



2015

HAEi Annual Report



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Overview of HAEi

HAEi Vision

HAEi's global vision is to improve time to diagnosis and facilitate access to and reimbursement for treatment that enables lifelong health.

As a global umbrella organization, our objective is to develop a network of member organizations who advocate for HAE awareness and access to modern therapy. Currently, HAEi is represented in 51 countries worldwide.

In some countries we have fairly large member organizations while in others there are a few enthusiastic advocates. The prospect for expanding global access to HAE treatments motivates us to inspire the formation of new HAE advocacy groups, and to help existing member organizations expand their activities.

HAEi Mission

1. Helping to find, organize, and empower patients with an interest in forming new HAEi Member Organizations
2. Supporting our existing groups in their ongoing efforts to raise awareness, increase diagnosis, and improve patient access to and reimbursement for life saving therapies.

We do this through three areas of focus:

- Patient advocacy, empowerment and engagement
- Improving HAE standards of care
- Driving continuous improvement

Executive Director's Message



On behalf of the Executive Committee, this annual report sets out the progress that HAEi has made on many fronts this year and introduces the initiatives we want to take forward into 2016.

As a global umbrella organization, our objective is to develop a network of member organizations who advocate for HAE awareness and access to modern therapy.

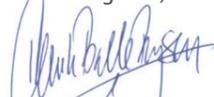
This year, we continued our efforts to develop Member Organizations in new countries, raise global awareness, and drive improvements in diagnosis and patient access to HAE treatments.

Some of our key achievements in 2015 included:

- welcoming 11 new HAEi Member Organizations,
- reaching thousands new HAE patients, clinicians and nurses with our meetings and workshops,
- our fourth global awareness day hae day :) supported by a revamped online platform, and
- overhauling our haei.org website and greatly adding to the written resources available there.

The HAEi team is proud to be part of the HAEi family. We constantly strive to improve the situation for HAE friends all over the world. Thank you to everyone who works with us and supports us to make this possible.

Warm regards,



Henrik Balle Boysen
Executive Director

President's Message



Thanks to the leadership of HAEi's Executive Committee and the hard work put in by the HAEi staff and patient advocates in our member organizations, 2015 was yet another busy and successful year. Our continued focus on helping new patient groups get started met with great success as 11 new member organizations joined HAEi creating global patient advocacy community that is now 51 nations strong.

HAEi's ultimate advocacy goal is to broaden access to modern HAE therapies. In 2015, we took a major step in that direction by introducing the HAEi Global Access Program (HAEi GAP) – a "first of its kind" patient group initiated method for bringing life saving HAE medicine to countries where modern therapies are not otherwise available. HAEi – together with the international specialty pharmacy Clinigen Group – has designed a model that initially features a 'Named Patient Program' where governments/hospitals can order and pay for HAE medicine. As the program matures, we plan to add two additional components – "Compassionate Use" that offers donated medication in areas where reimbursement is not possible, and an 'Early Access Program' where medication will be made available in conjunction with a phase II/III clinical trial.

As you will read in the following pages, during 2015 HAEi continued to vigorously fulfill its core mission of supporting member organizations through a wide variety of important activities including: Sponsoring Regional workshops attended by patients and health care professionals; publishing "State of HAE Management" reports for Europe and Latin America; and rolling out a comprehensive initiative to convince patients to get all family members tested for HAE.

While we continue to make good progress, we are motivated to take on the many challenges that face us. We are more committed than ever to leading aggressive advocacy efforts aimed at broadening access to life saving medicines in areas where limitations have a negative impact on patient quality of life. We look forward with enthusiasm to continue working with all of our stakeholders – member organizations, physicians, and pharmaceutical companies – to eliminate barriers that prevent access to life saving modern therapy

Warm regards,



Anthony J. Castaldo
President



Reaching new countries around the world

Supporting the development of new Member Organizations is one of HAEi's core activities. We actively seek out interested patients or physicians who wish to make a difference and establish a HAEi member organization HAE in their country.

In 2015 HAEi welcomed 11 new Member Organizations which brings our total number of Member Organizations to 51.

Initiating a new HAE group in any country takes time, dedication and partnership amongst many stakeholders. One country where HAEi sees an unmet need, but great potential in terms of HAE patient identification is the Philippines. The country has a strong medical infrastructure and an experienced organization that represents rare disease patients – the Philippine Society for Orphan Disorders (PSOD). HAEi is working with PSOD's President and an influential Physician/Board member to educate physicians, identify patients (we estimate there are 3,000 HAE patients in the Philippines), and establish a HAE patient group.

Current information on HAEi's global presence can be found at www.haei.org. The website includes an updated list of organizations by country, and

- a searchable map that includes
- a listing for each country including contact data for the Member Organizations, and
- information on care centers, hospitals, physicians, and trial centers, as well as available medications.

This year:

- 11 new Member Organizations established
- 51 HAE Member Organizations were established at the end of 2015

Next year:

- HAEi aims to increase the number of HAE Member Organizations
-

Supporting MOs around the world; Workshops

HAEi continued its strong support of its Member Organizations. For example, in 2015, we participated in Member Organization national meetings and conferences in Japan, Australia, Poland, USA and Denmark (HAE Scandinavia) helping to educate and empower over 1000 HAE patients.

In addition, we organized 3 regional workshops which brought together HAE patient advocates, nurses and physicians to meet and exchange information and ideas about HAE management and advocacy.

During the year, HAEi participated in the

- South Eastern European HAE Workshop for physicians in Macedonia,
- Belarusian and CIS HAE Workshop for patients in Belarus, and
- HAE educational meeting for physician, nurses and patients in Iceland.

This year:

- HAEi participated in 5 HAE Member Organization national meetings
- HAEi organized 3 regional workshops

Next year:

- Continue to participate in Member Organization national meetings
 - Organize 3-5 further regional workshops
 - Create the role of Regional Patient Advocates (RPA) to act as the bridge between HAEi and individual countries, to be in region and provide more local linguistic and cultural understanding. Secure 5 RPAs in 2016.
-



Supporting MOs and the HAE Family around the world

A key part of the HAEi support for Member Organizations and patients throughout the world involves sharing experiences and information primarily through www.haei.org. This year, HAEi redeveloped and relaunched the website that now includes new functionality to host Member Organization's country specific websites under the HAEi-umbrella - at no cost to the Member Organization. In 2015, Spain became the first Member Organization to have their country website, in Spanish, hosted and supported by HAEi.

A key section of [HAEi.org](http://www.haei.org) is the Resource Center. This part of the website covers four areas; Advocacy, Advice, Treatment, and World Map.

Within the Advocacy section HAEi hosts educational materials and this year we increased the number of publications available. For example, we launched the Support Family Testing package of materials which consists of three booklets designed to (1) help both physicians and families talk about what a diagnosis of HAE means, and (2) have the discussion to encourage blood relatives to be tested for HAE. Getting tested is an incredibly important first step in determining how best to manage this debilitating and potentially fatal disease.

2015 was a key year for our 'State of Management of HAE' advocacy publications. The first State of Management of HAE in Europe report developed in 2012 has been an invaluable advocacy and education tool, and it was essential to ensure it remained up-to-date. The Current State of HAE Management In Europe report launched this year, built on the 2012 report and included new burden of illness data. It also contained a new feature, HAEi's Modern HAE Management Principles which were based on recently published recommendations and consensus documents.

After seeing the usefulness of the European document, our Member Organizations in Latin America (LATAM) worked with HAEi to develop a report tailored to their region. HAEi supported a meeting of LATAM Member Organizations and the subsequent development of

the first report on 'State of Management of HAE in Latin America'. The document was launched in Spanish and English (a Portuguese version is to follow) and included the first survey data on the reality of living with HAE in LATAM countries.

In the Advice section, we increased our collection of patient stories addressing the reality of living with HAE and the importance of consistent access to modern HAE medication.

To ensure that HAE patients are able to keep up-to-date with the latest developments and information, we regularly updated the 'news and events' pages of www.haei.org.

Our HAEi newsletter is a key mechanism to share the latest news, patient stories, research and clinical trial news. The newsletter helps Member Organizations and all stakeholders to stay up-to-date.

New to the HAEi newsletter this year is a QA section, where key HAE physicians provide answers to HAE patient questions, and the introduction of both single page and magazine formats. HAEi also issued a short survey to understand what our readers like best about the newsletter and how they use it in their countries. This information will be used to inform the content and direction of the newsletters in 2016.

In 2012, HAEi launched the first **hae day :-)** The aim is to establish a global and national awareness day for HAE and gives Member Organizations an annual focal point for awareness and fundraising efforts. Member Organizations are able to use **hae day :-)** in different ways as their resources allow. To support a wide range of different potential activities, HAEi updated the Toolkit of documents and information to guide member organizations through key stages of organizing an event, raising awareness through the media and holding meetings with key physicians. For 2015 www.haeday.org was also redeveloped to include more patient stories and also a short video on the 'cover the world in smiles' campaign.

At the end of 2015, HAEi opened registration for the 2016 HAE Global Conference, which for the first time will include a participation event of walking part of El Camino de Santiago in the host country, Spain. This year much of the initial planning work for the conference took place but we look forward to showcasing a full update on the HAEi HAE Global Conference in our 2016 report.

This year:

- Revamped www.haei.org and hosted www.angioedema-aedaf.org the HAE Spain website through this platform
- Launched Supporting Family Testing, The Current State of Management of HAE in Europe and The State of Management of HAE in Latin America publications
- Revamped www.haeday.org
- 12 new patient stories hosted online
- 8 editions of the HAEi newsletter produced and distributed
- Planning and launch of registrations for 2016 HAE Global Conference and El Camino walk

Next year:

- Increase number of languages supported on [HAEi.org](http://www.haei.org)
- Increase number of Member Organization's with web presence hosted via [HAEi.org](http://www.haei.org)
- Co-ordinate and deliver HAEi central participation event El Camino Walk around hae day :-)
- Co-ordinate and deliver the 2016 HAE Global Conference
- Create a Global State of Management of HAE survey and report publication



Social Media

HAEi uses numerous social media channels to communicate with our global HAE family.



Follow us on Twitter:
<http://twitter.com/HAEDAY>



Join us on Facebook:
<http://facebook.com/groups/172320032283>



Visit our You Tube Channel:
<http://youtube.com/user/haedaychannel>



Join us on LinkedIn:
<https://www.linkedin.com/company/haei---international-patient-organization-for-c1-inhibitor-deficiencies>

Advocating for and supporting access to medicine



This year HAEi, in partnership with the international specialty pharmacy Clinigen Group, launched a unique Global Access Program (HAEi GAP). It is the first time that a patient group has initiated this type of medication distribution program.

The HAEi GAP model initially includes a 'Named Patient Program' where a doctor orders the medication and the government, hospital or the patient's medical insurance, pays for the cost of the medication. Later it is also planned to include a 'Compassionate Use Program' that offers donated medication to patients in parts of the world where this type of program is

allowed, and an 'Early Access Program' where access to medication will be given in conjunction with a phase III clinical trial.

The first pharmaceutical company to join HAEi GAP is Pharming Group. As a result, HAEi GAP enables patients in all countries where Ruconest© is not commercially available to gain access to the drug through an ethical and regulatory compliant "Named Patient Program" mechanism.

Find more information about the HAEi GAP on our website www.haei.org.



Advocating on behalf of patients by engaging healthcare professionals

As passionate patient advocates, HAEi constantly seeks input and collaboration with leading HAE experts. Attending medical conferences provides an efficient and cost effective way to interact with HAE key opinion leaders and other healthcare professionals. This year, HAEi attended the following meetings:

- American Association of Asthma, Allergy and Immunology (AAAAI), USA, 20-23 February
- International Plasma Protein Conference, organized by Plasma Protein Therapeutic Association, Italy, 9-12 March
 - HAEi participated in a Patient Advocacy Meeting organized by Plasma Protein User Group and Plasma Users
 - HAEi's Henrik Balle Boysen was elected to be part of the steering committee for PLUS
- 9th C1-inhibitor workshop, Hungary, 8-31 May
- European Academy of Allergy and Clinical Immunology (EAACI), Spain, 7-10 June
- Orphan Drug Summit 2016, Denmark, 16-17 September
 - HAEi hosted and participated in round-table discussion on patients' access to medication
- Week of Health and Innovation (WHINN), Denmark, 20-21 October
- EURORDIS Council of European Federations, France, 28-29 October
- Shire Global HAE Forum, Spain, 13-15 November
 - HAEi participated and presented at the meeting
- Middle East Asthma, Allergy and Clinical Immunology Conference, UAE, 11-13 December
 - HAEi distributed HAEi GAP flyer and met with the Gulf Region HAE patient representative to agree plans for patient identification, increasing HAE awareness and education

This year:

- Attended 9 HAE related medical conferences
- Held one-to-one meetings with several global HAE experts

Next year:

- Maintain attendance at HAE related medical conferences (global or regional)

Updates and looking to the future

HAEi Research Program

HAEi has created a grant program to support research that seeks to result in an improvement in the lives of the global HAE community. The grants were funded in 2014 and 2015. Subject to availability of funds, the grant program will be re-opened in 2016.

HAEi Regional Patient Advocate Training

5 Regional Patient Advocates will be selected in 2016. HAEi will conduct a Regional Patient Advocate workshop designed to support core skills required to fulfill the role and responsibilities in the regions.

HAEi Development Program

The development program is a dedicated fund to support patient identification, diagnosis, and formation of a member organization in less developed countries that have a health care infrastructure that recognizes the existence of rare diseases.

HAEi Research Catalogue

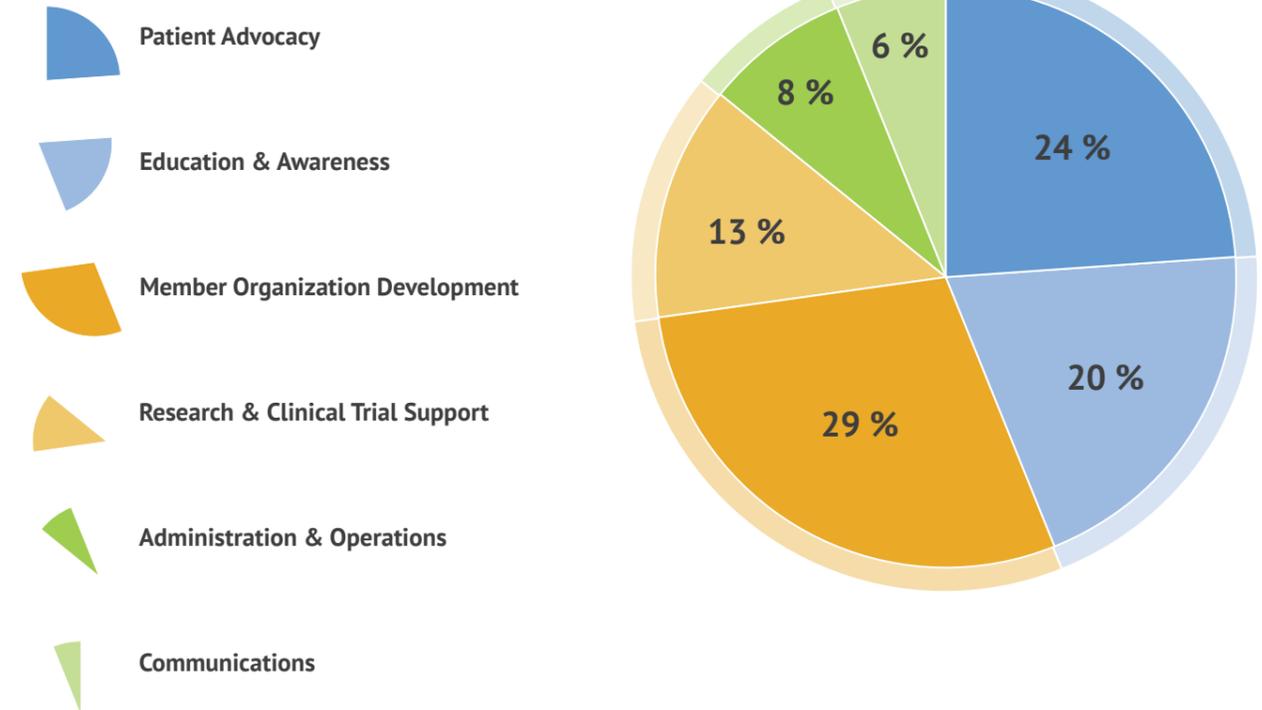
HAEi will collaborate with key research opinion leaders to create a catalogue that identifies the contents the world's HAE data and sample repositories. The goal is to create a central catalogue to facilitate sharing clinical and biological data needed to conduct innovative HAE research.





Fiscal Year 2015

HAEi Expenses by Key Activity Category





HAEi

HAEi is a global non-profit umbrella organization dedicated to working with its network of national HAE member organizations to raise awareness of HAE.



You are not alone

Corporate Information

HAEi is officially registered as a non-profit/charity organization in the Canton of Vaud in Switzerland.

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1006 Lausanne
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Corporate Registration Number:
CHE-160.474.141

Bank Connection:
UBS Nyon, Switzerland

EUR Account:
IBAN: CH06 0022 8228 1117 3360 T
SWIFT/BIC: UBSWCHZH80A

USD Account:
IBAN: CH54 0022 8228 1117 3361 Z
SWIFT/BIC: UBSWCHZH80A

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