

Input paper of the European Association of E-Pharmacies to the public consultation on a "European health data space"

July 2021

In February 2021, the European Association of E-Pharmacies (EAEP) submitted initial [remarks](#) on the combined Evaluation Roadmap and Inception Impact Assessment on a European health data space (EHDS). This input paper to the public consultation on the EHDS gives a more detailed view of the EAEP's position on issues such as facilitating access to health data, potentials of telehealth, a labelling scheme, data ownership and data transmission. This paper is issued alongside the public consultation questionnaire.

As e-pharmacies we are patient-centred healthcare providers, and as such our focus is on the primary use of health data for better healthcare. In practical terms we very much welcome the work undertaken past and present on the standardisation of electronic prescriptions and the electronic health record exchange format.

At the same time, we have to agree with the European Commission's assessment that the free movement of digital health services remains limited due to uneven national legal frameworks for prescription-only medicines and barriers to the reimbursement of tele-pharmaceutical services.

We would encourage the Commission to further tackle remaining barriers across the EU within the work on the European health data space and during the corresponding ongoing reviews of pharmaceutical and healthcare legislation.

The EAEP puts forward the following elements as response to some of the questions posed in the public consultation:

- The EAEP believes that access to health data for healthcare providers is important as it allows informed, evidence-based decision-making and eventually better healthcare. The question on who should provide access to health data is clear to us: **Access may only be granted by the data holder. The data subject must always be the data owner** who should always be in the one able to release his or her data to a service provider. This scenario matches the status quo which is compliant with the General Data Protection Regulation (GDPR). Given the sensitivity of health data, the **ownership of the granted data should remain with the data holder**. If decided otherwise, centralisation could potentially restrict the freedom of the data subject and make the health sector, given the sensitivity of the data, particularly vulnerable.
- If the EHDS is to provide a *lex specialis* to the GDPR, we trust and hope that the parallel work on the regulation establishing a framework for a **European Digital Identity will ensure a trusted, secure and efficient means for patients to authenticate** and conditionally share the specifically required data with their healthcare provider, provisioning for telehealth and mobile health, including cross-borders.
- If increased and better access to health data needs to be provided with the purpose of facilitating research, innovation, and regulatory decisions, then the **costs for healthcare professionals and providers, including e-pharmacies, should be as low as possible**. Providers should not be faced with additional (financial) burdens to grant access to the data for the abovementioned purposes.
- According to the Healthcare Information and Management Systems Society's (HIMSS) Annual European Digital Health [Survey](#) 2021, the **acceleration of telehealth** was

unprecedented during COVID-19 as healthcare providers and professionals “raced to implement solutions that would support patient engagement and remote working in a climate of rapid transmission, self-isolation, social distancing and quarantine”. This increasing take-up of telehealth shows that there is a patient need in terms of being consulted by healthcare providers and professionals using digital channels. The EAEP believes that **telehealth offers chances for patients as well as for doctors**. It contributes to ensuring high quality health especially where resources are limited, for example in rural areas. As e-pharmacies, digitisation and data privacy – the latter being more profoundly outlined in our [Privacy paper](#) – is at the heart of what we do, and therefore we continuously ensure the highest quality standards and provision of privacy and cybersecurity. We are, however, concerned about the skills and capabilities of patients and clients in dealing with telehealth in a safe way. Therefore, we suggest that the European Commission, together with the member states, **invests in ensuring appropriate digital skills to learn how to safely use telehealth services**.

- The EAEP would **welcome a labelling scheme**, a voluntary label indicating the interoperability level, to foster the uptake of digital health products and services at national level and across borders within the EU. Such a labelling scheme would increase the overall acceptance of digital health products and data sharing among citizens as well as their level of trust when it comes to their data being dealt with properly for health purposes. Citizens, in addition, should be made aware of such a scheme by means of a broadly rolled out **communications plan** by the European Commission.
- As underlined in our response to the feedback period, we believe that **artificial intelligence** holds a lot of potential but a proper framework needs to be put into place to that end. Health data being among the the most vulnerable data that the EHDS will have to deal with, can allow for AI to support in making better and informed decision, but the **‘human check’** must always remain in place.
- Regarding the transfer of data, **citizens should have the possibility to transfer the data from m-health and tele-health into their electronic health records**. In many EU member states, this facility/option is already in place or currently being implemented. Quite on the contrary, we would **oppose a strong centralisation of data transmission into an EU health data exchange infrastructure** unless there is a 100% guarantee that the data are stored safely without any external parties able to access these in an unlawful way.
- The EAEP is of the opinion that healthcare professionals can **request** the transfer of data, but **access** to patients’ digital health records and to data should not be taken lightly. A control mechanism needs to be implemented as to how and at which level (full access, limited access, only access to anonymised data, etc.) data could potentially be shared. We do see the **benefit of data sharing with healthcare professionals in order to allow for fast screening, advice and better personalised treatment, therapy and services for patients**. For example, if a patient receives medication from doctor A and then goes to doctor B where, again, they receive medication, doctor B should be able to check that there is no negative interaction of the medication that could potentially harm the patient. In these instances, data sharing would be helpful. Nevertheless, rules should be set up to clarify who decides on and who has access to the health data. These rules should be set by an independent body.
- As indicated in our response to the feedback period, EAEP suggests establishing an **EU-wide authentication system as default infrastructure to clarify the rules and responsibilities** for a secure login framework. Based on this authentication system, a dedicated authorization management could be built, which then clarifies which party is allowed to access which data.

- As put forward in our response to the feedback period, we would like the Commission to establish **a regulatory framework at EU level** that defines how to deal with personal data related to one's individual health. Such an EU regulatory framework would do away with the vast amount of heterogeneous legal bases and would thus supersede the currently fragmented national treatment of (access to) health data. To our disappointment, we identify that the Commission has communicated legislative proposals on the **Data Governance Act (2020)** and the **Data Act (forthcoming)** including specific rules for the use of data in the health sector, which, in our opinion, lack a clear and consistent legal as well as governance framework. Both these acts and the EHDS require a clear governance framework, especially given the current fragmentation of health data regimes and a lack of coordination across Europe. The exact structure should be defined in a dialogue with public and private stakeholders. We would therefore like to suggest to the Commission to **keep it as simple as possible** while ensuring that all provisions related to the EHDS are not included in several legislative documents.
- Finally, regarding reimbursement we would very much welcome the **facilitation of reimbursement of all telehealth services across the EU** (i.e. mutual recognition). In most member state systems, EU-foreign healthcare providers currently have little say in devising reimbursement frameworks for tele-pharmaceutical services. European guidelines on reimbursement for digital health services might provide a benchmark for future debates.

We would be happy to exchange views with the European Commission on how to create the EHDS. As e-pharmacies, we see ourselves as a central and integral player to ensure the success of the EHDS with as its main aim to improve the health of Europe's citizens.

About EAEP:

We strengthen the European healthcare system by ensuring better access to health-related products and services for people across the continent. As the Association of European E-Pharmacies (EAEP), we represent the interests of our members and safeguard the needs of our members' patients and customers. We inform the public in a transparent manner, enter into a dialogue with politics, business and market partners and leverage our concepts to strengthen the European healthcare sector and lower costs through digitalisation. The members of the EAEP are pioneers in providing digital solutions that continuously improve the quality, safety and efficiency of healthcare for Europeans. We combine our members' voices in position papers and encourage interaction and knowledge sharing.

More information: <https://www.eaep.com>