

ENSURING A TRUE LEVEL-PLAYING FIELD IN THE EUROPEAN HEALTH DATA SPACE (EHDS) FOR PATIENTS AND HEALTHCARE STAKEHOLDERS

A call for a patient-centric digitalisation of healthcare systems

We, the signatories, representing healthcare stakeholders along the supply chain, including patients, healthcare professionals, and manufacturers, convinced of the power of digital health in achieving the underlying objectives of the European Health Data Space (EHDS), call on European policymakers to ensure a **true level-playing field in the EHDS, leaving no patient behind**.

The EHDS has the ambition to create a **highway for a true European single market for digital health data and services**, whether for primary use for healthcare professionals, or secondary use for amongst others research and innovation purposes. Although the European Commission's EHDS proposal rightfully identifies the **critical role played by digital health in ensuring patients' access to healthcare**, we regret that the latest proposed amendments in the European Parliament and compromise text in the Council of the EU indicate that co-legislators are leaning towards the opposite direction.

We urge the co-legislators to:

- Create a **true level-playing field for patients**:
 - First and foremost, this means **guaranteeing** that all healthcare professionals have **access to the infrastructure** made mandatory by the EHDS – **MyHealth@EU**, in order to support patients in a safe and transparent way.
 - Therefore, as proposed by the European Commission, the **reference to online pharmacies across the text (recital 21, Art. 2, Art. 12)** must be **retained in the final text**.
 - Not making specific reference to online pharmacies in the EHDS would mean that, once the MyHealth@EU infrastructure becomes mandatory with the implementation of the legislation, we will have **first-tier and second-tier patients**:
 - First-tier patients not ordering with online pharmacies will be able to obtain e-prescriptions and other digital services;
 - Second-tier patients ordering with online pharmacies will not be able to access those services. This constitutes a dangerous barrier especially for chronic patients and patients living in rural areas or with mobility issues.
- Harmonise provisions on and **encourage uptake of (cross-border) tele-health services**:
 - As acknowledged in the EHDS Communication¹, tele-medicine has become an intrinsic part of the delivery of healthcare, also as a consequence of the COVID-19 pandemic. **Tele-health services contribute to fostering equitable access to healthcare**, as recently shown by the World Health Organization². Notably, tele-medicine ensures medical care in rural and remote areas, allows flexible working models (also for doctors), and enables the provision of consultation services in the patient's mother tongue.
 - Removing entirely Article 8 on "Telemedicine" from the EHDS, as proposed by the compromise texts in the Council of the EU, would *de facto* jeopardise the objective to finally put digitalisation at the services of patients, especially those that currently do not have access to healthcare. Co-legislators should **seize the momentum to foster patients' access to healthcare via tele-health services**, such as tele-medicine. Facilitating the (cross-border) provision and use of tele-health services would ultimately favour equitable access to patients in need.

¹ https://health.ec.europa.eu/publications/communication-commission-european-health-data-space-harnessing-power-health-data-people-patients-and_en

² <https://www.who.int/europe/publications/i/item/WHO-EURO-2022-6810-46576-67595>

Lastly, the signatories trust that co-legislators will come to a **final agreement before the next EU elections in 2024**. As this legislation will constitute a core pillar of healthcare systems across Europe for the years to come, we urge co-legislators to support the above-mentioned approach, rejecting any unjustified attempts to delay and prevent patients' access to healthcare via digital means.

We, the signatories, are confident that the European Parliament and Council of the EU will consider our request, and look forward to continuing to engage on the debate on the EHDS.

Signatures



About the signatories:

The [Alliance for Safe Online Pharmacy](#) (ASOP EU) is a non-profit independent multi-stakeholder coalition, with patient safety at the heart of everything that it stands for. Participants are united by a single mission that together, we can create an environment that enables patients to buy their medicines online safely, in countries where it is legal for them to do so. ASOP EU consists of various groups: patient organisations, healthcare providers, pharmacists, pharmaceutical companies, distributors, wholesalers, and online intermediaries.

The [European Alliance for Access to Safe Medicines](#) (EAASM) is an independent, non-profit pan-European patient organisation dedicated to protecting patient safety. The Alliance champions many patient safety issues to enhance medical practices, including the reduction of medication errors and the development of a robust and harmonised EU regulatory framework in the field of nanomedicines to protect patient safety. Other key activities include campaigning for the safer use of unlicensed/off-label medicines, better harmonisation of compounding practices, and the exclusion of falsified and substandard medicines from the supply chain.

The [European Association of E-Pharmacies](#) (EAEP) represents the interests of e-pharmacies on the European continent. E-Pharmacies have digitalised the classical pharmacy, and therefore act at the crossroads of digitalisation, healthcare, e-commerce and sustainability. EAEP members continuously seek for ways to enhance the quality, safety and efficiency of healthcare for Europeans.

The [European Health Telematics Association](#) (EHTEL) is a unique pan-European multidisciplinary stakeholder platform, bringing together organisations and individuals engaged in all aspects of eHealth. EHTEL's distinctive structure enables the exchange of ideas, opportunities and knowledge with a community of 5,000 digital health and care experts and innovators. It does that through webinars and projects, leading to innovation in the delivery of eHealth solutions and the transformation of health and social care. EHTEL's growing membership includes more than 50 organisations from all relevant stakeholder groups. The multiple

interests and viewpoints of its members enables EHTEL to take a uniquely holistic approach on the implementation of eHealth solutions.

The [European Specialist Nurses Organisation](#) (ESNO) is a non-profit organisation which promotes and represents the interests of Specialist Nurses in Europe. Through collaboration with stakeholder organisations and utilising advanced science, we pursue recognition under the Directive of Professional qualification. We contribute to effective co-operation between health professionals, organisations, institutes and agencies, thus setting professional standards for education and continuing development.

The [Fight the Fakes](#) (FTF) Alliance is a multi-stakeholder non-profit association that aims to raise awareness and influence change about the proliferation of substandard and falsified medicines. Substandard and falsified medicines not only put patients' lives at risk but undermine trust in healthcare systems and modern medicine, and hamper crucial progress made so far by countries towards universal health coverage.

The [International Alliance of Patients' Organizations](#) (IAPO) is a unique global alliance representing patients of all nations across all disease areas. With 300 member organizations from 71 countries representing 50 disease areas, IAPO works to promote patient-centred healthcare around the world. IAPO's vision is to see patients placed at the centre of healthcare.