



European
Council of
Optometry
and Optics



EUROPEAN HEALTH DATA SPACE (EHDS)

Guidance for ECOO members

Prepared by the ECOO IT Working Group
June 2026

AT A GLANCE

Regulation number	EU 2025/327
Full title	Regulation (EU) 2025/327 on the European Health Data Space
Published	5 March 2025 (EU Official Journal)
Entered into force	26 March 2025
Scope	All 27 EU Member States; non-EU countries may associate from approximately 2035
Structure	Two pillars: primary use (patient care) and secondary use (research, policy, AI)
Cross-border platform	MyHealth@EU: the EU infrastructure through which health data is shared across borders

WHAT IS THE EUROPEAN HEALTH DATA SPACE?

The European Health Data Space (EHDS) is the EU's first sector-specific data space. It establishes a common EU-wide legal, technical and governance framework for accessing, managing and sharing electronic health data across all 27 Member States.

The regulation was adopted by the European Parliament in April 2024 and by the Council in January 2025. It entered

into force on 26 March 2025. It builds on the existing MyHealth@EU cross-border infrastructure and amends the cross-border healthcare directive (2011/24/EU).

The EHDS applies to all healthcare providers, including optometrists and opticians as health data holders. It is built around two pillars: primary use and secondary use.



01 PRIMARY USE: PATIENT ACCESS AND CROSS-BORDER CARE

The primary use pillar empowers individuals to access, control and share their own health data for the purpose of direct care. It establishes the rights and infrastructure to allow patients to make their records available to healthcare professionals anywhere in the EU.

What it means in practice

- Every EU citizen will have access to a digital personal health data space to view their own electronic health records
- Patients will be able to share their records with any registered healthcare provider in any EU country through MyHealth@EU
- Data is exchanged in standardised, interoperable formats i.e. records created in one Member State can be read and used in another
- Patients have the right to download their data, restrict access to specific records or providers and request corrections

Health data covered: phased schedule From March 2029:

- Patient summaries (key conditions, allergies, current medications)
- ePrescriptions and eDispensations
- Laboratory results and reports

From March 2031:

- Medical images and image reports (X-rays, MRI, retinal imaging)
- Hospital discharge reports
- Additional national data categories designated by Member States

MyHealth@EU: what it is and how practices will interact with it

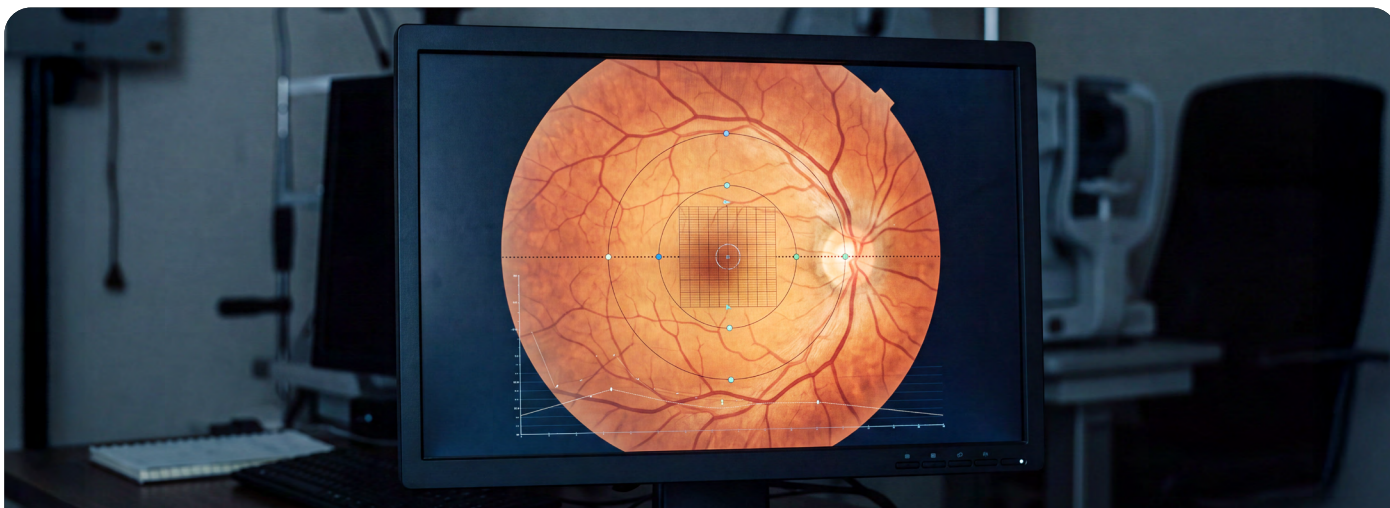
MyHealth@EU is the EU-level digital platform through which patient health data is exchanged across borders. It already exists, it has been operating since 2019 under the name eHDSI (eHealth Digital Service Infrastructure) and is being significantly expanded under the EHDS.

- From 2029, when an EU patient attends your practice and wishes to share their health summary, they will present it via MyHealth@EU either through a patient-facing app or portal, or through a link your EHR system can access
- Your EHR system will need to be integrated with the national node of MyHealth@EU to send and receive patient data cross-border
- Incoming records may be in any EU language; standardised formats (HL7 FHIR) are designed to be machine-readable so your EHR system can process them even if the language differs
- You will not need to access MyHealth@EU directly as a practitioner, this is handled through your certified EHR system

Implications for optometrists and opticians

- Eye health records (visual acuity, refraction, intraocular pressure, retinal findings) must be captured in structured, standardised data fields, i.e. not only in free text, to be shareable under EHDS
- Strict data governance will become mandatory, not optional. Many EHR systems today mix designated data fields with open-text fields, and clinicians often use them inconsistently, even within the same practice. Under EHDS, data entered only in free text will be invisible to automated data exchange and excluded from national datasets. As changing this habit may take time, associations should begin raising awareness with members now, regardless of the formal compliance timeline.
- EHR systems used in practice must be certified for EHDS interoperability; vendors were required to initiate this process by January 2026

- Opticians hold patient records (dispensing records, optical prescriptions, measurements) that may be classified as health data under national implementation, national associations should seek clarity on whether dispensing opticians are formally within scope
- Whether optical prescriptions (spectacles, contact lenses) fall under the EHDS ePrescription provisions is a current question that will depend on national implementation, associations should engage with national authorities to clarify this
- Patients will have stronger rights over their eye health data, update consent notices and information leaflets accordingly
- Practices may receive patients from other EU countries with digital health summaries, establish a process for reviewing these



02 SECONDARY USE: RESEARCH, POLICY, AND AI

The secondary use pillar allows anonymised or pseudonymised health data to be accessed by authorised parties such as researchers, public health authorities, regulators and industry, for purposes beyond direct patient care.

How it works

- Authorised users (researchers, public health bodies, health technology assessment bodies, companies) apply to access data through national Health Data Access Bodies (HDABs)
- Access is granted for specific approved purposes: scientific research, health technology assessment, policy development, regulatory approvals, AI training
- Data must be used in a secure processing environment and cannot be used to disadvantage patients (e.g. insurance profiling or targeted advertising are prohibited purposes)
- Patients in most Member States will have the right to opt out of their data being used for secondary purposes, the precise mechanism (opt-in vs opt-out) varies by country

Data covered

- Electronic health records (phased from 2029 to 2031)
- Disease registries and health surveys
- Health insurance claims and reimbursement data
- Data from connected medical devices and digital health applications
- Genomic data and clinical trial data (from March 2031)

Implications for optometrists and opticians

- Clinical data held in practice EHR systems, including retinal images, visual field results, and examination findings, may be included in secondary use datasets depending on national implementation
- The quality and completeness of records held in practice directly affects the value and representativeness of optometric data in national datasets i.e. poorly structured records will be excluded
- AI tools for eye care (retinal screening for diabetic retinopathy, glaucoma, AMD) are likely to be trained using EHDS secondary use data, the profession has a stake in ensuring optometric data is included and that AI tools are validated appropriately
- As a health data holder, your practice must be able to respond to requests relating to secondary use access, opt-out requests from patients and audits by the national HDAB
- The EHDS secondary use framework operates alongside the EU AI Act: AI tools used for clinical decision support are classified as high-risk and must meet requirements for transparency, accuracy and human oversight

EHDS and GDPR: How they interact

The EHDS does not replace or override the General Data Protection Regulation (GDPR). The two frameworks operate in parallel:

- Health data remains special category data under Article 9 GDPR, the existing protections and processing conditions continue to apply
- The EHDS provides the additional sector-specific legal basis and technical framework for health data access and sharing that goes beyond what GDPR alone enables
- Patient rights under EHDS (access, download, restriction, correction, opt-out from secondary use) are additional to, not a replacement for, existing GDPR rights
- Practices remain data controllers under GDPR and must continue to maintain records of processing activities, appoint a data protection officer where required, and uphold data minimisation and purpose limitation principles
- National data protection authorities and the new National Digital Health Authorities will coordinate on enforcement where both frameworks overlap
- Several Member States have enacted national health data legislation that goes beyond GDPR's baseline requirements, for example, stricter rules on consent for secondary use, additional patient rights or more restrictive conditions on data sharing. These national differences will interact with EHDS implementation and may result in varying obligations for healthcare providers across countries. National associations should monitor how their country's legislation intersects with both GDPR and the EHDS, and advise members accordingly.

IMPLEMENTATION TIMELINE

26 March 2025	Regulation (EU) 2025/327 enters into force
June 2025	Each EU Member State required to appoint a National Digital Health Authority (NDHA)
January 2026	EHR vendors required to certify systems for EHDS interoperability compliance
2025-2027	Secondary legislation phase: Commission drafts implementing and delegating acts
2027-2029	Member States establish national health data access bodies and data hubs
March 2029	Primary use live: patient summaries and ePrescriptions across all EU states. Secondary use rules apply for most EHR data categories
March 2031	Primary use extended to medical images, laboratory results, hospital discharge reports. Secondary use extended to genomic and clinical trial data

WHO IS AFFECTED?

Healthcare providers in EU Member States

- All registered healthcare providers, including optometrists and optical practices, are directly in scope as health data holders
 - Opticians who are healthcare providers under their national law are also in scope. The extent of obligations depends on national classification of optical records as health data
 - EHR system manufacturers and vendors must certify their systems for EHDS interoperability
 - Digital health companies, app developers and connected device manufacturers are also in scope
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Researchers and secondary data users

- Academic institutions, public health authorities, health technology assessment bodies, and industry can apply to access anonymised health data through national Health Data Access Bodies
 - Insurance companies and other entities processing health data within the EU are subject to EHDS governance obligations
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Non-EU countries

- The EHDS Regulation does not directly apply to non-EU countries
- Non-EU health data holders are excluded from the secondary use framework unless their country has a reciprocal access agreement with the EU
- Non-EU countries may apply to associate with the EHDS framework from approximately 2035
- Practical convergence toward EHDS data standards is expected through market forces and international research collaboration
- Norway: Norway is not an EU Member State but participates in the EU internal market through the European Economic Area (EEA) Agreement. The EHDS Regulation has been formally designated as EEA-relevant, meaning it is expected to be incorporated into the EEA Agreement and become binding in Norway, Iceland and Liechtenstein once a formal EEA Joint Committee decision is adopted. The Norwegian Health Directorate has been tasked with analysing the regulation's impact. Norwegian practices and associations should treat EHDS obligations as highly likely to apply and monitor the formal EEA incorporation process closely.

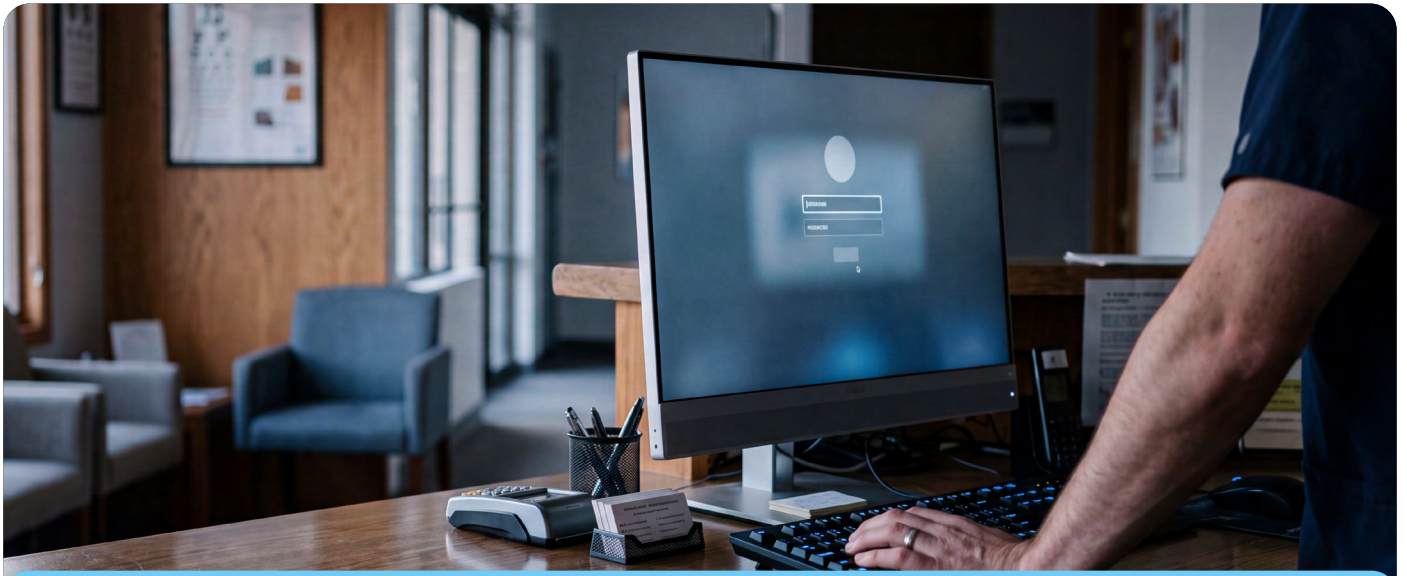
- **UK:** Following Brexit, the UK is a third country and the EHDS Regulation does not apply directly. The European Commission's ability to formally recognise third countries such as the UK for participation in EHDS is deferred for ten years from entry into force (i.e., not before approximately 2035). However, UK-based health data users may still be able to participate in EHDS data access mechanisms where their country is separately recognised as providing reciprocal access. The College of Optometrists has already engaged with the question of national EHR standards for eye care. Voluntary convergence toward EHDS data standards may be beneficial for cross-border research and industry purposes. UK associations should monitor EU-UK data-sharing negotiations for any developments relevant to health data.
- **Switzerland:** Switzerland is neither an EU Member State nor part of the EEA and is therefore a third country under the EHDS framework. Like the UK, formal third-country participation in HealthData@EU is not possible before approximately 2035. However, Switzerland is developing its own Swiss Health Data Space (SHDS) under the DigiSanté programme, with governance structures explicitly designed to align with EHDS in order to facilitate future integration. Swiss associations should track the SHDS programme as well as any bilateral agreements with the EU that may affect health data exchange.

NEW PATIENT RIGHTS

From March 2029, EU citizens will be entitled to:

- Access their electronic health records through a personal health data space, free of charge
- Share their records electronically with any registered healthcare provider in any EU country via MyHealth@EU
- Download their health data in a standardised, machine-readable format
- Restrict access to specific data items or to specific healthcare providers
- Request corrections to health records that are inaccurate or incomplete
- Opt out (or opt in, depending on the Member State) of their data being used for secondary purposes such as research or AI development
- Receive clear information about who has accessed their data and for what purpose

Member States retain discretion over some of these rights, for example, whether secondary use operates on an opt-in or opt-out model. Optometrists and associations should monitor national implementation to understand how rights operate in each country and update patient-facing materials accordingly.



PRACTICE OBLIGATIONS: DATA SECURITY

The EHDS places security obligations on practices as health data holders, not only on EHR vendors. Practices should:

- Ensure their EHR system is being updated toward EHDS interoperability and security certification
- Conduct a basic review of data security practices: access controls, password policies, software update schedules, and backup procedures
- Report any personal data breaches to the relevant national supervisory authority within 72 hours as required under GDPR, this obligation continues unchanged
- Be aware that healthcare data is a high-value target for cybercriminals; practices should ensure they are covered by current national cybersecurity guidance
- Understand that as a data controller, the practice is accountable even if a data breach originates with a vendor or third-party system



WHAT NATIONAL ASSOCIATIONS SHOULD DO

ECOO member associations play a critical role in ensuring optometry's and opticianry's voice is heard in the national implementation of the EHDS. The table below sets out recommended actions:

- Identify and engage with your National Digital Health Authority (NDHA)
- Advocate for inclusion of optometry and eye health data fields in national patient summary templates
- Ensure opticians and optometrists are included in national EHDS scope discussions, not just ophthalmologists.
- Monitor EHR vendor certifications relevant to optometry and opticianry practice
- Update member guidance on patient data rights and consent obligations
- Clarify with national authorities whether optical prescriptions fall under EHDS ePrescription provisions
- Feed national EHDS developments back to ECOO ITWG twice yearly via the biannual survey

PRACTICE CHECKLIST

The following checklist is intended as a practical starting point for individual practices:

- Check with your EHR software vendor that they are working toward EHDS interoperability certification. When engaging your vendor, the following simplified overview of the CE marking process for EHR systems may help structure the conversation:
 1. Harmonise the system with EHDS essential requirements (Annex II, Article 15, Article 36);
 2. Test the system in a digital test environment (Article 40);
 3. Compile technical documentation (Article 37);
 4. Provide information sheets and manuals (Article 38);
 5. Create an EU declaration of conformity (Article 39);
 6. Apply CE marking (Article 41);
 7. Register in the EU database for EHR systems (Article 49).
- Ensure patient eye health data (visual acuity, refraction, IOP, retinal findings) is recorded in structured fields, not only free text
- Review and update your patient privacy notice to reflect new rights under the EHDS (access, download, restriction, correction, opt-out from secondary use)
- Establish a practice process for receiving and reviewing digital health summaries from patients arriving from other EU countries
- Verify your data security practices meet current standards, as a health data holder, the practice itself carries obligations, not only the EHR vendor. When discussing security with your EHR vendor, it is also worth being aware that cryptographic security requirements are expected to evolve significantly in the coming years. The EU has published a coordinated roadmap for the transition to post-quantum cryptography, which is relevant to any system handling sensitive health data over the longer term. Practices do not need to act on this immediately, but it is a useful topic to raise with vendors to ensure they are planning for future compliance. Further information is available via the [European Commission's digital strategy library](#).
- If you use AI diagnostic tools, verify they are CE-marked as medical devices and document their use in the patient record
- Contact your national professional association for country-specific guidance on EHDS implementation
- For opticians: confirm with your national association whether dispensing records and optical prescriptions fall within the scope of EHDS data categories in your country