Word from the Vice-President Finance

2015 was another financially positive and prosperous year for the EHC, in which – thanks to new and growing partnerships, collaborations and activities, as well as a very strong result from the EHC Conference in Belgrade, Serbia – the organisation was able to achieve a 60 per cent growth in income over the previous year. This allowed the EHC to generate a surplus of approximately €505,000 and, combined with positive results from 2014, the EHC now has a healthy operational reserve, thereby meeting its strategic objective of working to ensure the organisation's longer-term sustainability.

In 2015 again the EHC is particularly indebted to the excellent and hard work of its volunteers whose unpaid contribution to the work of the organisation was financially equivalent to €252,000. These volunteers, together with two new staff members hired in 2015 and the existing staff base, helped to advance and deliver on important new programmes and areas of work, including the multi-faceted and multi-annual European Inhibitor Network, the pilot EHC Leadership Conference and joint advocacy work with the EAHAD in the Baltic countries.

Of course none of this would have been possible without the support of our external partners. We are particularly grateful for the financial and other support of our industry partners as well as for the co-funding from the European Commission, which we have received over the last six years for work, together with EAHAD and other partners, on both the EUHASS and subsequently EUHANET. Although that funding finished in 2015, it helped to lay strong foundations and the commitment to carry this work forward remains!

Finally, in line with the EHC's commitment to external financial oversight, our 2015 accounts were independently audited under Belgian Audit Standards and the results are published on pg 54.

Report of the auditor

Rosier & Co
Réviseurs d'entreprises

INDEPENDENT AUDITOR'S REPORT TO THE STEERING COMMITTEE
OF THE AISBL

Consortium Européen de l'Hémophilie
(European Haemophilia Consortium)
0887.106.966

FOR THE YEAR ENDED 31 DECEMBER 2015

As required, we report to you in the context of our appointment as the association's independent auditor. This report includes our opinion on the "internal statements", further the annual accounts.

Report on the annual accounts – Unqualified opinion

We have audited the annual accounts of the AISBL *Consortium Européen de l'Hémophilie* for the year ended 31 December 2015, prepared in accordance with the financial-reporting framework applicable in Belgium, which show a balance sheet total of € 984.449 and a positive result for the year of € 504.600.

Responsibility of the board of Directors for the preparation of the annual accounts

The board of Directors is responsible for the preparation of annual accounts that give a true and fair view in accordance with the financial-reporting framework applicable in Belgium, and for such internal control as the board of Directors determines is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

Responsibility of the statutory auditor

Our responsibility is to express an opinion on these annual accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISAs). Those standards require that we comply with the ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts. The procedures selected depend on the independent auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts, whether due to fraud or error. In making those risk assessments, the independent auditor considers the company's internal control relevant to the preparation of annual accounts that give a true and fair view, in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of Directors, as well as evaluating the overall presentation of the annual accounts.

We have obtained from the board of Directors and company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Unqualified opinion

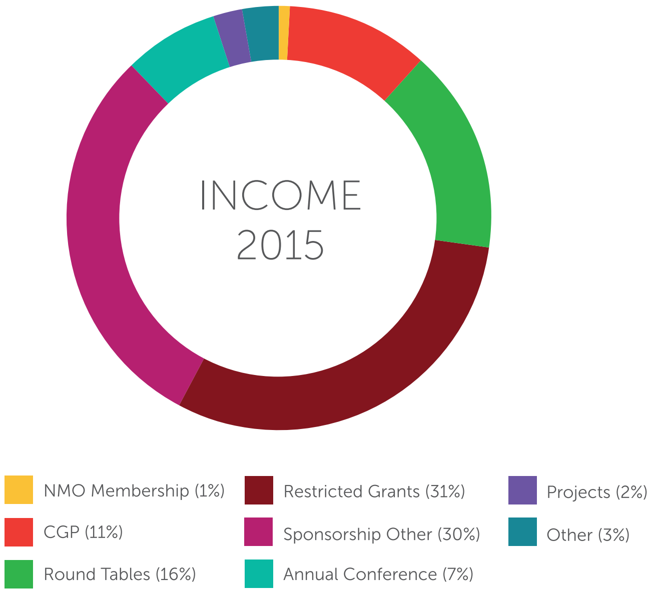
In our opinion, the annual accounts of the AISBL's give a true and fair view of the association's equity and financial position as at 31 December 2015, and of the results of its operations for the year then ended, in accordance with the financial-reporting framework applicable in Belgium.

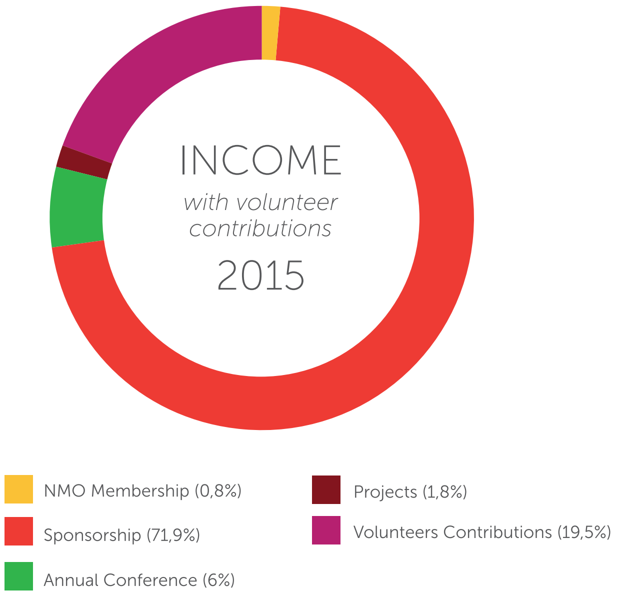
Limal, May 9th 2016

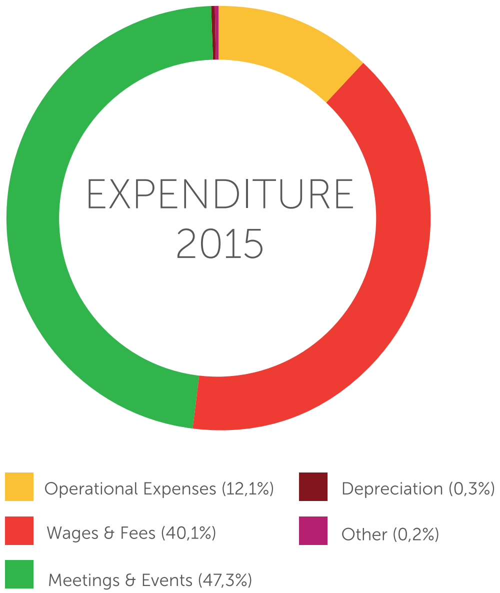
Rosier & Co
Independent auditor's

represented by
Stéphane Rosier
Certified Public Auditor

Income and expenditure







INCOME	FINALS (€)
NMO Membership	10,817
Sponsorship	930,743
CGP	116,000
Round Tables	167,500
Restricted Grants	327,243
Sponsorship Other	320,000
Annual Conference	78,247
Projects	22,942
Other	27,950
TOTAL INCOME	1,070,699

INCOME	FINALS (€)
NMO Membership	10,817
Sponsorship	930,743
Annual Conference	78,247
Projects	22,942
Volunteer Contributions	252,000
TOTAL INCOME	1,294,749

EXPENDITURE	FINALS (€)
Operationnal Expenses	68,596
Wages and fees	226,583
Meetings and events	267,632
Depreciation	1,405
Other	1,168
TOTAL EXPENDITURE	565,384

Balance sheet

FIXED ASSETS	**20/28**	**5.059,75**
Tangible assets	22/27	2.874,05
Furniture and vehicles	24	2.874,05
Fully owned by the association	*241*	*553,80*
241000 COMPUTER EQUIPMENT		2.230,88
241009 DEPRECIATION / COMPUTER EQUIPMENT		(1.677,08)
Other	242	*2.320,25*
242000 OFFICE FURNITURES		3.867,09
242009 DEPRECIATION / OFFICE FURNITURE		(1.546,84)
Financial assets	28	2.185,70
Other financial assets	284/8	2.185,70
Amount receivable in cash garantees	*285/8*	*2.185,70*
288000 CASH GARANTEES		2.185,70
CURRENT ASSETS	**29/58**	**979.390,10**
Amounts receivable within one year	40/41	94.566,91
Trade debtors	40	84.822,76
400000 CUSTOMERS		906,66
404000 INCOME RECEIVABLE		82.584,74
404400 CREDIT NOTES TO BE RECEIVED		1.331,36

Others amounts receivable	41	9.744,15
411200 C/A V.A.T. ADMINISTRATION		9.744,15
Cash at bank and in hand	54/58	880.549,22
550000 KBC 736-0015727-77 (SIGHT ACCOUNT)		49.959,46
550001 KBC 746-0011961-78 (SAVING ACCOUNT)		798.923,48
550002 KBC 746-0001443-54 (COMPTE EPARGNE EUHANET)		30.245,39
550003 KBC 736-002608-76 (COMPTE A VUE EUHANET)		1.390,85
570000 PETTY CASH - EUR		14,22
570006 PETTY CASH - RSD		15,82
Deferred charges and accrued income	490/1	4.273,97
490000 DEFERRED CHARGES		4.273,97
Total assets		***984.449,85***
SOCIAL FUNDS	**10/15**	**865.577,12**
Associative funds	10	9.419,96
Permanent means	101	9.419,96
101100 PERMANENTLY FUNDS IN CASH		9.419,96
Accumulated profits	140	148.971,93
140000 ACCUMULATED PROFITS (LOSSES -)		148.971,93
*** 149999 Balance 6 and 7		707.185,23

AMOUNTS PAYABLE	**17/49**	**118.872,73**
Amounts payable within one year	42/48	114.372,73
Trade debts	44	101.982,34
Suppliers	440/4	101.982,34
440000 SUPPLIERS		35.656,20
444000 INVOICES TO BE RECEIVED		61.152,22
***445000 CREDITOR CUSTOMER		5.173,92
Taxes, remunerations and social security	45	12.390,39
Remunerations and social security	454/9	12.390,39
455000 REMUNERATIONS TO BE PAID		5.333,81
456000 HOLIDAY PAY		7.056,58
Accrued charges and deferred income	492/3	4.500,00
492000 ACCRUED CHARGES		4.500,00
Total Liabilities		***984.449,85***

INCOME STATEMENT

Operating income	**70/74**	**1.070.699,91**
Contributions, donations, legacies and subsides	73	1.019.808,17
730000 NMO MEMBERSHIP FEES		10.817,00
730010 CORPORATE GIVING PROGRAM MEMBERSHIP		116.000,00
730020 ROUND TABLE MEMBERSHIP		167.500,00
730030 RESTRICTED GRANTS		327.243,47
730040 EHC ANNUAL CONFERENCE		78.247,70
730050 SPONSORSHIP OTHER		320.000,00
Other operating income	74	50.891,74
740010 EUHANET PROJECT		22.941,54
743200 RECHARGE OF EXPENSES		12.207,10
743400 VAT REVISION		13.959,33
743900 SOCIAL WITHHOLDING TAXES REFUND		469,22
746000 OTHER OPERATING INCOME		1.314,55
Operating charges	**60/64**	**(565.383,60)**
Services and other goods	61	(499.431,61)
610100 OFFICE RENT		(20.432,79)
610110 RENTAL CHARGES OFFICE		(1.015,68)
610120 RENT OF MEETING ROOM		(846,38)
610140 PARKING RENT		(743,33)
612130 POSTAGE		(298,23)
612140 MOBILE COSTS		(922,77)
612150 TELEPHONE AND INTERNET COSTS		(2.583,80)
612200 DOCUMENTATION		(765,93)
612300 OFFICE EQUIPMENT		(8.336,67)

612400 PRINTING	(4.794,83)
612610 WEBSITE	(5.232,38)
612620 IT SUPPLIES	(3.934,03)
612900 REIMBOURSED EXPENSES	(11.250,17)
613100 FIRE INSURANCE (BUILDING)	(95,73)
613160 INSURANCE PR	(624,28)
613170 TRAVEL INSURANCE	(4,23)
613200 ADMB FEES	(927,52)
613211 AUDITORS FEES	(1.452,75)
613212 ACCOUNTANCY FEES	(11.624,00)
613213 ADVISORY FEES	(831,58)
613214 FEES MEAL VOUCHERS	(165,37)
613215 CONSULTANCY PUBLIC AFFAIRS	(37.240,11)
613216 CONSULTANCY	(94.738,83)
613217 Consultancy	(47.487,11)
613218 VARIOUS FEES	(9.910,00)
613220 CONFERENCE ORGANISERS FEES	(156.295,63)
613221 Consultancy	(9.975,02)
613410 TRAVEL COSTS	(20.177,85)
613420 RESTAURANT	(4.905,29)
613430 PARKING	(791,28)
613440 TRANSPORTATION - URBAN TRANSPORT	(2.792,07)
613450 HOTEL	(25.690,09)
613470 COSTS OF MEETINGS CATERING	(1.859,28)
613480 TAXI	(4.130,26)
613500 MEMBERSHIP FEES	(4.056,34)
613600 GRANT	(2.500,00)

Remuneration; social security costs and pensions (+)(-)	62	(63.378,64)
620200 GROSS SALARIES BELGIUM		(45.260,19)
621200 O.N.S.S. CONTRIBUTIONS		(10.790,36)
623001 LEGAL WORKERS INSURANCE		(319,30)
623003 EMPLOYEE URBAN TRANSPORT COST		(608,79)
623101 CATERING COSTS		(1.229,93)
623900 MEAL VOUCHERS		(1.542,51)
625000 PROVISION PECULE DE VACANCES		(7.056,58)
625010 REPRISE PROVISION PECULE DE VACANCES (-)		3.429,02
Depreciation of and other amounts written off formations expenses; intangible and tangible fixed assets	630	(1.405,37)
630200 DEPRECIATION OF TANG. FIX. ASS		(1.405,37)
Other operating charges	640/8	(1.167,98)
640120 NON DEDUCTIBLE V.A.T.		(853,44)
642000 Depreciation on the customers		225,00
643050 Other taxes		(406,00)
643105 WITHHOLDING TAXES /INTERESTS		(133,54)
Positive (Negative) operating result (+)(-)	***9901***	***505.316,31***
Financial income	75	912,74
Income from current assets	751	900,67
751010 Interests / Bank accounts		900,67
Other financial income	752/9	12,07
754000 Exchange differences		12,07

Financial charges	**65**	**(757,15)**
Other financial charges	652/9	(757,15)
654100 OTHER REALIZED EXCHANGE LOSSES		(33,02)
657000 BANK CHARGES		(724,13)
Positive (Negative) result on ordinary activities	***9902***	***505.471,90***
Extraordinary charges	**66**	**(871,18)**
Others Extraordinary charges	664/8	(871,18)
664000 Others extraordinary charges		(871,18)
Profit (Loss) for the current financial year before taxes	**9903**	**504.600,72**
Profit (Loss) for the financial year	**9904**	**504.600,72**
APPROPRIATIONS AND TRANSFERS		
Profit (Loss) to be appropriated	**9906**	**504.600,72**
Profit (Loss) for the period avail. for appropr.	9905	504.600,72
Profit (Loss) to be carried forward	**(14)**	
ACCOUNTS OFF BALANCE SHEET		
149999 -BROUGHT FORW. PROVIS. RESULT		707.185,00
445000 -CREDITOR CUSTOMERS		5.174,00

SPONSORS

PLATINUM SPONSOR:

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GOLD SPONSOR:

Novo Nordisk

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FOR MORE THAN 25 YEARS,
BAYER HAS BEEN COMMITTED TO SCIENTIFIC ADVANCES IN THE TREATMENT OF HEMOPHILIA

In addition to improving rFVIII therapeutic options, Bayer has expanded its commitment in hemophilia with innovative technology to include:

Antibody technology	Gene therapy	Gene editing

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CENTENARY

20 CELEBRATION 16

CELEBRATING 100 CSL™
Parent Company of
CSL Behring

CSL Behring has, this year, marked 100 years of delivering on our promise for patients

Achieving this milestone is a testament to CSL Behring's values, science, people and the patients we serve — yesterday, today and tomorrow.

Few organizations have the vision, focus and agility to accomplish such a feat. Fewer still have such a rich heritage with an even brighter future ahead. In many ways, we're just getting started; delivering on promises is what we do at CSL Behring.

We're a patient-centered organization with a unique combination of R&D focus, operational excellence and commercial strength that enables us to consistently identify, develop, and deliver innovations that patients with life-threatening conditions, such as hemophilia, need.

We have grown into a global biotherapeutics leader. Today, we provide life-saving biotherapies to people in more than 60 countries. Our 16,000 people are driven by a deep passion and commitment to serve the thousands of patients who depend on our medicines to help them to live their lives to the full.

We've been able to sustainably deliver on our promise because innovation is at the heart of everything we do. It is at the heart of how we safely and effectively produce medicines for a range of serious medical conditions and it is led by the 1,100 dedicated R&D experts who focus on solving patients' unmet needs every day.

Emerging innovations, such as treatments for hemophilia A and B, along with support programs, promise to provide new opportunities to improve patient well-being, unlike at any other time in history. But there's more to be achieved — especially in helping to raise awareness of serious diseases and the importance of early diagnosis. For example, 75% of the people with blood disorders in the world are either undertreated or not treated at all.

So, we work closely with the patient advocacy community, including the European Haemophilia Consortium, to find ways to raise awareness of serious medical conditions and encourage the right conversations with healthcare professionals to prompt early diagnosis and timely treatment.

CSL is the parent company of CSL Behring. As we begin our second century, our promise to save lives and protect the health of people gets stronger by the day.

For more information about CSL Behring, please visit:
www.cslbehring.com

Date of preparation: June 2016 EU006

Partnering to Change the World for People with Haemophilia

Pfizer Haemophilia is proud to support the following initiatives in Europe:

EUROPE ASPIRE
Advancing Science Through Pfizer - Investigator Research Exchange

Promoting basic science, translation and clinical research to advance knowledge in the pathogenesis and treatment of haemophilia

MILES FOR HAEMOPHILIA
YOUR PERSONAL BEST!

Action to inspire the haemophilia community to join us and pledge your personal best to raise awareness of haemophilia

Pfizer Ultrasound Programme
Innovation and Imaging in Haemophilia

Sharing understanding and technical training on the use of ultrasound as a point-of-care tool for early detection of joint disease in haemophilia

WFH
Twinning Programme

Pfizer Haemophilia is proud to be the exclusive sponsor of the WFH Twinning Programme, encouraging exchange of experience, skills and resources related to haemophilia treatment between countries

The London Preceptorship

Hands-on, practical training course supporting the next generation of haemophilia treaters

Haemophilia Global Summit

Educational meeting initiatives, striving to ensure global access to education and best practice approaches, including one of Europe's largest gatherings of haemophilia treaters

Haemoassist 2

Smartphone app and website designed as an advanced alternative to paper-based diaries, enabling reporting and documentation of bleeds and factor infusions at the touch of a button

Pfizer Haemophilia

PP-REF-EUR-0151
Date of preparation: May 2016

Supporting haemophilia community leaders of the future

A key focus for the European Haemophilia Consortium (EHC) in recent years has been to secure succession planning and future leaders for the community. By identifying, supporting and developing younger EHC members, future generations of leaders and potential leaders will be equipped to continue the years of successful advocacy and be ready to meet the challenges and opportunities in the evolution of haemophilia diagnosis, treatment and care.

The EHC held its first Youth Leadership Workshop in 2014 to support young people from the haemophilia community in developing core skills that will help them be active participants and leaders for the community. The Sobi symposium slot at the EHC Annual Conference has been donated back to the EHC to host a Youth Leadership debate, with the objective of creating a platform where the EHC youth could put into practice the skills they have learnt. The EHC training and development offering has been further expanded in 2015 with the first EHC Leadership Conference, something that is set to continue on an annual basis.

So how do the EHC leaders and leaders of the future see the developments? EHC and Sobi invited award-winning film-maker Goran Kapetanovich to interview some of the current and future leaders to find out. We invite you to watch their stories to understand the role that the EHC's leadership development programmes are playing in contributing to the future of the haemophilia community.

Scan the QR code to see their stories


Ivan Šebest, Slovakia
youth delegate

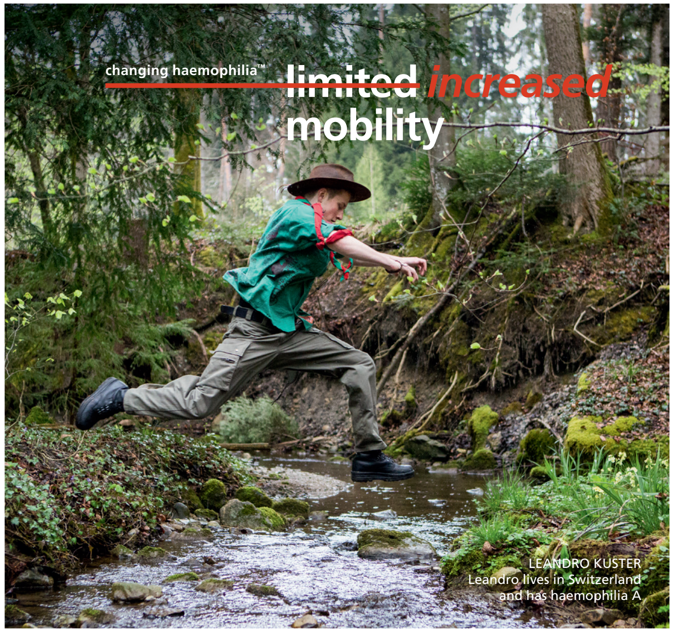

Stefan Radovanović, Serbia
youth delegate


Ilmar Kruis, Netherlands
youth delegate


Dr Paul Giangrande
EHC Medical Advisory Group


Brian O'Mahony
EHC President


Amanda Bok
EHC CEO



Together we are driving change in haemophilia

Novo Nordisk is committed to driving change in haemophilia. Our key contribution is to discover and develop effective and safe medicines for people with haemophilia and other rare bleeding disorders. But we know that to truly change haemophilia, we need to do more than supply the right medicines. That is why we work with our partners such as the European Haemophilia Consortium (EHC) to advocate for better access to diagnosis and multidisciplinary care.

Changing Haemophilia™ is our commitment to address the unmet needs in haemophilia.

Learn more at **novonordisk.com/changinghaemophilia**

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HQMMA/CH/0816/0163 Date of preparation: August 2016

EHC

european haemophilia consortium

www.ehc.eu