EUROPEAN COMMISSION

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Dear Chair,

The Commission would like to thank the Poslanecká sněmovna for its Opinion on the Communication from the Commission to the European Parliament and the Council 'A European Health Data Space: harnessing the power of health data for people, patients and innovation' {COM(2022) 196 final} and the proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space {COM(2022) 197 final}.

The COVID-19 pandemic has clearly demonstrated the importance of digital services in the health area. The uptake of digital tools increased significantly during this time. However, the complexity of rules, structures and processes across Member States makes it difficult to access and share health data, especially cross-border.

The European Health Data Space is a health specific ecosystem comprised of rules, common standards and practices, infrastructures and a governance framework that aims at (i) empowering individuals through increased digital access to and control of their electronic personal health data and support to their free movement, (ii) fostering a genuine single market for electronic health record systems, relevant medical devices and high-risk artificial intelligence systems and (iii) providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities.

It makes the European Health Union stronger and places patients at its centre. It is the first common European Union data space in a specific area to emerge from the European Union strategy for data and is an integral part of the digital transition priority of the Commission.

In response to the more technical comments in the Opinion, the Commission would like to refer to the attached annex.

Discussions between the Commission and the co-legislators, the European Parliament and the Council, concerning the proposal are now underway and the Commission

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remains hopeful that a timely agreement will be reached. The Opinion of the Poslanecká sněmovna will be used by the Commission to inform the discussions in the ongoing negotiations of the co-legislators.

The Commission hopes that the clarifications provided in this reply address the issues raised by the Poslanecká sněmovna and looks forward to continuing the political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

Stella Kyriakides
Member of the Commission

Annex

The Commission has carefully considered each of the issues raised by the Poslanecká sněmovna in its Opinion and is pleased to offer the following clarifications to the concerns, expressed under point 2.

Letter a): Under the Commission's proposal, when health data is used for research, innovation or policy-making, by default, anonymised data (which cannot be reasonably linked to an identifiable person) is processed, based on a permit from the national health data access body, for specific purposes with strong public benefit for the health sector and in a secure environment. For access to pseudonymised data (with direct identifiers removed and identification data, where it is kept, segregated), the re-user needs to provide justifications to the health data access body as part of the procedure for being granted a permit. Also in this case, no personal data leaves the secure processing environment. It is important to underline that citizens can be assured that their personal health data will not be misused.

The European Health Data Space proposal aims, in a balanced way, to protect people's privacy, while allowing science and innovation to benefit from access to health data. With the safeguards included in the proposal to ensure the protection of personal data, the Commission is confident that this is a balanced and proportionate approach when it comes to the re-use of health data for research purposes. The Commission's approach is in line with the possibilities offered by the General Data Protection Regulation. Article 21 of that Regulation on the right to object for grounds relating to the data subject's particular situation applies.

Letter b): The European Health Data Space proposal requires that the systems are interoperable and that a common data exchange format is used. As shown by the Impact Assessment[1]*, currently, the costs and time entailed by repeating the same laboratory tests or images with different healthcare providers because of lack of interoperability are enormous and add to an already strained health system.*

It will be for electronic health records systems providers and for medical facilities to assess the type and number of changes needed to make the existing system interoperable and decide on the best interoperable IT solution to connect to the system. The proposal does not mandate a full redevelopment of existing systems. Some solutions may involve the addition of small software components dedicated to interoperability.

As part of the Impact Assessment for the European Health Data Space proposal, the need for digital training of the healthcare professionals has been identified as an important contributing factor to the success of the implementation of the European Health Data Space system. European Union funding is available to Member States in order to assist them in this transition.

[1] https://health.ec.europa.eu/publications/impact-assessment-european-health-data-space_en

Finally, the priority categories of personal electronic health data for primary use will be implemented through a phased and gradual approach.

Letter c): So far, the vendor lock-in made very difficult for smaller producers to enter new markets, as also shown by the EHDS Impact Assessment. The use of an interoperable format will prevent such issue and allow customers to switch software more easily. Therefore, by using wider and more open standards, the EHDS has, on the contrary, the potential to allow smaller manufacturers to compete more fairly with bigger providers of legacy systems by proposing products better suited to their customers' needs.

Letter d): The proposed solution is decentralised, i.e. health data will only be stored in the Member State or with the healthcare providers where it is collected. There is no plan to establish a single data store for collecting all health data at a European level. There will be no significant changes regarding healthcare providers' storage and recovery plans for their data. The European Health Data Space proposal would establish infrastructures (MyHealth@EU and HealthData@EU) necessary for sharing the data for the purposes of healthcare provision (primary use) and for secondary use that would benefit the society (such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities). These infrastructures do not centralise data in one European Union wide database. Two joint controllership groups will be created and tasked to manage the common cross-border infrastructures. Disaster recovery plan is a standard element of the implementation of complex network infrastructure. Thus, the source data stay untouched so any downtime of the proposed infrastructure will not affect the data housed in each medical facility. In addition, business continuity plan will be part of the implementation of the infrastructure to ensure sufficient resilience/uptime.

Letter e): The European Health Data Space proposal is not linked to the provision of healthcare, in the sense that it does not regulate the preconditions for the patients to receive healthcare. However, with the proposal, the patient has the right to ask a data holder (for example a healthcare provider) to share their data with other healthcare providers immediately, free of charge and without hindrance from the data holder or from manufacturers of the systems used by that data holder. As the Impact Assessment shows, improved interoperability of health data would facilitate access by various medical practitioners.

Letter f): As indicated under the reply to letter d), there is no European Union wide centralised database of all health data being created under the European Health Data Space proposal. Regarding the re-use of electronic health data, a copy of the necessary data set will be collected by the Member States' health data access bodies from the data holders and made available to the data user within a secure processing environment. Only the data deemed necessary for the needs of the data user will be made available. The data user can only extract anonymous data from the secure processing environment.

Following the expiration of the data permit, the data offered to the user through the secure processing environment will be deleted. On the purposes for re-use, see also reply to letter g) below.

Letter g): The data user must clearly indicate and explain, in its data access application, the intended use and purpose of the requested data. It will allow the health data access body to distinguish between projects beneficial for society which are allowed, and harmful projects which are clearly prohibited under Article 35 of the proposal. The data permit is granted on the basis of that declaration. Should, at a later stage, the data user not comply with these requirements, the health data access body will stop the data user's access to the data and can also issue penalties linked to such abuse.

Letter h): Regarding access to the patient's health data for primary use, such access will still be regulated by the applicable national and professional rules in this domain. In addition, healthcare professionals need to comply, in any event, with the data minimisation rules and all other requirements of the General Data Protection Regulation.

Access to the patient's data for secondary use will also be limited to what is deemed necessary by the health data access body to allow the data user to complete their project with the data made available. In addition, all the data made available will be anonymised, or at least pseudonymised in exceptional cases (see also the reply to letter a) above). Access to such data will be done through a secure processing environment that prevents patient re-identification and unlawful combination of various datasets.

Letter i): Information added by patients will be clearly marked, distinguished and isolated from information provided by healthcare professionals. The data provided by patients such as smoking, drinking habits or nutrition behaviour as well as data collected by devices such as smart watches is in many cases useful for the provision of healthcare.

Letter j): The certification of electronic health records systems aims at improving interoperability and cybersecurity. Improved cybersecurity of systems that process electronic health records will reduce the risk of costly disruptions across healthcare systems and also improve protection of confidentiality and integrity. Interoperability can increase the efficiency of healthcare systems by reducing duplications, errors and saving time, while also facilitating the re-use of health data, which would promote innovation and better decision-making in health, among other advantages. Therefore, it is expected that the additional costs incurred by actors in the health system will be offset by the benefits of a more effective use of health data and will contribute to a high level of health care provision. According to the Impact Assessment, the European Health Data Space as a whole would contribute with EUR 11 billion in benefits over the next ten years.

Letter k): The Impact Assessment report accompanying the European Health Data Space proposal includes a section[2] on monitoring and evaluation. The indicators for the monitoring and evaluation framework of the European Health Data Space are developed and described in the Impact Assessment report[3]. Considering the current challenges to monitor the progress in Member States on digitalisation in healthcare, the monitoring and evaluation framework provides for a series of yearly indicators collected at national level and monitored at European Union level. The Commission will review the indicators periodically and evaluate the impacts of the legislative act after seven years.

Letter l): In accordance with the provisions of the European Health Data Space proposal, the Commission will carry out two evaluations on this Regulation: five years after its entry into force it will carry out a partial evaluation on the self-certification of electronic health records systems and seven years after its entry into force it will carry out an overall evaluation of the Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Letter m): The patients and healthcare providers will directly benefit from the European Health Data Space. New vaccines or new generation therapeutics may arrive more quickly because it will prove far easier to conduct research on a European scale with higher-quality data. Data would be readily and widely available for researchers, start-ups and other developers to develop medicines, medical devices, including with artificial intelligence for limited purposes that support the health of European Union citizens, under strict conditions of privacy, security and supervision. This can contribute to making drugs or medical devices more effective and with less side effects.

For example, the pooling and sharing of knowledge, experience and data can help developing practical solutions for cancer patients and to better understand some of the causes of cancer. Understanding the cause is key for more targeted and effective cancer screening, which would result in earlier diagnosis and therefore better chances of survival for the patients.

The European Health Data Space will also address the needs of rare diseases patients. The vast majority of people living with a rare disease are willing to share their health data to advance care and research. The European Health Data Space will unleash the potential for better cross-border access to such data and will support the development of treatments and health services for rare disease patients.

As regards financial aspects, single data holders (for example, private/public hospitals) will be allowed to charge fees for making data available based on the provisions of Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) in relation to their tasks. To ensure a harmonised approach concerning

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[2] See section 9 of the Impact Assessment on the European Health Data Space (europa.eu).

[3] See table 9 of the Impact Assessment on the European Health Data Space (europa.eu).

fee policies and structure, the Commission may adopt implementing acts. Such fees will compensate for the administrative expenditure for making the data available; they are not intended to provide revenue for 'selling' data.
