ID in Transparency Register: 221589017973-83

Annual Report

[2023] – 1st January to 31st December 2023

Submission Date: 25 March 2025

Agreement Number: EUEYE-900-2023
Activity Start Date and End Date: 01 January 2023 to 31 December 2023
AOR Name: Tanja Mitrovic

Submitted by: Ioanna Psalti
Dime Limited
74 Oxford Road, Littlemore Oxford, OX4 4PE, UK
Tel: 0044 1865 711594
Email: ismp@dimeltd.com

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.
The 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 Cataract and Refractive Surgeons **ESCRS**
- 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
Paul Rosen	Vice-President / ESCRS Representative
Jesper Hjortdal	Secretary / EEBA Representative
Tunde Peto	Treasurer / EASDec Representative
Martin Zinkernagel	Board Member / EURETINA Representative
Thomas Fuchsluger	Board Member / EVER Representative
Marie-José Tassignon	Board Member / ESCRS Representative
José Güell	Board Member / EuCornea Representative
Darius Hildebrand	Board Member / EPOS Representative
Hendrik Scholl	Board Member / EVI & 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 have an ongoing commitment to the integration of research priorities, policies and strategies in eye health at European level.
We advocate for people-centred eye health care and we maintain a varied portfolio of activities with the 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

ACT-EU	Accelerating Clinical Trials in the EU
CLEO	Council of Lived Experience in Ophthalmology
DG SANTE	Directorate-General for Health and Food Safety
ECHA	European Chemicals Agency
EHDS	European Health Data Space
EHPA	European Association of Hospital Pharmacists
EMA	European Medicines Agency
EPTRI	European Paediatric Translational Research Infrastructure
ESC	European Society of Cardiology
HaDEA	Health and Digital Executive Agency
HCP POG	Healthcare Professionals Policy Officer Group
HCPWP	Healthcare Professionals Working Party
HMA	Heads of Medicines Agencies
HPP	Health Policy Platform
MEP	Member of European Parliament
PCWP	Patients and Consumers Working Party
PFAS	Per-and poly fluoroalkyl substances
SIOPEurope	European Society for Paediatric Oncology
SmPC	Summary of Product Characteristics
SoHO	Substances of Human Origin

Summary

In 2023 EU EYE was selected as a member of the HTA Network of the European Commission in addition to membership to EMA's HPCWP. Engagement expanded to ECHA due to the proposed universal restriction on per- and polyfluoroalkyl substances and its impact on eye surgery. Invitations were received to the DG SANTE/HaDEA Hospital Exemption Study and the ReaderSHip Project on the SoHO management in hospitals. Work continued with the EHDS Stakeholder Group and the TRANSFORM Alliance on the respective legislations with the publication of EU EYE's first joint position paper on the ATMP Hospital Exemption regulation together with EHPA, EPTRI and SIOPEurope. The EU EYE work at EU level enjoyed increased visibility among the greater ophthalmology community thanks to a series of EUROTIMES articles.

EU EYE Activities 2023

1. General Organisation

The highlight in 2023 was the formation of a new informal alliance around the EU EYE work on Hospital Exemption Regulation together with the European Association of Hospital Pharmacists (EHPA), the European Paediatric Translational Research Infrastructure (EPTRI) and the European Society for Paediatric Oncology (SIOPEurope) with the European Blood Alliance and the European Society for Organ Transplantation expressing intention to join in late 2023. The aim of the alliance is to overturn the Amendments 30 and 31 of the Draft Report Pharmaceutical Package directive/ENVI committee, European Parliament which would result in a total restriction of the implementation of the Hospital Exemption Regulation in the EU. Following the publication of the Hospital Exemption joint position paper, EU EYE intensified its proactive communication with the European Commission including Ms Gallina, Director, DG Sante and Ms Kyriakides, Health Commissioner and DG SANTE (Health and Food Safety) Unit B4 regarding the concerns of the healthcare professional organisations about the future of the Hospital Exemption regulation.

Involvement continued with both the EHDS Stakeholder Coalition[1] focused and the TRANSFORM Alliance MEP Interest Group[2] in the respective legislations: on the draft of a second joint statement on the implementation of EHDS with the former coalition and supporting the advocacy efforts of the latter group with Dominique Brémond Gignac as a key panelist in the roundtable discussions in France entitled Colloque : l'Union européenne, un espace de recherche et d'innovation pour les thérapies géniques et cellulaires organised by the TRANSFORM group in July 2023.

Dominique Brémond-Gignac and Mor Dickman continued as the EU EYE clinical representatives to the working meetings of the HPCWP of the EMA. In addition Mor Dickman was nominated as the Healthcare Professionals Working Party observer in the EMA's Executive Steering Group on Shortages of Medical Devices (MDSSG). Ioanna Psalti, the strategy and policy advisor to the EU EYE, continued the work with the Healthcare Professionals Policy Officers' Group (HCP POG[3]) of EMA which included the

---

[1] The EHDS Stakeholder Coalition is an informal alliance of 35 large health stakeholder organisations representing patients, health professionals, researchers, and industrial actors throughout the healthcare ecosystem at both European Union (EU) and Member State levels. The group is led by the European Association of Urology and provides targeted input on the challenges of the implementation of the European Health Data Space.

[2] TRANSFORM Alliance is a multi-stakeholder Alliance connecting Members of the European Parliament (MEPs), policy-makers, patient groups, medical experts and associations, scientists, researchers, industry actors, networks and other relevant stakeholders.

[3] HCP POG is composed of policy officers of the EMA eligible organisations who act as the single point of contact for EMA activities. They can be either a healthcare professional or individuals with other background who liaise within their network to gather input on a topic of interest or identify experts.

co-leading of the academic stream on surrogate endpoints and new ways of conducting clinical trials, together with the European Society of Cardiology; and providing input to the academic work stream on 'pharmacovigilance with focus on medication errors' Other regulatory work with the EMA included participation of EU EYE in the HMA/EMA Big Data Stakeholder Forum; the EMA's framework of engagement with healthcare professionals; and providing clinical and patient expertise to the EMA for their marketing authorisation process.

Work expanded further from the regulatory aspects of therapies to reimbursement challenges: EU EYE was appointed as a member of the Health Technology Assessment (HTA)Stakeholder Network of the European Commission with João Barbosa Breda as the EU EYE clinical representative in the launch meeting of the network.

The EU EYE Working Group (WG-CLEO), which was established in August 2021[4], continued the discussion on operational factors of the Council of Lived Experience in Ophthalmology (CLEO). However recruiting patients for the pilot was proven more challenging than originally thought and the launch of CLEO is now expected in 2025 instead of 2024.

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.

Following the increase in visibility of the EU EYE work among the ophthalmology community as a result of manning a booth at the EURETINA Congress in Hamburg 2022, the EU EYE planned presentation was scheduled for the 24th Euretina Congress in Barcelona in 2024. Additionally, there was an increase in awareness about the EU EYE among the greater ophthalmology community thanks to a series of EUROTIMES articles, namely Ensuring Safe and Timely Access to Advanced Cell and Gene Therapies and Newsmaker Interview: Who is Looking Out for Ophthalmology?.

External and internal individual inquiries on policy, applications and other matters increased from 2023. The EU EYE's social media profile in LinkedIn has doubled its followers compared to 2022. The overall website traffic was decreased by 50% possibly because of a temporary pause in the production of the Focus EU, the EU EYE newsletter on policy developments in the EU and across the world. User locations are mainly the USA, UK, China and The Netherlands.

[4] The WG-CLEO aims 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).

2 ADVOCACY

In 2023 the advocacy efforts of EU EYE were strengthened by the following external experts:

Hilde Beele, Universitair Ziekenhuis Ghent, Gent, Belgium
Mario Romano, Humanitas University, Milan, Italy
David Steel, Sunderland Eye Infirmary and Newcastle University, UK
Massimo Nicolò, University Eye Clinic, Genova, Italy
Anniken Burés Jelstrup, Instituto de Microcirugía Ocular, Barcelona, Spain

Public consultations

Engagement continued with the decision making process of the EU institutions and its agencies through submission to key public consultations on the following topics:

- Transparency rules of Clinical Trials Regulation (CTR) and CTI System (EMA);
- Outer packaging warning for opioid-containing medicines regarding their risk of opioid use disorder (Pharmacovigilance Risk Assessment Committee, EMA);
- Assessment of SmPC section 5.1 (Committee for Medicinal Products for Human Use, EMA);
- Universal Restriction of PFAS in the EEA under the REACH Regulation (ECHA);
- Final consultation of the European Commission on the revision of the EU general pharmaceutical legislative package [both proposal for a Directive (2023/0132) on medicines, with an emphasis to driving innovation and access towards medicines for children and rare disease patients, and the proposal for a Regulation (2023/0131) on what, how and when medicines are authorised and supervised in the EU];
- First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU (targeted stakeholder consultation, EMA).