

July 2022

ONLINE PHARMACIES' VIEWS ON THE EUROPEAN HEALTH DATA SPACE

With this paper, the European Association of E-Pharmacies (EAEP) aims to provide a constructive input to the debate about the European Health Data Space (EHDS) proposal, as we believe it has the potential to create a highway for a true European single market for digital health data and services.

Our views on the EHDS

We welcome the works undertaken past and present on the EHDS and related initiatives, as we strongly believe that the EU is currently lacking a sound single market for digital health data and services. In particular, the EAEP applauds the European Commission's ambition, reflected in the EHDS proposal, to foster a **level-playing field for all healthcare providers**. Below we provide our views on how the EHDS can contribute to breaking some of the existing barriers:

✦ Accelerating the potential of health data

- **Enable access to health data for healthcare providers**, to foster informed, evidence-based decision-making, and make it a lot easier and less time consuming for healthcare providers to interact with each other and with the patient and thus optimising healthcare outcomes¹. In some cases, EAEP members are excluded from national medication plans, which presents a risk for patients since online pharmacies cannot execute interaction checks and advise patients on their medication use in an open and transparent way. Therefore, we recommend ensuring that all healthcare providers have access to health data, in the interest of the patient.
- **Ensure less error proneness by using digital health services**: as acknowledged in the European Commission's Communication on the EHDS, e-prescriptions could reduce errors in dispensing medical products up to 15%². Processing prescriptions digitally ensures that in the whole 'prescription supply chain', namely from doctor to the pharmacy to the patient, all information is stored correctly. Mistakes due to e.g. unclear handwriting of a doctor are thus avoided, allowing the pharmacy to provide proper and fitting advice to the patient. Ultimately, the patient is empowered since he or she has continued access to personal health data, regardless of place and time. Hence, we believe the EHDS should further promote the deployment of electronic prescriptions at the Member State level, by putting forward mandatory requirements for Member States to develop the necessary infrastructure.

✦ Developing a European single market for digital health

- **Ensure clear and harmonised interoperability standards**, by putting forward mandatory requirements and certification for Electronic Health Record (EHR) systems. Currently, lack of interoperability leads to healthcare providers not being able to access complete medical records, causing poor medical decisions for diagnosis and treatment. Despite proposing common standards

¹ See more here: <https://www.linkedin.com/pulse/what-benefits-secure-health-data-sharing-/?trackingId=pnW%2BzcpMAngK5rW38LoglQ%3D%3D>

² European Commission's Communication on the EHDS https://ec.europa.eu/health/publications/communication-commission-european-health-data-space-harnessing-power-health-data-people-patients-and_en

among Member States, the current EHDS proposal leaves a lot of room for interpretation and, therefore, risks jeopardising the goal of facilitating the sharing of health data across the EU. Therefore, in our view, Annex II “*Essential Requirements for EHR Systems and Products Claiming Interoperability with EHR Systems*” and Annex III “*Technical Documentation*”, which add to Article 24, should refer to a common template document to be used in all Member States, with clear technical specifications, fostering real interoperability of EHR systems.

- **Creating a true health data space** by establishing a single **EU e-medication database**. As spelled out in Article 12, the MyHealth@EU constitutes “*a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States*”. While supporting the MyHealth@EU infrastructure, we believe its effectiveness is limited since it only facilitates the exchange between national contact points and does not lead to one common space, as the title on the EHDS suggests. Cases already exist where specific markets apply very specific requirements for handling health data: in France, for instance, storage and processing in locally certified data centers (local/regional level) is required. In order to fully benefit from the potential of the EHDS, the legislation should create a single EU point where all medication data can be stored (single EU e-medication database) – similar to e.g. the European Open Science Cloud (EOSC)³, based on the same FAIR principles⁴ as referred to in the EHDS proposal. Online pharmacies should be allowed to access the database, in order to improve access to healthcare, regardless of the place. The database should also be based on a uniform drug identification number format, which currently differs in each Member State. Only by means of such an EU storage point, with clear policy to access health data, meaningful health data sharing will be possible.

Why is a single EU e-medication database needed?

Sara, a 40-year-old woman from France suffering from diabetes and asthma, is on a business trip to Poland. On her trip, she realises that she did not bring her medication with her. Sara goes to a doctor in Poland to obtain the prescription for her medication. Once obtained, she orders her medication via a Polish pharmacy. However, given that the medication in Poland looks different from the one back home, Sara is concerned about taking the prescribed medicine. Nonetheless, thanks to the single EU e-medication database, with a simple and easy check the pharmacist can run an interaction check based on her data from France and comfort her that she can indeed take the medication.

³ The European Open Science Cloud (EOSC) is an environment for hosting and processing research data to support EU science <https://eosc-portal.eu/about/eosc>

⁴ FAIR principles: Findable, Accessible, Interoperable and Reusable

- **Develop a European Digital Identity**, to ensure a trusted, secure and efficient means for patients to authenticate. A European Digital Identity, for which plans have been proposed in 2021, only makes sense if a holistic and coherent approach is taken: the European Digital Identity should also be able to include connection or inclusion of patients' health data. By gathering all information in a one-stop-shop, a user-friendly model is created – ultimately fostering the uptake by patients. User-friendliness is key to the success of digital identities.
- **Facilitate reimbursement of all tele-health services** across the EU (i.e. mutual recognition or EU-level framework). To date, reimbursement policies prioritise physical care, ultimately preventing patients from fully benefitting from remote consultations, which is important especially in rural areas. While the EHDS proposal states, under recital 21, that *“different reimbursement policies should, however, not constitute barriers to the free movement of digital health services such as telemedicine, including online pharmacy services”*, in practice this is complicated given the fact that EU Member States have different EU reimbursement systems and, linked to that, different prices. Concrete initiatives of e.g. healthcare providers in the Netherlands, which allow reimbursement of medication if a patient has bought them in a Dutch online pharmacy, should serve as best practice to foster harmonisation among Member States. This should also be foreseen on a cross-border basis in the EU.

What are the practical implications of different reimbursement policies?

Peter, a 28-year-old national from Germany, is on holiday in Spain. During his holiday, he falls ill with a throat infection that needs to be treated with antibiotics. The doctor prescribes him medication and Peter can obtain the medication at a Spanish pharmacy. However, due to the fact that these antibiotics are much more expensive in Spain than in Germany, Peter only gets his medication partially reimbursed by his statutory health insurance in Germany. As a result, while in Germany Peter would have gotten the medication reimbursed, when abroad he could not claim his right to full reimbursement of medication.

+ Empowering patients to obtain high-quality care

- **Empower citizens to control their health data in electronic format** (e.g. e-prescriptions), and to transfer the data from mobile-health and tele-health into their Electronic Health Records. This would allow them to: (1) obtain e-prescriptions and redeeming them in other EU Member States; (2) improve safety of medical examinations and treatments; (3) receive faster and more personalised diagnosis and treatment, and regular insights on the development of individual health status. Article 5 (1) of the EHDS proposal states that *“Member States shall implement access to and exchange of personal electronic health data for primary use”* in six defined categories. We believe such mandatory requirement for Member States is instrumental in creating the conditions to enhance patients' access to health data.

However, we are of the opinion that, to ensure the wide uptake of e.g. electronic patient summaries, not only access but also use should be made mandatory. Without a proper deployment of such electronic tools, the EHDS will not achieve the goal of empowering citizens to control their health data in electronic format.

Why is mandatory use of patient summary crucial?

In Germany, since 1 January 2021, all statutorily insured persons can receive an electronic patient file (ePA) from their health insurers, in which medical findings and information from previous examinations and treatments can be comprehensively stored across practice and hospital boundaries. The ePA is an electronic file managed by the insured person and its use is voluntary for the insured person (opt-in). Patients can store data from existing applications and documentation in the ePA, such as emergency data, medication plan, doctor's letters, findings, X-rays, or a diary of blood glucose measurements. As of 2022, it is also possible for privately insured people to use the ePA and to store the vaccination card, the maternity passport, the examination booklet for children as well as the dental bonus booklet in it. Unfortunately, the ePA is not popular among patients in Germany due to a combination of a lack of social acceptance of digital innovations, and the lack of user-friendliness and perceived benefits, as well as a lack of financial incentives for healthcare providers to feed the ePA. As a result, despite the infrastructure is up and running, the advantages for patients of using the ePA are not exploited.

Final remarks

Ensuring **better access to health data**, including across borders, will ultimately **improve access, quality and continuity of care** offered to all European citizens, no matter where, and **reduce healthcare costs**. Never before such imperative has been stronger. Therefore, we are excited by the potential of the EHDS and look forward to engaging in a fruitful discussion with national and EU decision-makers, with the goal of encouraging future innovation and promoting a regulatory framework that empowers healthcare providers to better support patients. As e-pharmacies, we see ourselves as a central and integral player to ensure the success of the EHDS.

About the EAEP

Online pharmacies have digitalised the classical pharmacy, acting at the crossroads of digitalisation, healthcare, e-commerce, and sustainability.

✚ We strengthen the European healthcare system

By ensuring better access to medicines (OTC/Rx) and health-related products, providing expert professional advice and care for people across Europe, especially in suburban areas. We strengthen the European healthcare system with the ultimate goal of fostering a true **European Health Union**.

+ We are patient-centred healthcare providers

We continuously seek for ways to enhance the quality, safety and efficiency of healthcare for Europeans. As such, the focus of our activity is on the primary use of health data for better healthcare. Our digital health track record, based on high-quality data and strong digital infrastructure across borders, fosters patients' access to **high-quality medical care across the EU**.

+ We have a European DNA

EAEP members have deep roots in Europe and are active in 11 European markets, serving more than 20 million customers and employing more than 4,000 people in Europe.

For more information about the e-pharmacies sector and our positions, please visit our websites: www.eaep.com

CONTACT US

Martino Canonico

Public Affairs Manager

EAEP – European Association of E-Pharmacies

Phone: +32-2-8082624

Mobile: +32 493 842577

E-Mail: martino.canonico@eaep.com