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Annual Report

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This document was produced for review by the European Alliance for Vision Research and Ophthalmology (EU EYE), Belgium.

THE ORGANISATION

The EU EYE constituency comprises of ophthalmological societies representing over 9,000 medical specialists active in clinical medicine, research, education and training in 100 countries.
EU EYE works towards building a respected forum which brings medicine, science, education and advocacy together and is accessible to all – citizens, decision makers, research and healthcare workforce.

EU-EYE Full Members

- European Society of Retina Specialists **EURETINA**
- European Glaucoma Society **EGS**
- European Association for Vision and Eye Research **EVER**
- European Eye Bank Association **EEBA**
- European Society of Cornea and Ocular Surface Disease Specialists **EuCornea**
- European Association for the Study of Diabetes/Ophthalmology Section **EASDec**
- European Paediatric Ophthalmological **EPOS**
- European Vision Institute **EVI**
- European Vision Clinical Research network **EVICR.net**

EU-EYE Associate Members

- COST Action CA18116 Aniridia network **Aniridia-Net.eu**

EU-EYE Board

Carlo Traverso	President/EGS Representative
Jesper Hjortdal	Secretary / EEBA Representative
Martin Zinkernagel	Treasurer / EASDec Representative
Thomas Fuchsluger	Board Member / EVER Representative
José Güell	Board Member / EuCornea Representative
Darius Hildebrand	Board Member / EPOS Representative
Hendrik Scholl	Board Member / EVI Representative
Marie-José Tassignon	Board Member / EVICR.net Representative

General Assembly Representatives

Current Board Members represent their individual organisations at the General Assembly. Associate member Aniridia-Net is represented by Neil Lagali.

EU-EYE Objectives

We advocate for people-centred eye health care and have an ongoing commitment to the integration of research priorities, policies and strategies in eye health at European level.

Our varied portfolio of activities aim to open up the space for the patient empowerment process and the creation of new translational and fundamental research networks in our discipline.

ACRONYMS AND ABBREVIATIONS

aces-rwm	Automation in care and evaluation of system with real world monitoring
ACT-EU	Accelerating Clinical Trials in the EU
ATMPs	Advanced therapy medicinal products
CLEO	Council of Lived Experience in Ophthalmology
DG SANTE	Directorate-General for Health and Food Safety
EC	European Commission
ECHA	European Chemicals Agency
EHDS	European Health Data Space
EMA	European Medicines Agency
EORTC	European Organisation for Research and Translational of Cancer
EIS	EURETINA Innovation Spotlight
EXPAMED	Experts in Medical Devices
HaDEA	Health and Digital Executive Agency
HCP POG	Healthcare Professionals Policy Officer Group
HCPWP	Healthcare Professionals Working Party
HPP	Health Policy Platform
HTA	Health Technology Network
MEP	Member of European Parliament
MSP AG	Multi-stakeholder Advisory Group
PCWP	Patients and Consumers Working Party
PFAS	Per-and poly fluoroalkyl substances
SmPC	Summary of Product Characteristics
SoHO	Substances of Human Origin

Summary

In September 2024 EU EYE was selected as an ad hoc member of the MSP AG of the ACT EU initiative of EC in addition to its membership to the HPCWP of the EMA and the HTA Stakeholder Network. The organisation led a coalition of 12 organisations in support of the Hospital Exemption Regulation in the revised pharmaceutical legislation with active participation in workshops organised by the HaDEA/DG Health and Food Safety. Engagement continued with the EHDS Stakeholder group and with EURETINA on the PFAS topic. EU EYE presented its work at the EIS, EURETINA 2024, Barcelona.

EU EYE Activities 2024

1. General Organisation

In 2024, the highlight was the selection of EU EYE as an ad hoc member of the ACT EU Multi-stakeholder Advisory Group of the ACT EU initiative of the European Commission with Luc Van Os as the EU EYE representative.

The informal alliance on Hospital Exemption Regulation which was formed in 2023, grew unexpectedly in 2024 when the Lymphoma Coalition joined EU EYE in co-leading the group of key stakeholders in the healthcare ecosystem at both the European Union and Member State level. The group grew over the year comprising of the following health care professionals' associations, patient organisations and national competent authorities for organs, tissues and cells:
European Haematology Association
Association of European Cancer Leagues
European Society of Paediatric Oncology
European Paediatric Translational Research Infrastructure
Centro Valutazioni Biologiche e Farmacologiche
European Association of Hospital Pharmacists
European Blood Alliance
Advanced Cell Therapy Centre of the Finnish Red Cross Blood Service] .
European Eye Bank Association
European Society for Organ Transplantation
European Association for Clinical Pharmacology and Therapeutics
Spanish Advanced Therapy Network
European Committee on Organ Transplantation.
National Transplant Organisation, Ministry of Health, Spain.
Aniridia Europe
Core SoHO consortium

The collective efforts of the group were intensified in support of the retaining of an unrestricted Hospital Exemption Regulation for the ATMPs in the revised pharmaceutical legislation. The Joint Statement on Hospital Exemption was updated to reflect the perspectives of the additional organisations and presented to the relevant units of the European Commission, members of the European Parliament and the European Health Committee of the Council of Europe. EU EYE was pleased to see that the positions of the joint statement were reflected in the compromise text on the directive following the vote of the ENVI Committee in March 2024 and the European Parliament vote on the pharmaceutical package in April 2024: the Hospital Exemption regulation is preserved unrestricted within the Member States as the national authorities see fit for their healthcare systems and its implementation is strengthened

even for cross border care delivery[1]. Together with the other organisations, EU EYE pledged to continue their efforts to ensure the Council's support for the Hospital Exemption regulation in the final stage of the trilogues: the joint statement was disseminated further to the European Health Committee of the Council of Europe and the ministries of research and development of the various Member States.

Attention was drawn by EURETINA on the proposed universal ban on PFAS and the work of the EURETINA consensus panel under Mario Romano on the topic. EU EYE supported EURETINA in this exercise by providing advice on the strategy and the evidence needs for derogation for PFAS use in ophthalmology in general. The EURETINA panel on PFAS is to agree on evidence-based recommendations regarding use and risks of PFAS in vitreoretinal surgery aiming to a more sustainable surgical practice.

Dominique Brémond-Gignac and Mor Dickman continued as the clinical representatives of the EU EYE to the working meetings of the HPCWP of the EMA. Additionally the appointment of Dominique Brémond-Gignac was renewed in EXPAMED, the expert panels in the field of medical devices of the European Commission. EU EYE continued to provide clinical and patient expertise to the EMA and the work of eligible organisations was acknowledged in the EMA report entitled EMA's biennial report on stakeholder engagement activities 2022-2023. Participation in the HCP POG as continued as follows:

- EU EYE joined the drafting group for the review of the EMA Engagement framework with healthcare professionals and their organisations and submitted a detailed report on the existing framework based on the experience and involvement in a) product-related assessments and b) general policy discussions such as the Clinical Trials;
- within the Healthcare Professionals Policy Officers' Group (HCP POG) of EMA, work continued on academic stream on surrogate endpoints and new ways of conducting clinical trials continued with also the intention to join the Shortages of Medicines drafting group to advocate that there is a need to address the gap in terminology as the current definition of shortages does not necessarily apply to shortages of medical devices;
- discussions with other eligible organisations of the EMA on issues faced by clinical researchers with the new Clinical Trials Information System, resulted in the EU EYE applying to the MSG of the ACT EU initiative.

[1] The compromise text on the directive can be accessed at: https://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/ENVI/AMC/2024/03-19/Pharma_Directive_Final_CA_EN.pdf; inks presenting various views on the new legislation: https://www.sidley.com/en/insights/newsupdates/2024/03/uneasy-compromises-100-amendments-to-the-eus-pharmaceutical-review; https://www.euractiv.com/section/health-consumers/news/compromises-on-the-pharma-package-provide-balance-say-meps-ahead-of-envi-vote/

EU EYE joined the core drafting group of the EHDS Alliance and worked on updating the original joint statement of the group and disseminating the EHDS Joint Statement to the Members of the European Health Committee. The EHDS Alliance expressed concerns following the announcement by the European Commission that the e-health stakeholder group ceases to exist end of 2025 with ad-hoc exchanges planned in 2026 until the launch of the EHDS stakeholder forum in 2027. The updated EHDS joint statement appeared in Politico's issue 24 April 2024 and called for the European Commission to:
- address the risk of a fragmented interpretation and implementation of opt-out and opt-in mechanisms;
- provide clear information to patients;
- enhanced legal clarity & improved definitions;
- limit the additional burden on healthcare professionals and
- ensure systematic stakeholder involvement in the implementation/operation phases.

Awareness of the EU EYE work at EU level among the greater ophthalmology community was increased thanks to a session presented at the EIS, EURETINA 2024, Barcelona. Entitled, EUEYE: from bench to bedside to policy innovation and back, the session presented key elements of the work with the EU institutions and agencies in the co-designing of policy innovation to improve health outcomes in EU while empowering the ophthalmology community in the political process.

In November 2024, EU EYE welcomed **Marie-José Tassignon** as the nominated representative of EVICR.net. EU EYE updated its entry in the EU Transparency Register and it continued as a registered user of the Health Policy Platform (HPP) of the European Commission.

External and internal individual inquiries on policy, applications and other matters increased considerable compared to the previous year with invitations to provide input to projects such as Real4Reg[2]; and studies such as the **Deployment of Artificial Intelligence (AI) in Healthcare[3];** or participation in high level events such as the Research Infrastructures in a Changing Global, Environmental and Socio-economical Context organised by the Belgian Presidency.

[2] a consortium of ten European institutions which aims to promote the use of real-world data (e.g. national healthcare registers and claims data) in regulatory decisions about medicines.

[3] This study of the European Commission aims to identify and assess the most prominent sector-specific challenges and the accelerators for the deployment of artificial intelligence (AI) in healthcare both within the EU and internationally.

Work on setting up the EU EYE Internal Communications Group and the Council of Lived Experience in Ophthalmology (CLEO) by the EU EYE Working Group (WG-CLEO)[4] were finalised with the aim for the ICG will become fully operational during 2025 and CLEO in 2026. The ICG aims to improve awareness among the greater ophthalmology community about policy developments through timely alerts with a series of briefings focussing on emerging concerns of patients, healthcare professionals in ophthalmic practices and researchers.

Compared to 2023, the overall website traffic is doubled in 2024 from 87 countries with the USA, Poland, UK, China and The Netherlands being the main locations. Poland showed an impressive 4000% increase in first time users with 150% for USA and 125% for UK. The EU EYE's social media profile has shown a slight increase with EU EYE LinkedIn having 144 followers.

2 ADVOCACY

In 2024 the advocacy efforts of EU EYE were strengthened by the following external experts who participated in various workshops of the European Commission and the EMA:

Barbara Poli, Italy and Ivana Kildsgaard, Sweden Aniridia Europe
Anja Tuulonen, Project Lead of aces-rwm TM[5], Tampere University Hospital, Finland
Erja Kerkelä, Advanced Cell Therapy Centre, Red Cross Blood Service, Finland
Chiara Del Noce and Aldo Vagge, University of Genoa, Dipartimento di Neuroscienze, riabilitazione, oftalmologia, genetica e scienze materno-infantili (DINOGMI), Italy.
Hilary Grabe, Universitätsklinik für Augenheilkunde, Inselspital, Bern, Switzerland
Carlo Catti, San Martino Hospital, Genova, Italy
Tom Bailey, Faculty of Health, Medicine and Life Sciences, Maastricht University, The Netherlands.

Public consultations, workshops and events

Engagement continued with the consultation and decision-making process of the EU institutions and its agencies through participation in the following:

[4] The WG-CLEO was established in August 2021 with the aim to set a loose basis for CLEO, propose inclusion criteria and short-term tasks and provide support when needed. Once CLEO is formed, its members will decide an appropriate organisational structure (formal or informal); refine concepts involved; and generate solutions for the expansion of CLEO. It is hoped that CLEO will address existing gaps in policy for all eye diseases such as lack of awareness about the challenges patients and their carers face (available therapies, reimbursement, etc); improve communications with citizens regarding eye health; and integrate in research, the needs, perspectives and expectations of different groups as far as it is possible (age, ethnic, groups including vulnerable populations such as children, elderly etc).

[5] aces-rwm TM is a health collaborative ecosystem by all public eye clinics of Finish university hospitals aiming at real-world monitoring for a holistic care delivery model for eye diseases.

- perspectives of healthcare professionals on biosimilars (EMA);
- first union list of Critical Medicines (EMA);
- Metamizole-containing medicinal products review (EMA);
- Multi-stakeholder workshop on Patient Registries (Joint Heads of Medicines Agencies/EMA);
- Early contact/3rd Party interventions on Thyroid Eye Disease; teprotumumab (EMA);
- Updating 2019 SCHEER Guidelines on benefit-risk of phthalates in certain medical devices. (Scientific Committee on Health, Environmental and Emerging Risks)
- AUGMENT Biosimilars Survey[6];
- Austrian National Public Health Institute survey for health services providers as part of the study to monitor the availability of medical devices and in vitro diagnostic medical devices on the EU market;
- Tissues and Cells thematic focus groups, ReaderSHip Project (DG SANTE);
- Implementation of the Hospital Exemption in the EU and its role in boosting innovation and patient access to innovative therapies event & thematic workshop on how the HE enables the translation of deep science into innovative products (DG SANTE).

A number of consultations targeting individual healthcare professionals were also disseminated such as the ReaderSHIP project survey for hospital managers and professionals collecting, preparing, and using different SoHO in their daily activities.

[6] In 2024, the AUGMENT Consortium was commissioned by the European Health and Digital Executive Agency (HaDEA) to conduct the project "Capacity building to support the uptake of biosimilars in a multistakeholder approach".