

POSITION PAPER

RECOMMENDATIONS FOR THE EUROPEAN HEALTH DATA SPACE

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INTRODUCTION

The European Health Data Space (EHDS) regulation aims to provide a common framework across EU Member States for accessing and sharing of health data such as electronic health records, patient registries, hospital discharge reports, and genomic data to support healthcare delivery, and to facilitate health research, policymaking, and legislation. For this endeavour to be truly successful, the EU must do more to promote digital health literacy and to put safeguards in place to protect its citizens' health data, both against cybersecurity attacks and corporate interests.

The EHDS proposal intends to empower citizens to take control of their own personal health data, for example, by giving them access to their electronic health records. It is, however, crucial to ensure that people have internet access as well as adequate digital and health literacy. Recent data demonstrate that over 4 out of 10 EU citizens lack basic digital skills¹, and while the EU has launched several initiatives to address this issue, these all aim to equip workers with necessary digital skills for their workplace². Therefore, a clear focus on digital skills for the use of rapidly growing digital health tools is lacking and the EU must prioritise digital health literacy as a key issue for modern-day public health.

The secondary use of health data for research and innovation, as described in the EHDS regulation, has the potential to help discover new and more efficient treatments for many conditions and people at large. "Secondary use" of data refers to any application of data beyond the reason for which they were first collected, and it may include personal electronic health data originally collected to, for example, treat patients. However, for high quality health data to be collected and used for research and other purposes, building citizens' trust through transparent and clear communication about how their health data will be stored, accessed and (re) used is essential. The Commission also must ensure sufficient safeguards that would prevent health data from being misused or leaked, which is particularly of importance for vulnerable communities such as undocumented migrants, ethnic minorities, LGBTIQ+, as well as people living with certain medical conditions such as HIV/AIDS.

For years now, EPHA has been advocating for an inclusive approach to digital health tools. As pointed out in a previous EPHA article³, the implementation of the regulation without fully understanding the users' concerns and needs could result in mistrust, in both governments and digital technology. It is thus important that the EU reaches out to ordinary citizens and healthcare professionals more, as well as to civil society groups representing them, throughout the different implementation stages, and to ensure their proper representation in the European Health Data Space Board and other data governance structures.

1 <https://digital-strategy.ec.europa.eu/en/policies/desi>

2 <https://digital-strategy.ec.europa.eu/en/activities/digital-programme>

3 <https://epha.org/the-european-health-data-space-is-there-room-enough-for-all/>

RECOMMENDATIONS FOR THE EHDS

- 1. Dedicate extra funding and take a proactive role in ensuring individuals living in the EU have sufficient digital skills and health literacy to truly empower them to make use of the European Health Data Space.**

As mentioned already, more than 40% of EU residents lack basic digital skills, and they are unevenly distributed among Member States. The percentage of EU citizens with at least basic digital skills was the highest in Western states (Netherlands, Finland, and Ireland) and the lowest in Eastern states (Romania, Bulgaria, and Poland)⁴. While data on digital health literacy – the ability to use digital tools to search for and interpret health information – in the EU is scarce and outdated, research also shows that low rates of health literacy are mostly found in post-communist EU Member States⁵. The Commission should thus also pay special focus to Eastern Member States to address the gap in digital literacy within the EU.

- 2. Ensure proper representation of patients, healthcare professionals, and civil society groups representing them in the European Health Data Space Board (EHDS Board), as well as all other data governance authorities**

Articles 64 and 65 of the EHDS Regulation proposal establish the EHDS Board and task it with, among other things, the exchange of views on the primary and secondary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators, and policy makers in the health sector. It is crucial that the Commission ensures proper representation of patients, healthcare professionals, and civil society groups representing them on the Board so that they may have an equal say in matters related to the primary and secondary use of electronic health data. This should be extended to all national data governance authorities as well.

- 3. Allow individuals to opt-out of having electronic health records and continue providing paper alternatives.**

Currently, the EHDS proposal does not specify whether individuals living in the EU could opt-out of having electronic health records nor the implications that this would have. Whereas standardized electronic health records should be used to ensure interoperability between different national health records, every individual should have the option of not having an electronic health record, and paper alternatives for those individuals as well as individuals without adequate digital and health literacy should continue to be provided and used.

4 <https://ec.europa.eu/eurostat/en/web/products-eurostat-news/-/ddn-20220330-1>

5 Baccolini, V., Rosso, A., Di Paolo, C. *et al.* What is the Prevalence of Low Health Literacy in European Union Member States? A Systematic Review and Meta-analysis. *J GEN INTERN MED* 36, 753–761 (2021). <https://doi.org/10.1007/s11606-020-06407-8>

4. Give individuals control over which health information contained in their health records can be processed for primary and secondary use of electronic health data.

While the Regulation establishes that individuals will have control over whom they share their electronic health records with, it does not clearly specify whether and how they will be able to block certain health data from being visible to healthcare providers for primary use, as well as for secondary use of electronic health data. For example, patients living with certain medical conditions such as HIV/AIDS might not want to disclose their HIV status with a healthcare provider and should have the option of restricting access to this information when it is not necessary for the medical practitioner to know. Additionally, individuals might also feel uneasy about sharing their genomics data when it comes to the secondary use of health data and should therefore have the right to disallow certain categories of health data to be used for secondary use, as well as to entirely opt-out of secondary health data (re)use. Lastly, Article 34 of the EHDS proposal should provide more clarity regarding all purposes for which health data can be processed for secondary use.

5. Clarify and specify the consent model that will be implemented for the secondary use and processing of electronic health data.

Currently, the EHDS proposal does not specify the rules under which individuals will give their consent regarding secondary use of electronic health data. The Regulation should specify whether an opt-in or an opt-out consent model will be used. In case the opt-in model is chosen, the Regulation should specify in which situations and how often individuals will have to give their consent for the secondary use of their electronic health data, as well as how this consent can be revoked. Furthermore, the Commission should propose specific measures to combat growing concerns over “consent fatigue” should an opt-in consent model be implemented.

6. Exclude wellness apps and behavioral data from the scope of the legislation due to data quality and privacy concerns.

In its current form, the EHDS Regulation equates data generated by medical devices, digital health apps, and wellness apps. Wellness apps, as well as behavioral data in general, should be removed from the scope of the legislation as they do not have the same data quality requirements nor characteristics. Wellness applications generate a large amount of data by users, most often without the supervision of a healthcare provider, potentially resulting in health data of low quality. In addition, they can be highly invasive as they relate to everyday activities that individuals undertake during their day, allowing for inferences regarding sensitive information such as religious practices or sexual orientation to be made. When it comes to the collection and processing of health data, GDPR principles surrounding data protection should always be followed.

7. Health data access bodies shall be obliged to provide specific information to individuals concerning the secondary use of their electronic health data.

Article 38(2) of the EHDS Regulation should be amended as it is currently at odds with GDPR and it undermines citizens' rights. In its current form, the Article 38(2) states that health data access bodies shall not be obliged to provide specific information to individuals regarding the use of their data for secondary use and that instead they shall provide general public information on all data permits issued for secondary use. This, however, is insufficient and individuals should be notified every time their health records are used in a project for which a data permit was obtained. This notification should at the very least contain basic information about the purpose for which their health data will be used.

8. Health data access bodies should not automatically issue data permits when they fail to approve them within the two-month time frame.

Article 46(3) should be amended to prevent applicants from automatically obtaining a data permit when the two-month timeframe to respond to an application lapses. There are many reasons for why a health data access body may not be able to respond on time, ranging from the complexity of an application to the lack of human and other resources. Given the sensitivity of health data and the careful examination that each application for a data permit requires, under no circumstances should an applicant be granted a data permit automatically.

9. The use of health data for research and innovation made available by the EHDS should be disclosed and fully transparent.

There should be transparency around the use of health data for research and the development of new therapies, pharmaceuticals, health tools, and medical devices. Private entities should disclose to the public the cost of research and development as a result of using data made available by the EHDS as this has important implications for the negotiation of the pricing of new pharmaceutical and biomedical goods.



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