# PGEU GPUE

# Pharmaceutical Group of European Union

# Position Paper on the European Health Data Space

*The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million citizens daily.*

Rue du Luxembourg 19, 1000 Brussels, Belgium | Phone: +32 2 238 08 18 | AISBL BE 0468 971 838

pharmacy@pgeu.eu | www.pgeu.eu

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

# Executive Summary

PGEU welcomes the proposal for a European Health Data Space (hereinafter, "EHDS" or the "Proposal") and supports the general objective of the EHDS of facilitating the access of health data across the Union for primary and secondary uses, whilst ensuring citizens have control over their own health data. PGEU also agrees it is vital to strengthen health systems and the healthcare workforce, including by digital transformation, appropriate training, increasing integrated and coordinated work among the Member States, as well as by sustained implementation of best practices and data sharing, while in full compliance with the General Data Protection Regulation (GDPR) rules and by taking the necessary measures to avoid any misuse. Digital transformation shall also be seen as an opportunity to promote increased collaboration between healthcare professionals providing healthcare to the same patient.

However, to ensure a consistent application of the Regulation as well as creating a trustworthy and fit-for-purpose environment, certain aspects shall be further developed and a better balance of public interests at stake shall be achieved, including broader involvement and collaboration of the relevant stakeholders. This position paper aims to set out some proposals that we believe will further improve the text and contribute to better achieve its objectives.

The COVID-19 crisis has demonstrated more than ever the vital role of all healthcare professionals which lies on strong ethical principles and demonstrated expertise. For this reason, the EHDS shall also consider confidentiality duties of healthcare professionals when regulating data registration and shall not create disproportionate burdens for those practices that do not qualify as microenterprises.

At the same time, the proposal shall also respect the competences of Member States[1] and be compliant with other pieces of EU legislation, including the GDPR. In this regard, the report issued by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) notes some legal uncertainty derived from the interplay between the Proposal and the GDPR which should be properly addressed[2].

Moreover, due to the unprecedented impact on health data and healthcare systems, we believe that there should be a further analysis of the actual impact of this Proposal on national health systems. In this regard, we note that some elements of the Impact Assessment accompanying the Proposal, including some of its economic estimations such as the quantification of expected costs and benefits, should be reconsidered.

[1] Specifically considering article 168 TFEU and existing live infrastructures in some Member States.
[2] Joint opinion adopted by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), July 2022 https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

# Introduction

## Community pharmacists and digital health, a history of success

The implementation of eHealth, mHealth, Artificial Intelligence (AI) and automation in healthcare is linked to the collection, the analysis and the speed in the application of data. The remarkable amount of health data contributed so far to the widespread adoption of electronic health records and e-prescribing systems, with community pharmacists being at the forefront of these developments in several European countries. As it emerges from daily practice, more and more patients ask pharmacists to provide advice on how to interpret health information (especially related to medicines) that they acquire from other sources, such as the media, internet or mobile apps. This involves the interpretation by pharmacists of health data generated through wearable devices and digital information generated from point-of-care tests in community pharmacies, which offers an enormous capability in early detection of undiagnosed chronic disease and potential adverse events as well as in monitoring of adherence and effectiveness of therapies.

Moreover, community pharmacists have made significant proactive investments in information and communications technology (ICT) infrastructure over the past decades, considering that all pharmacies in Europe have modernized computer systems. This makes pharmacists ideally placed to play a pivotal role in designing, developing, testing, implementing, evaluating, and ensuring the uptake of new ICT innovations and confirming they are fit for practice in community pharmacies. ICT creates the potential for remote monitoring and care, read-write access to shared medical records, electronic prescriptions (e-prescriptions), secure pharmacist advice in online services, secure analyses of big data repositories, registries and other pharmacy-held databases for epidemiological studies to improve health outcomes. It can also allow indications of the medicine on the e-prescription and two-way e-communication between pharmacists and other healthcare professionals.

This multi-professional proactivity in digital health can thus result in high quality healthcare that fulfils the needs of all citizens. However, patients should always remain in control of their own health data and be able to decide freely and independently about their treatment, the team of healthcare professionals involved in their care as well as their access points for treatments.

At the same time, it is known that the level of digital literacy (i.e. the ability to use digital devices effectively) and skills among people in Europe still varies strongly across different subgroups and age

categories of the population. According to Eurostat data in 2021, the share of people aged 16 to 74 who had at least basic overall digital skills ranged from 79% to only a 28%, depending on the Member State[3].

A key prerequisite for the increasing integration of digital health solutions in healthcare systems is, therefore, to safeguard equity for all patients and ensure that alternative solutions remain available for those patients who are not able to rely on digital solutions. Overall, technology should be used according to the goals of healthcare and not vice versa, and in such a way that it does not prevail over direct human contact, nor cause digital exclusion.

## The European Health Data Space

The COVID-19 pandemic has demonstrated the importance of digital solutions in the healthcare sector but also highlighted the need to build fit-for-purpose interoperable infrastructures that can further facilitate the provision of healthcare. Beyond successful use cases, such as the so-called COVID Passport, Member States, healthcare professionals and citizens witnessed the complexity of rules, structures and processes that hinder adequate access and use of health data, especially in cross-border settings.

On 3 May 2022, the European Commission published its proposal for a Regulation on the European Health Data Space. PGEU welcomes the general objective of the EHDS of facilitating the access of health data across the Union for primary and secondary uses, whilst ensuring citizens have control over their own health data.

There is generalized support to the fact that optimal data generation, gathering and interoperability can be used to optimize treatments for patients and foster personalized advice. In this regard, some progress has been made already under the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare: the assessment of the cross-border prescriptions use case has provided indicative evidence of an estimated increase of approximately 300% for foreign prescriptions presented to pharmacists in the EU between 2012 and 2021 (from 1.46 foreign prescriptions per pharmacy per month in 2012 to 5.87 in 2021)[4]. However, further approximation and interoperability shall be enhanced in order to unleash the possibilities of e-prescription and other eHealth features.

Moreover, and regarding secondary uses of health data, preparatory work, and research around the EHDS have identified challenges that negatively affect access to and reuse of health data, including limited data

[3] https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220330-1

[4] Commission staff working document impact assessment report Accompanying the document proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022SC0131&qid=1654132972171

interoperability, fragmented rules for access to data for research, and barriers for individuals to exercise access to and control of their own health data[5], which can be solved through a fit-for-purpose EHDS.

In the following pages, PGEU sets out its position on the Proposal along with some recommendations that in our view would improve the balance and safeguards of the EHDS without limiting its operational possibilities.

[5] In this regard, please refer to the work conducted by the Joint Action Towards the European Health Data Space – TEHDAS (https://tehdas.eu/results/) and, in particular, to reports on Milestone 8.2 and Deliverable 5.1.

# The EHDS: from data-sharing to unleashing better healthcare building from data

## A. CHAPTER I: GENERAL CONSIDERATIONS

### 1) Legal basis: the Proposal shall be fully compliant with the Treaty of the Functioning of the European Union.

The Proposal is based on Articles 16 and 114 of the Treaty on the Functioning of the European Union (TFEU). One of the reasons the European Commission provides to justify its choice is that "article 114 TFEU is the appropriate legal basis since the majority of provisions of this Regulation aim to improve the functioning of the internal market". The selection of this legal basis is already an indication of the perspective under which the Proposal has been conceived and drafted. While we support full respect to the EU law principles on free movement of goods and services as included in the Treaty and chiselled by the Court of Justice of the European Union, we believe the main objective of the proposal should be to improve public health and quality of care.

From that perspective, it is equally necessary to note that article 168 of the Treaty provides that a high level of human protection is to be achieved while respecting Member State responsibility for the definition of their health policy and for the organisation and delivery of health services and medical care. The Proposal just broadly states that it is in full respect of the Treaty. However, due to its significant impact on healthcare systems and the fact that it can undoubtedly interfere with Member States competences, we call to include article 168 of the Treaty as legal basis of the Proposal. This would also be consistent with other EU pieces of legislation, such as the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU), adopted under both articles 114 and 168 of the Treaty.

We also call for the utmost respect for competences attributed to Member States in order to accommodate different realities and ensure legal certainty, especially when deciding on the content of the strikingly high number of delegated and implementing acts to be adopted[6].

[6] Enough provisions to ensure high levels of security, confidentiality and legal certainty shall always be set out by the legislator and not to be left entirely to delegated and implementing acts as the Proposal seems to suggest.

2) **The impact assessment conducted shall be re-evaluated, as it does not fully capture some dimensions of the effect of the EHDS**.

Considering the estimated economic impact of EHDS over the course of the years, economic assessments shall be based on robust evidence. Although we value the work conducted by the Commission, there are some estimations included in the impact assessment which should be re-examined. For example, there is an over-estimation of the benefits of telemedicine in particular by taking certain assumptions in the calculations (e.g. European average salary) which may overestimate the European population ability to pay for both ''traditional medicine'' and ''telemedicine'' services.

Also, the impact analysis of the cross-border provision of telemedicine shall be reviewed, as it is based on assumptions that do not necessarily reflect the real uses in the EU and on economic estimates that lack justification.

3) **Impact on fundamental rights and potential inconsistency with ethic obligations of healthcare professionals**

The EHDS will imply the processing of large amounts of sensitive health data, which is a category of data specially protected under the GDPR. As will be further explored in the next sections of this paper and has also been noted by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), there are evident doubts as to the compliance of the provisions in the Proposal with the GDPR.

The treatment of health data has, however, another important effect, which is its direct impact on the fundamental rights of citizens. In this regard, according to the proposal, market operators in the health sector (either healthcare providers or providers of digital services and products) will be obliged to share electronic health data with user-selected third parties from the health sector. Without prejudice to some pharmacies being excluded from certain obligations due to their condition of micro-enterprises, the obligation to facilitate health data from patients or even the possibility of said data being facilitated without knowledge of the healthcare professional is contrary to the custody and secrecy duties reflected in the professional codes of ethics for healthcare professionals in force in Member States. For the EHDS to truly advance healthcare and citizens to be involved in the roll out of the data space it is of utmost importance to maintain the link of trust between patients and healthcare professionals and the Proposal shall in no way limit the capacity of healthcare professionals to honour and comply with their ethical duties. Therefore, we call for the obligation to facilitate exchange of health data to be limited to situations where the patient consents in such sharing.

## B. CHAPTER II: PRIMARY USES OF HEALTH DATA

Concerning primary uses of health data, PGEU believes that community pharmacists can largely contribute to evidence-based health policy and best practices in patient care if given the tools to do so. Therefore we think that the primary use of electronic health data should support the use of data for safer and better healthcare at national and cross-border levels, through pharmacy services. Pharmacists are highly qualified healthcare professionals and have the necessary resources to contribute to real-world evidence ready datasets, such as national, regional or local electronic health records when given access to them. They are also a trusted source of reliable and independent health information for patients as they have ethical and legal obligations to protect patients' sensitive personal data. Therefore, they are key stakeholders in ensuring the access and control of individuals over their own electronic health data.

PGEU also welcomes that the Proposal brings the opportunity to link electronic health records with e-prescribing systems, thus allowing healthcare professionals directly involved in patient care to access necessary patient information from the electronic health record in order to provide better patient-centred and personalised care. We believe patient-centeredness shall be one of the cornerstones of the EHDS.

Given the bond of trust and confidentiality between patients and healthcare professionals like community pharmacists, we welcome provisions foreseeing the possibility for healthcare professionals to register and update health data, and even assist in rectification purposes. However, we call for further clarification of the categories of data that each healthcare professional will be able to register and clarify the liability and impact regarding data recorded by the citizens or their representatives and situations where restriction to data access conducted by citizens prevents from adequate pharmaceutical intervention.

We believe that healthcare professionals should be provided with appropriate electronic means, such as health professional portals, to use personal electronic health data for the exercise of their duties.

From an operational standpoint, PGEU acknowledges the progress already made by some Member States that already engaged in the Myhealth@EU or otherwise managed to implement national e-Services. We believe the functioning of such services shall be maintained where possible and particularly in data transfers without cross-border elements, without prejudice of the EHDS governing dataset interoperability or common formats and standards for the purposes of data exchange.

**1) The provision of healthcare can benefit from the use of EHDS to enhance community pharmacy services**

The role of community pharmacists goes beyond dispensing medicines and medical devices, as pharmacists often are the first healthcare professionals to provide essential prevention and primary care services[7], including detecting treatment interactions and adverse medicines reactions. From this perspective, we strongly believe that access to digital data will improve the provision of pharmacy services, and, at the same time, the provision of pharmacy services will be a source of added value for the EHDS.

A clear example of this is the growing role of community pharmacists in vaccinating the population. In some Member States, pharmacists have built a custom-made digital infrastructure and service portals which allow a secure and easy processing of health data for this purpose. In similar terms, community pharmacists will be able to provide more efficient referral to the medical professional, which will allow a decongestion of medical services and visits to the emergency rooms that could otherwise be avoided, promoting new models of care delivery which move away from traditional hospital-centred care towards patient-centred care.

In light of the above, we believe the EHDS and its implementing acts shall further accommodate as a primary use of health data the provision of healthcare services by community pharmacists. This shall include personalized medicine dosage or patient-tailored advice, among others, and reflect them explicitly in the definition set out in article 2(2)(d) along with other categories already listed such as "*relevant social security, administrative or reimbursement services*".

Some technical and ethical aspects of the system will be regulated at implementing acts level. In that regard, PGEU will remain a collaborative and trustful stakeholder aiming to share experience and best practices of our members.

**2) Interaction between the duty to ensure safe provision of healthcare and the right to selective data sharing shall be further elucidated.**

In line with the general objective of empowering citizens to tailor the use of their health data for primary purposes, the EHDS foresees the possibility for natural persons to conduct selective sharing of personal health data. While we fully support measures intended for citizens to control their own data, we also welcome the acknowledgement by the Proposal that such restrictions may have life-threatening consequences and, therefore, access to certain personal electronic health data should be possible to protect vital interests as an emergency override.

[7] PGEU Annual Report, 2021, p. 27

Also, recital 13 of the Proposal notes that, even in situations without life-threatening consequences, "*because the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services*".

Due to the sensitivity of these situations, we call for further clarification on the prerequisites and mechanisms enforceable in cases where there is a conflict between restricted access to data and proper provision of healthcare in the best interest of the citizen. Also, it is necessary to clarify in article 4 of the Proposal that the healthcare provider or professional shall be informed of the existence and nature of the restricted electronic health data in order to provide adequate healthcare when relevant data cannot be taken into consideration when providing health services. The current wording stating "*including where*" the professional is informed in article 4(4) is not fully clear on this regard.

While the Proposal leaves the adoption of specific legal provisions on the mechanisms of restrictions to Member States, expertise gained at EU level shall be reflected in the EHDS. Some proposed solutions at EU-level shall be explored, including mechanisms for healthcare professionals to distinguish whether the data categories access has been restricted to are linked to the specific consultation posed (e.g. restricting access to data concerning unrelated pathologies).

**3) The EHDS will have a positive impact on electronic prescription recognition in the context of cross-border healthcare. However, it shall ensure adequate protection levels.**

The Proposal includes e-prescriptions among priority categories of personal electronic health data for primary use, which implies that Member States shall implement its access to and exchange. We fully support this inclusion and would like to highlight the importance to set out measures to enhance recognition of electronic prescriptions across different Member States and ensure full applicability of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

Although the work conducted on the European electronic health record exchange format constitutes a solid foundation to ensure interoperability of electronic prescriptions, the use of interoperable exchange formats should become more generalised at EU and national level. This also includes considering the existing systems in community pharmacies to identify the electronic prescriptions issued by other Member States – which in some cases is currently conducted through social security number. Other issues pharmacists face should be considered, such as the fact that the same medicine is not necessarily marketed under the same name or in the same strength across Member States, and therefore an

electronic prescription may not necessarily correspond to the packaging and substitution options available in the Member State where the prescription is to be dispensed.

We also note that the recognition of electronic prescriptions in a cross-border setting shall comply with the necessary standards of trust and safety. In that regard, it is necessary in order to improve legal certainty for the EHDS to be coherent with the principle of subsidiarity which recognizes the capacity of Member States to, based on their own competences and with the aim to safeguard public health, regulate the online sale of prescription-only medicines and to limit direct reimbursement to medicines which have been obtained according to the respective national regulations.

In order to avoid possible interpretative deviances, we recommend that article 12(6) of the Proposal includes a specific reference to the fact that pharmacies, when dispensing electronic prescriptions issued by other Member States, are also subject to the conditions set out under national law according to article 85c of the Directive 83/2001/CE.

4) **The regime on telemedicine foreseen in the Proposal does not duly consider the different spectrum of existing services at a distance and has serious implementation hurdles that have not been considered.**

Brick-and-mortar community pharmacies across Europe offer in many cases online services for their patients to complement their face-to-face relationship whilst guaranteeing trust, professional advice, and patient safety at all times. As part of this wide service approach, community pharmacies can enable patients to reserve and order their medicines from their trusted local pharmacy, among other solutions.

With regards to such pharmacy services, PGEU notes that the Proposal does not adequately ponder the particularities and real impact of the use of the concept "online pharmacies" when including them under the definition of "telemedicine" in article 2. We note that there is no definition of "online pharmacy" in the European regulatory framework and the use of such a concept causes legal uncertainty and unpredictability, as such figures are differently regulated across the European Union. Following this reasoning, we note that previous documents produced by the European Commission, such as the Communication on telemedicine for the benefit of patients, healthcare systems and society[8], while already recognized that the term "telemedicine" encompasses a wide variety of services, did not include online pharmacies due to such specificities.

[8]Communication on telemedicine for the benefit of patients, healthcare systems and society https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52008DC0689&from=EN

The Proposal includes a definition of "telemedicine" that reads as "the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location". Therefore, the definition of telemedicine focuses on remote services and clearly regulates a different figure of that to the sale at a distance to the public and both regimes shall be coherent yet clearly differentiated.

Therefore, we call for the deletion of the specific mention to online pharmacies throughout the Proposal[9], including in the definition of telemedicine and define telemedicine through the concurrence of the elements already present in the proposed definition.

Moreover, from an implementation standpoint, issues such as the funding of the services and reimbursement rules, methods to ensure appropriate care and knowledge of the local health system from healthcare providers located abroad (including its rules and processes and available treatments and treatment providers, available medicines on the patients' local market) among others shall be taken into consideration.

PGEU acknowledges that in any case article 8 of the Proposal shall aim to provide a legal framework in line with Member States' competence to decide on the level of protection they wish to grant to the health of their citizens and ensure a level playing field for the competition of all health services provided locally and online in line with article 168 of the Treaty and in line with article 85c of the Directive 83/2001/CE.

5) **Despite the preparatory work on ethical principles, the Proposal lacks measures aimed at ensuring sufficient levels of digital literacy, which is as a prerequisite for the functioning of the EHDS.**

PGEU observes that the Proposal does not contain measures oriented towards ensuring sufficient levels of digital and health literacy for citizens and healthcare professionals. It is well known for the European Commission that a 2017 report conducted by the Commission itself revealed that 169 million Europeans between 16 and 74 years – 44% – do not have basic digital skills.[10]

[9] For instance, in articles 2(2) and 12(6) of the Proposal
[10] http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=47880

Moreover, according to Eurostat data in 2021, the share of people aged 16 to 74 who had at least basic overall digital skills ranged from 79% to only 28%, depending on the Member State[11], which clearly shows different speeds in digital transformation. Epecially in more rural areas, which are often populated by an elderly population, there is usually more limited access to digital solutions compared with urban areas. People with lower financial resources tend to have higher disease burdens and health needs, yet they are more vulnerable regarding access to and understanding of health information. They may be less aware of issues of privacy, health data use, and data protection and are also more likely to experience digital exclusion.

Hence, we strongly believe that it is essential for a truly operational EHDS to address digital literacy through appropriate policies and funding. The EU could facilitate this by offering appropriate financial support for the Member States, for example via the EU4Health programme. Community pharmacists already help and invest to close the gap between citizens and the understanding, accessibility and use of innovative technologies in healthcare. In addition, in our view it is essential that Member States safeguard equity in healthcare by guaranteeing alternatives to digital health solutions for those patients with little digital literacy or skills or with limited access to the Internet and digital tools.

## C. CHAPTER III – EHR SYSTEMS AND WELLNESS APPLICATIONS

Chapter III of the Proposal focuses on implementing a mandatory self-certification scheme for EHR systems, where such systems must comply with essential requirements related to interoperability and security. PGEU welcomes measures aimed at ensuring that electronic health records are compatible between each system and a clear scheme of obligations for each economic operator of EHR system. However, we note that interoperability standards shall be aligned as much as possible with detected best practices and existing technical solutions in order to avoid that the burden of implementing additional regulatory requirements has economic repercussions in healthcare professionals (e.g. through higher prices for mandatory software licenses). We therefore call to consider such policy and economic implications when designing common specifications for EHR systems.

Additionally, EHR systems and other central data sources shall be used, as a general rule, to transmit data in a safe and trustworthy manner and only where this is not possible, other data holders such as healthcare professionals shall be individually approached.

[11] https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220330-1

## D. CHAPTER IV - SECONDARY USE OF ELECTRONIC HEALTH DATA

Community pharmacists are familiar with secondary uses of health data as they routinely collect and process electronic health data of individuals, which can be used to generate real-world evidence. Every pharmacy collects dispensing data that can be used to generate evidence on medicine use, prevalence of diseases, adherence or medicine shortages. Community pharmacists report adverse medication reactions, medication errors or help patients do so themselves: this data is used at a national and European level for pharmacovigilance purposes.

This patient control over their own health data and the protection of the bond of trust and confidentiality between patients and healthcare professionals like community pharmacists, which is protected by criminal law in the Member States, must be regarded as the primary principle for the EHDS. Any misuse of individual patient data or any breach of data security would constitute an outstandingly great risk, given the large amount of very sensitive health data in the EHDS. Therefore, very strong fences of highest reliability must be integrated into the system from the beginning. Member States should reinforce this by introducing appropriate sanctions for breaches of confidentiality and data security.

Furthermore, community pharmacists are strategically placed at the heart of the communities, providing patients high quality information, including on the use of medicines, digital technologies and medical devices. As certain medicines/medical devices can be complemented with mobile applications that allow the patient to better understand and control their health, pharmacists are key professionals to further educate and upskill patients in owning their own data.

We believe that secondary uses of electronic health data, if included in a balanced and protective enough legal landscape, can enormously improve the provision of healthcare. It should not be forgotten, however, that health data is a very sensitive type of data that has a recognized specific protection. In other words, unappropriated uses of health data can also strip citizens of their privacy rights and hinder the provision of healthcare from a social perspective instead of improving it. Therefore, in line with the concerns raised by the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS), we call to include some amendments to ensure that secondary uses of electronic health data fully comply with the GDPR, and that health data is not treated as a commercial good.

1) **Real applicability and enforcement of data protection principles, and namely data minimization, shall be safeguarded.**

PGEU welcomes the purpose-based system as a first filter and necessary mechanism for the use of electronic health data for secondary uses. However, it should also be noted that the system shall aim to detect and avoid data access requests that, although based on legitimate purposes, go beyond what is necessary because they ask for greater datasets or for longer periods of time than necessary.

In this regard, and although article 44 of the Proposal formally recognizes the principle of data minimization, other articles referring to secondary uses of electronic health data were drafted following political options that do not maximize the principles of data minimization, consent, and other guarantees enshrined in the GDPR.

While we understand that speed is critical for some research activities such as clinical trials and therefore it is necessary to have efficient and functional working times, this cannot come at the cost of undermining protection for individuals or disregarding other pieces of legislation. Consequently, we call for the following suggestions to be reflected in the final text:

- Further develop anonymization and pseudonymization standards, including a specific mention in article 33 of the Proposal for those categories, such as genomic or genetic data, or data from biobanks, among others, where anonymization is not possible or where there are high chances of privacy breaches in the anonymization processes. For the latter categories of data, due to the impossibility of full anonymization, we recommend setting out opt-in mechanisms where necessary to safeguard privacy rights.

  Please note that, in general, removing the requirement to obtain consent from national persons as set out in article 33(5) of the Proposal may not only collide with ethical principles of professional secrecy applicable to healthcare professionals but also with article 9(2)(h) and 9(2)(i) read jointly with article 9(3) of the GDPR and therefore violate basic safeguards protecting the rights and freedoms of citizens.

- Article 33 shall be further adapted as in its current form would introduce a potentially huge workload for health professionals which often do not classify as “micro”, but “small” enterprises. Also, it does not contain an appropriate level of protection for health data and even business secrets (single data holders shall be obliged to make their complete administrative data, including claims and reimbursement, available upon request). Also, where the exclusion due to healthcare professionals qualifying as micro-enterprises is

applicable, data access bodies shall not conduct any practice with the aim to obtain that same data from private professional entities or professional associations.

- Article 35 shall include among forbidden conducts measures aimed at precluding incentives to excessive access applications or abusive requests for data in non-anonymized format and include an express prohibition to re-profile individuals.

**2) Health data access bodies should be duly involved in the evaluation of applications for data access.**

Data protection principles can also be guaranteed through adequate involvement of health data access bodies and, to that end, PGEU supports that all data access applications shall be reviewed by data access bodies. We note, however, that the current two-month deadline for health data access bodies to review applications can create perverse effects if, for example, entities requesting access to data know that the data access body of a certain Member State is saturated and will not be able to review the application within two months and submit and get approved due to this two-month deadline an illegal and abusive request to access data. Such dodges shall be corrected when dealing with sensitive data such as data on clinical conditions or clinical tests conducted. In order to alleviate possible excessive workload, we suggest ensuring that health data access bodies have sufficient human and material resources or even limit the tasks entrusted to them that may overlap with those already entrusted to other boards or bodies or unify fee criteria to facilitate even distribution of access applications.

Following the same reasoning, the Proposal foresees a situation where involvement of data access bodies is not even foreseen, which is that of access from a single data holder (article 49). According to recital 53 of the Proposal, the data user should be able to request this data directly from the data holder and the data holder should be able to issue a data permit to "alleviate the administrative burden". We believe this provision is a precursor of data shopping and contrary to the logic of the Proposal and even the most basic principles of data protection, which is why we call for it to be removed from the Proposal. In this regard, if entity A accessed data for legitimate purpose and entity B wants access to that same data for purposes allegedly included in the Proposal, nothing ensures that entity A has the knowledge or the resources to evaluate the use intended by entity B and more importantly, there will be no public surveillance on whether the purposes of entity B are actually legitimate under the Proposal.

**3) The exclusion of the need to gather consent from citizens when using their data for secondary purposes is not justified in the GDPR.**

Several studies conducted on health information exchanges concluded that there is some degree of concern from citizens regarding the effect of such exchanges on privacy and security[12]. In fact, most respondents are in favour of electronic data sharing, but elements of transparency are important: individual control, who has access, and the purpose for use of data[13]. Similar studies suggest also that citizens are more prone to data sharing when they understand the specific uses of such data[14];[15].

However, article 38(2) of the Proposal exempts certain entities (the health data access bodies) from applying the provisions of Article 14 GDPR concerning information to be provided to data subjects. In practice, citizens will not get personally notified when their data is used for secondary purposes. On this matter, the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) consider in their joint report on the EHDS that "*such exemption undermines the possibility for data subjects to exercise an effective control over their personal data rather than strengthen it and thus appears to be at odds with the objective laid down in Article 1(2)(a) of the Proposal*"[16]. Also, please note that some Member States already designed their IT systems on the basis of requiring consent prior to data use and setting out an obligation to switch such policy choice is legally questionable considering the competences of Member States under article 168 of the Treaty.

PGEU aligns with the conclusions by the EDPB and the EDPS and we strongly recommend that the EHDS aligns its content with the GDPR and grants even higher levels of data protection and includes effective control mechanisms, including consent, for secondary uses of health data.

[12] Cfr, inter alia, milestone 8.2 of the TEDHAS initiative Healthy Data, an online citizen consultation about health data reuse – intermediate report, June 2022. Accessible in https://tehdas.eu/results/tehdas-consultation-people-support-health-data-use-with-solid-safeguards/

[13] Katherine K Kim, Jill G Joseph, Lucila Ohno-Machado, Comparison of consumers' views on electronic data sharing for healthcare and research, Journal of the American Medical Informatics Association, Volume 22, Issue 4, July 2015, Pages 821–830, https://doi.org/10.1093/jamia/ocv014

[14] Weitzman ER, Kaci L, Mandl KD. Sharing medical data for health research: the early personal health record experience. J Med Internet Res. 2010 ;12 (2):e14

[15] Willison DJ, Keshavjee K, Nair K, Goldsmith C, Holbrook AM; Computerization of Medical Practices for the Enhancement of Therapeutic Effectiveness investigators. Patients' consent preferences for research uses of information in electronic medical records: interview and survey data. BMJ. 2003 Feb 15;326(7385):373. doi: 10.1136/bmj.326.7385.373. PMID: 12586673; PMCID: PMC148897.

[16] EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space adopted on 12 July 2022.

## E. CHAPTERS VI TO IX: EUROPEAN GOVERNANCE AND COORDINATION AND OTHER PROVISIONS

As stated in recital 23 of the Proposal, digital health authorities should have sufficient technical skills, possibly bringing together experts from different organisations. Governing structures of data-sharing initiatives should duly include representatives from trusted advocacy organisations, including healthcare professionals.

However, this provision does not result in the proper representation of healthcare professionals in all the governing bodies. Therefore, we ask for a specific reference to the representation of healthcare professionals in meetings where issues of their competence are included in the agenda for digital health authorities and, in particular, the EHDS Board (article 64§4 of the Proposal)[17]. Also, we would like to encourage the European Commission and other public entities to take advantage of the expertise and knowledge of healthcare professionals including community pharmacists.

All in all, PGEU welcomes the functionalities of an EHDS and remains a trusted stakeholder available to collaborate with institutions and governments in the construction of electronic systems, improve healthcare quality and address digital literacy. However, we suggest reviewing the implementation period foreseen in the Proposal, as due to the large number of implementing acts to be passed and technical and legal adjustments required, the 12-month implementation deadline may not be realistic for some of the EHDS functionalities.

[17] Study on Digital Health implementation in the EU - Final Report conducted by the Digital Health Delegation from the French Ministry of Health, in partnership with EY and its European network, April 2022. Study on digital health in the EU | Europe & International (esante.gouv.fr)

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

# Policy Recommendations

In light of the abovementioned considerations, PGEU proposes the following policy recommendations regarding the establishment and functioning of the EHDS:

- The Proposal will have a significant impact on public health and health care system therefore Article 168 of the Treaty should include as a legal basis. Public health objectives should prevail over considerations regarding the internal market.

- The proposal should guarantee the highest level of data protection and be compliant with the GDPR and other pieces of EU legislation. Sensitive patients' health data should not be considered as a commercial commodity.

- Some elements of the Impact Assessment accompanying the Proposal, including some economic estimations such as the quantification of expected costs and benefits, should be reconsidered and complemented with more granular economic calculations and robust evidence.

- For the EHDS to truly advance healthcare and citizens to be involved in the roll out of the data space it is of utmost importance to maintain the link of trust between patients and healthcare professionals and the Proposal shall in no way limit the capacity of healthcare professionals to honour and comply with their ethical duties (e.g. requiring unbalanced systematic and repeated data registration).

- The language used in the EHDS Proposal can be improved to further accommodate the reality of the provision of healthcare across Europe. In particular, we call to replace the mentions to “healthcare providers and pharmacies” (i.e. in recital 24) to simply “healthcare providers”, as pharmacists are already included in such definition and the reiteration might create interpretative hurdles. To name other examples, references to “medical data” often refer to “clinical data”, or references to “doctors” sometimes refer to “healthcare professionals”.

- Certain definitions included in article 2(2) can be further adjusted to ensure legal certainty and coherence of the Proposal, namely:

- The provision of healthcare services by community pharmacists shall be explicitly reflected in the definition of "primary uses of health data" along with other categories already listed such as "relevant social security, administrative or reimbursement services."

- The mention to "online pharmacies" in the definition of "telemedicine" shall be deleted. For coherence and legal certainty reasons, the mention to online pharmacies shall also be removed from article 12(6) of the Proposal. Rather, we support a definition based on the conforming elements of telemedicine, namely the provision of a healthcare service, the use of information and communication technologies and lack of same physical location.

- It should be clarified in article 4 of the Proposal that, in situations where patients exercise their right to restrict access to part of their electronic health data, the healthcare provider or professional shall be informed of the existence and nature of the restricted electronic health data. This should be done in order to provide adequate healthcare service and professional advice, taking into consideration that patient data are not complete when providing professional advice or a health service to that patient.

- Interpretative overlaps with Directive 83/2001/CE shall be avoided. In particular:

  - The concept of "telemedicine" shall under no circumstance be confused with that of sale at a distance to the public, a category regulated in the Directive 2001/83/EC. We recommend clarifying this point in article 2(2) of the Proposal.

  - We recommend that article 12(6) of the Proposal includes a specific reference to the fact that pharmacies are enabled to dispense electronic prescriptions issued by other Member States also subject to the conditions set out under national law according to article 85c of the Directive 83/2001/CE.

- Further develop anonymization and pseudonymization quality standards, including a specific mention in article 33 of the Proposal for those categories, such as genomic or genetic data, or data from biobanks, among others, where anonymization is not possible or where there are high chances of privacy breaches in the anonymization processes. For the latter categories of data, due to the impossibility of full anonymization, we recommend setting out opt-in mechanisms where necessary to safeguard privacy rights.

  Please note that, in general, removing the requirement to obtain consent from national persons as set out in article 33(5) of the Proposal may collide with ethical principles of professional secrecy

applicable to healthcare professionals and also with article 9(2)(h) and 9(2)(i) read jointly with article 9(3) of the GDPR and therefore violate basic safeguards protecting the rights and freedoms of citizens.

- Article 33 shall be further adapted as in its current wording would introduce a potentially huge workload for healthcare professionals which often do not classify as "micro", but "small" enterprises. Also, it does not contain an appropriate level of protection for health data and even business secrets (single data holders shall be obliged to make their complete administrative data, including claims and reimbursement, available upon request). Also, where the exclusion due to health professionals qualifying as micro-enterprises is applicable, data access bodies shall not conduct any practice with the aim to obtain that same data from private professional entities or professional associations.

- Article 35 shall include among forbidden conducts measures aimed at precluding incentives to excessive access applications or abusive requests for data in non-anonymized format and include an express prohibition to re-profile individuals.

- For a truly operational EHDS it is essential to address digital literacy through appropriate policies and funding.