Position Paper

Response to EC consultation on a European Health Data Space

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Section 1: Access and use of personal health data for healthcare, research and innovation, policy-making and regulatory decision-making

Q1. *The cross-border healthcare Directive has established the eHealth Network and an infrastructure to facilitate health data sharing across the EU (Article 14) and includes other aspects with relevance for digital health. In the last 5 years are you aware of any changes in the following aspects of health data sharing across border?*

	Greatly reduced	Slightly reduced	No changes	Slightly increased	Greatly increased	I don't know / No opinion
Exchange of health data such as patients' summaries and ePrescriptions						x
Continuity and access to safe and high quality healthcare						x
Development of methods for enabling the use of medical information for public health and research						x
Development of common identification and authentication measures						x

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	Greatly reduced	Slightly reduced	No changes	Slightly increased	Greatly increased	I don't know / No opinion
to facilitate transferability of data						
Access of patients to an electronic copy of the electronic health record						x
Cross-border provision of telemedicine				x		

Q2. *Should a European framework on the access and exchange of personal health data aim at achieving the following objectives?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Facilitate delivering healthcare for citizens at national level					x	
Facilitate delivering healthcare for citizens across borders				x		
Promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format				x		
Promote the use of digital health products and services by healthcare professionals and citizens			x			
Support decisions by policy-makers and regulators in health			x			
Support and accelerate research in health					x	

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Promote private initiatives (e.g. for innovation and commercial use) in digital health					x	
Other						x

Please specify:

A European framework on the access and exchange of personal health data should aim to establish a uniform legislative framework at EU level that strives for a true level playing field between equal players and benefits consumers. At present, EU member states have made significantly divergent use of the specification clauses of the General Data Protection Regulation (GDPR). The resulting fragmentation creates significant challenges when conducting cross-border services and for innovation and scientific research involving health-related data. This adds to an already complex scenario composed of different healthcare and social security systems across the EU.

The challenges concern not only healthcare in its strictest sense; rather they apply to all areas necessitating the processing of health-related data, including the provision of insurance services. For instance, the use of health data provided by a wearable device is regulated differently in different member states. While in some it is permitted, on the basis of consent, to use health-wearables data to define the premium of a health or life insurance product, with human oversight (employee agreement), in Belgium, for example, a recent law prohibits pricing on this basis (*Loi du 10 décembre 2020 modifiant la loi du 4 avril 2014 relative aux assurances en vue d'établir dans le domaine de l'assurance maladie et de l'assurance individuelle sur la vie une restriction de traitement des données à caractère personnel concernant le mode de vie ou la santé issues des objets connectés*). Innovative solutions such as health wearables can contribute to preventive strategies, which are also offered by insurance companies, and ultimately to the sustainability of healthcare systems by reducing costs and improving people's health. That being said, the reimbursement decisions should remain a matter of national competence because of the significant differences between national legal frameworks for social security healthcare.

Citizens' control over their own health data is of central importance for such a harmonised regulatory framework. It is important to ensure that they know who processes their health-related data for which purposes and that they can stop unlawful use of their data. This, however, does not mean that consent should always be the legal basis for the processing of health-related data. On the contrary, the requirement for additional consent for contracts to which the data subject already agreed and which require the processing of health-related data actually results in unnecessary bureaucratic effort and causes misconceptions that the data is not necessary for the contract. When promoting citizens' control over their data, it should be taken into consideration that many rights such as the right to access one's data and the right to request its transmission in electronic format are already guaranteed by the GDPR. The regulatory proposal for the European Health Data Space (EHDS) should avoid any double regulation and burdensome requirements.

1.1. Access to and exchange of health data for healthcare

Q4. *Which of the following elements do you consider the most appropriate for controlling access and sharing your health data with healthcare professionals?*

Insurance Europe believes that individuals should be able to allow access to their personal data to a much higher extent than is possible today. There should, for example, be practical solutions that would allow individuals to exercise control over their own data, with appropriate consideration given to the security of sensitive data. Individuals should be able to grant other parties access to the data generated by them in the course of medical treatment.

For example, the conclusion and the execution of insurance contracts (eg, life, health, liability and accident insurance) require patients to disclose relevant health data and provide verifying documents. Gathering that information often proves cumbersome and slow for them. The process could be noticeably improved and accelerated if patients could instead allow the insurer to collect the necessary data from electronic health records.

Q5. *In your view, who is best suited to develop these standards and technical requirements at EU level to support exchange of data in healthcare?*

☒ National digital health bodies cooperating at EU level
☐ An EU body
☐ Other

Standards and technical requirements should be developed by national digital health bodies that cooperate closely at EU level. National bodies possess a better grasp of the particularities of each country's healthcare sector and can build on already established systems when developing standards and technical requirements. However, in order to guarantee harmonisation and facilitate the cross-border exchange of health-related data, a mechanism is necessary to ensure comparable standards at EU level. As the enforcement of the GDPR has shown, where different national supervisory authorities have widely differing views on the necessary technical and organisational measures, the lack of an effective coordination mechanism will likely lead to fragmentation.

Q6. *In your views, how should these standards and technical requirements be made applicable at national level and across the EU?*

☒ By a labelling scheme (a voluntary label indicating the interoperability level)
☐ By a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)
☐ By an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)
☐ Other

Q7. *Which of the following measures would be the most appropriate:*

☒ By a labelling scheme (a voluntary label indicating the interoperability level)
☐ By a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)
☐ By an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)
☐ Other

Voluntary labelling schemes have traditionally proved to be effective means of ensuring high and transparent standards (eg, in the area of IT security). They enable easy identification of trustworthy services and allow providers to display the quality of their services and to further promote them. Many service providers would likely voluntarily opt for a label to safeguard their reputation and competitiveness and to ensure compliance

with current standards for interoperability. Meanwhile, mandatory certification or authorisation schemes could slow down the use of data spaces and data-sharing services due to the often complex and slow processes involved.

Q8. *(For healthcare professionals only) In your views, what would be the costs on healthcare professionals/providers of measures facilitating access to, control and transmission of health data for healthcare?*

	No impact	Moderate impact	High impact	I don't know / No opinion
Implementation costs for national healthcare providers (setting up infrastructure, complying with defined standards, etc.).			x	
Costs for healthcare professionals and providers (human resources, finances, etc.)			x	
Information and monitoring			x	
Other				x

Please specify:

While insurance companies cannot be considered healthcare professionals for the purposes of these questions, the insurance industry is in a unique position to provide additional insight (eg, in liability cases insurers often act on behalf of healthcare professionals when legal disputes or disagreements arise). In such cases, both technical implementation costs as well as additional costs have proved to have a major impact.

Q9. *In your views, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?*

Access to efficient and safe care

	No impact	Moderate impact	High impact	I don't know / No opinion
Facilitated access to healthcare across borders in the EU				x

Benefits for patients

	No impact	Moderate impact	High impact	I don't know / No opinion
Transparency on the processing of their health data			x	
Reduced costs stemming from not duplicating efforts and tests			x	
Reduced administrative burden			x	

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion
Better healthcare provision (including risks and errors)			x	
Reduced costs and reduced duplication of efforts			x	
Reduced administrative burden			x	
Technological progress			x	

Other

Please specify:

In general, facilitated access to and sharing of health-related data has many benefits for consumers, providers of health-related services and society as a whole. In addition to the positive effects on research, the reduced administrative burden and greater legal certainty can accelerate the provision of health-related services to consumers. This, in turn, leads to a reduction in costs for service providers, which allows them to offer consumers lower prices.

With greater digitalization and availability of data made available in secure and easily readable file formats, the insurer can benefit policyholders by facilitating easier and faster compensation. Initiatives on the usage of, access to and sharing of data should be considered in a broad context, with a focus on cross-sectoral data-sharing between all sectors of society.

1.2. Access and use of personal health data for research and innovation, policy-making and regulatory decision

Q10. *What mechanism do you consider more appropriate to facilitate the access to health data for research, innovation, policy-making and regulatory decision? (Please rank from the most (1) to the least (4) preferred option)*

	1	2	3	4	I don't know / No opinion
Voluntary appointment of a national body that authorises access to health data by third parties					X
Mandatory appointment of a national body that authorises access to health data by third parties					X
A public body collects the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data					X
A private not-for-profit entity collects the consent of individuals to share their health data for specified societal uses ("data altruism") and					X

	1	2	3	4	I don't know / No opinion
manages their health data – as designed in the proposed Data Governance Act					

Q11. *In your opinion, would additional rules on conditions for access to health data for research, innovation, policy-making and regulatory decision be needed at EU level?*

Health data categories

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Health data from medical records						x		
Administrative data in relation to reimbursement of healthcare						x		
Social care data						x		
Genetic and genomic data						x		

Format (for any of the above data categories)

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Anonymised aggregated format (e.g. statistics)						x		

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Pseudonymised format (without identifiers of individuals)						x		
Fully identifiable format						x		

Eligibility

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Criteria and conditions for providing / accessing data in the EHDS are defined						x		
Safeguards for the access to health data for the purpose of re-use, in line with ethical and data protection requirements, are defined						x		
Limit the transfer of non-personal health data outside the EU/EEA							x	

Security

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Conditions for the secure access to health data are defined						x		

Other

Please specify:

The sharing of administrative data in a digital format has the potential to further optimise reimbursement of healthcare by the insurance sector. A major consideration here is that data should be retrievable in a structured format that makes automated data feed and analysis possible (fully identifiable format). Data should therefore be made available in secure but easily readable file formats.

Additional rules on conditions for access to health data should focus on facilitating the secure, lawful sharing of that data and providing more legal certainty with regard to what is allowed under the GDPR. In contrast, introducing another layer of complexity to data protection legislation or adding further restrictive requirements would run counter to the very idea of the EHDS. The GDPR already provides extensive safeguards in the form of data subjects' rights, data protection principles (especially purpose limitation, integrity, confidentiality and data minimisation) and requirements for technical and organisational measures. What is hindering the effective sharing of health data is rather the lack of a sufficiently clear legal basis. This especially applies to the concept of anonymisation. There should be practical guidelines about which standardised anonymisation methods can be used to render data anonymous under the GDPR, as this currently prevents providers of health-related services sharing anonymised health data.

Q12. *How appropriate do you consider the below elements in facilitating access to health data held by private stakeholders (hospitals, businesses) for research, innovation, policy-making and regulatory decision:*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access to health data is granted by the data holder, on its own decision (current situation)				x		
Access to health data is granted by a national body, in accordance with national law		x				

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access to health data is granted by a national body, subject to agreement of data subjects			x			
Other				x		

Please specify:

The decision to grant access to health data should be traceable to the data subject. It should be made as easy as possible for the data subject to make that decision. It is especially important that the data subject does not have to repeat their agreement unnecessarily (ie, by requiring additional consent after requesting/agreeing to the provision of health-related services).

Q13. *Which incentives would facilitate sharing of health data held by private stakeholders?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
A fee						x
Other						x

Please specify:

Given the costs involved in setting up a data-sharing framework, it must be ensured that there is a fair cost allocation among the parties (eg, for developing and running APIs, the implementation of technical standards, etc.).

Q14. *Do you agree that an EU body could facilitate access to health data for research, innovation, policy making and regulatory decision with the following functions?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Bring together the national bodies dealing with secondary use of health data, for decisions in this area			x			
Setting standards on interoperability together with national bodies			x			

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
dealing with secondary use of health data						
Facilitating cross-border queries to locate relevant datasets in collaboration with national bodies dealing with secondary use of health data			x			
Acting as technical intermediary for cross-border data sharing		x				
Authorising access to cross-border health data (data processed in a cross-border or EU wide manner, such as European Reference Networks)		x				

Q15. *How useful would EU level action in the following areas be to address interoperability and data quality issues for facilitating cross-border access to health data for research, innovation, policy-making and regulatory decision?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Stakeholders participating in the EHDS cross-border infrastructure are subject to a voluntary labelling scheme on the use of data quality and interoperability technical requirements and standards				x		
Stakeholders participating in the EHDS cross-border infrastructure are subject to the mandatory use of specific technical requirements and standards						x
Stakeholders need an audit, certification or authorisation before participating in EHDS cross-border infrastructure						x

Q16. *(For healthcare professionals only) In your views, what would be the costs on healthcare professionals/providers of measures facilitating such access?*

	No impact	Moderate impact	High impact	I don't know / No opinion
Implementation costs (setting up infrastructure, complying with defined standards, etc.).				x
Operational costs such as human resources, finances, etc.				x
Information and monitoring				x
Other				

Q17. *In your views, what would be the benefits for stakeholders of measures facilitating such access?*

Access to cutting-edge, efficient and safe care

	No impact	Moderate impact	High impact	I don't know / No opinion
Availability of new treatments and medicines				x
Increased safety of health care and of medicinal products or medical devices				x
Faster innovation in health				x

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion
Better informed decision-making (including risks and errors)				x
Reduced administrative burden in accessing health data				x

	No impact	Moderate impact	High impact	I don't know / No opinion
Technological progress				x

Section 2: Digital health services and products

Q19. *How useful do you consider action in the following areas to ensure access and sharing of health data nationally and across borders through digital health services and devices?*

Citizens

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Citizens have the possibility to transmit the data from m-health and tele-health into their electronic health records					x	
Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure					x	

Healthcare professionals

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Healthcare professionals have the right to access to patients' digital health records and to data pertaining to the patient's use of digital health products or services.					x	
Healthcare professionals can request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patients					x	

Please specify:

The possibility to grant access to patients' digital health records should not be restricted to healthcare professionals. The patients should also be able to allow providers of health-related services access to necessary data, as the difficulties concerning (cross-border) access to and sharing of health data are similar. With greater digitalization and availability of data made available in secure formats, the insurer can benefit policyholders by facilitating easier and faster compensation.

Q20. *Please indicate the most important impacts of the deployment and use of digital health products and services. Please consider relevant economic, environmental, social or fundamental rights impacts.*

Overall, the deployment and use of digital health products and services would lead to improvements in the general population's health and a reduction in healthcare costs. Additionally, innovative solutions such as health wearables may contribute to preventive strategies, promoting healthier lifestyles, improving health outcomes and ultimately leading to more substantiable healthcare systems by reducing their costs.

Q21. *Please indicate the most important impacts of the deployment and use of digital health products and services. Please consider relevant economic, environmental, social or fundamental rights impacts.*

☐ Yes
☐ No
☒ I don't know / No opinion

Q22. *If you see such risks, how should they be addressed?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Through protocols/rules for tele-health established at EU level			x			
Through minimum standards for tele-health equipments established at EU level			x			
Through liability rules established at national level			x			
Through liability rules established at EU level		x				

Q23. *How appropriate do you consider the following actions to foster the uptake of digital health products and services at national and EU level?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
A labelling scheme (a voluntary label indicating the interoperability level)			x			
A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)						x
An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)						x
Other						

Other:

Voluntary labels have traditionally proved to be effective means of ensuring high and transparent standards (eg, in the area of IT security). They enable customers to easily identify products that are especially trustworthy and allow businesses to display the quality of their services and to further promote them. Many companies would be likely to voluntarily opt to certify their digital health products to strengthen their competitiveness and to ensure compliance with current standards and regulation and ethical principles. In contrast, the slow and bureaucratic nature of mandatory prior certification/approval would hinder the uptake of such services.

Q25. *In your view, should access to EU funds for digitalisation in healthcare by Member States be conditional to interoperability with electronic health records and national healthcare systems?*

☐ Yes
☐ No
☒ I don't know / No opinion

Section 3: Artificial Intelligence (AI) in healthcare

Q26. *How useful do you consider the following measures to facilitate sharing and use of data sets for the development and testing of Artificial Intelligence in healthcare?*

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access to health data by Artificial Intelligence manufacturers for the development and testing of Artificial Intelligence systems could be securely, including compliance with GDPR rules, facilitated by bodies established within the EHDS				x		
Bodies established within the EHDS provide technical support (e.g. on control datasets, synthetic data, annotation/labelling) to data holders to promote suitability of their health data for Artificial Intelligence development.				x		
Bodies established within the EHDS, alone or with other bodies established under the Testing and Experimenting Facilities, provide technical support to medicine agencies, notified bodies for medical devices, and other competent bodies in their supervision of Artificial Intelligence products and services			x			
Other						x

Insurance Europe considers it important to have measures to facilitate the using and sharing of data sets for the development and testing of artificial intelligence in healthcare. However, data-sharing always has to be in line with the GDPR. In the case of health data, the requirements of Article 9 of the GDPR need to be considered, and perhaps clarified with practical guidance, if the sharing of health data on a larger scale is to be promoted.

Q27. *In your view, is the introduction of Artificial Intelligence in healthcare creating a new relationship between the Artificial Intelligence system, the healthcare professional and the patient?*

☐ Yes
☐ No
☒ I don't know / No opinion

Q29. *In your view, are there specific ethical issues involved in the use of the Artificial Intelligence in healthcare?*

☐ Yes
☐ No
☒ I don't know / No opinion

The use of AI in healthcare can involve specific ethical issues since it is based on health data that is classified as sensitive data under Article 9 of the GDPR. The insurance industry takes this issue very seriously, and appropriate safeguards are already in place. This has also already been acknowledged in papers by the High-Level Expert Group of the European Commission and the recently published EIOPA report on AI governance principles.