Response to consultation on EC proposal on the establishment of a European Health Data Space

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Insurance Europe welcomes the European Commission's (EC) efforts to create an EU policy framework that unlocks the value of the data economy and creates a beneficial European Health Data Space (EHDS). The initiative has the potential to empower individuals and create new ways of communication between health care professionals and patients.

To support the ambition of ensuring that individuals have access to and control over their own data, it is important to focus not only on making data available, but also on building an infrastructure that facilitates seamless sharing of data — based on consent — between relevant partners regardless of whether these are private or public entities.

A better digital bond between the public and private sector will not only improve the user experience of individuals. It will also ensure the availability of efficient administrative procedures for both public and private entities, which is a necessity considering the strain on resources that will impact the health sector in the coming years.

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. The Commission's proposal can help to both ensure that EU citizens have increased control over their electronic health data, and promote better exchange and access to different types of electronic health data for the common good.

The proposal is a step in the right direction, but it is important to consider that different member states have different maturity levels in relation to digitalisation of healthcare. It is, therefore, crucial that the proposal does not introduce measures that undermine initiatives already introduced in member states with well-developed health digitalisation that allow individuals to share their data with entities of their own choice.

However, vague definitions and the unclear scope of several provisions threaten to prevent Commission's goals from being achieved.

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Primary use of health data

Under the proposal, individuals will have the right to access a minimum set of health data and share it with third parties free of charge. Harmonised standards would also be established to allow for easier access and sharing of such data. Insurance Europe welcomes the initiative as it believes that there should be more practical solutions allowing individuals to exercise control over their own data.

For example, the conclusion and 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 possibility for individuals to receive their electronic health data immediately, free of charge and in machine-readable format is welcomed, as consumers will be able to easily share their data with their own insurer, thereby facilitating easier and faster compensation.

On the other hand, the scope and definition of "primary use of electronic health data" in Article 2(2)(d) should be better defined to avoid legal uncertainty. Under the text, primary use is defined as "*the processing of personal electronic health data for the* ***provision of health services to assess, maintain or restore the state of health*** *of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security,* ***administrative or reimbursement services***."

This definition is of central importance, since it is key to determine the scope of application of the enhanced portability rights and obligations under Article 3. The context and the accompanying material of the proposal seems to suggest that the Commission is primarily aiming to improve electronic health data exchange between healthcare providers, public institutions and the service providers they employ for fulfilling their tasks but intends to exclude other entities like insurance companies. In fact, insurers do not hold any "new" priority category of health data — as listed in Article 5 — that is not already held by policyholders or healthcare providers. However, the definition currently refers to "the provision of health services to assess, maintain or restore the state of health of a natural person" and to "administrative or reimbursement services", both of which could be interpreted to include a wide variety of services. For instance:

- "Administrative and reimbursement services" could be understood to include any kind of insurance service that involves the processing of (electronic) health data: eg private health insurance, personal liability insurance, accident insurance etc. By its nature, insurance involves the reimbursement for damages and medical treatment.

- In telematics insurance, policyholders may also make use of an insurer's service to receive proposals and advice for a healthier lifestyle based on an evaluation of the data from their wearables. This could be construed as "processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates."

Since such a wide interpretation is not in line with the Commission's intention, further clarification is needed either in the recitals or through additional definitions or amendments to Article 2(2)(d). Otherwise, such legal uncertainty will likely lead to different interpretations of the scope of Article 3 and thus provoking legal disputes. This would counteract the goals pursued with the EHDS, such as strengthening individuals' control over their health data and making the most of the potential of digital health.

Secondary use of health data

Insurance Europe welcomes the Commission's efforts to promote better exchange and access to different types of electronic health data for secondary use. Not only will this support healthcare delivery, but it will also help health research and innovation.

There is, however, a need to clarify the definition of "data holder" in Article 2 (2) (y) to avoid further legal uncertainty, which was also acknowledged by the EDPB and EDPS in their Joint Opinion 03/2022 of 12 July 2022[1].

For context, the proposal considers a "data holder" "*any natural or **legal person, which is an entity or a body in the health or care sector**, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data*".

Such a definition is too broad and may cover a variety of health-related services. Consequently, the scope of the health data that can be processed for secondary use may be interpreted extensively and may also cover broader data with an impact on health, such as socioeconomic data and information regarding the health insurance of individuals. If the text does not clearly define who falls under this definition, then it may lead to legal uncertainty as to who has the obligation to make data available for secondary use, which in turn, might undermine the rights to privacy and data protection of individuals.

As mentioned above, the context of the proposal — including the supporting recital 40 on the definition of "data holder" — as well as the accompanying material seem to suggest that the scope for secondary use should cover mainly healthcare providers, researchers and public institutions but it should exclude other entities like private insurers.

To avoid disputes arising from the legal uncertainty and to foster the quick uptake of the EHDS, co-legislators should further clarify the definitions in the text to ensure more predictability for stakeholders, including insurers.

Requirements for data holders

Besides the need to clarify definitions, co-legislators should also consider the proportionality of the requirements imposed on data holders.

For example, Article 49 would allow data users to file a data access application or a data request directly to the data holder. The data holder would then have the responsibility to issue a data permit in accordance with Article 46 or to provide an answer to a data request in accordance with Article 47.

The responsibility to assess data access applications and issue permits should lie solely on health data access bodies, which will be created principally to carry out this function, including carrying out an ethical assessment in cases of data access requests for pseudonymised data. Data holders should not take on this additional burden as their primary responsibility should be to comply with the approved data access requests, which will already require a considerable number of resources. Ensuring that this responsibility lies on health data access bodies will also ensure a more harmonised application of the secondary use mechanism under the EHDS.

Finally, Article 33(4) allows for health data protected by intellectual property and trade secrets from private enterprises to be made available for secondary use. In principle, IP and trade secrets should be excluded from data sharing obligations. Data holders should not be obliged to share proprietary data that they have generated and analysed/enriched themselves, and which is the outcome of their own work. The mere risk of having to disclose trade secrets can have negative consequences in the long term by stifling innovation.

[1] See p.14

- **Allowed purposes and access to data**

The proposal lays out a list of allowed and non-allowed purposes for which electronic health data can be processed for secondary use. Article 35 (b) lays a specific prohibition in relation to premium setting in insurance. Such prohibition contradicts the objectives of the EHDS proposal, as well as current EU risk management rules requiring insurers to guarantee that they use high-quality data in the exercise of their function[2].

Insurance plays a crucial role in society by providing safety and security against unforeseen events. It contributes to the social protection of citizens by enhancing their financial security. To provide reliable insurance cover, insurers must carry out sophisticated risk assessments and calculations, using various types of information. In particular, insurers carry out statistical analysis of past events to estimate the probability of such events reoccurring.

Article 82 and 84 of the Solvency II Directive requires insurance companies to guarantee the appropriateness, completeness and accuracy of all the data used in the calculation of their technical provisions. Article 19 of the Delegated Regulation (EU) 2015/35 containing implementing rules for Solvency II establishes detailed data accuracy/quality requirements. For example, insurers need to prove that they use sufficient historical information to assess the characteristics of the underlying risks and to identify trends in the risks.

The prohibition under Article 35(b) would, therefore, impede insurers to use newly available health data which can be used to underwrite and assess risks more accurately. This is crucial for insurers, not only because it is required by EU risk management rules but also because:

- Insurers must be able to assess risk accurately to keep the price of insurance as competitive as possible and to provide cover that is adequate for consumer needs.
- Alternatively, not matching price with risk could lead to a situation where:
    - Some consumers would pay too much relative to the risk they bring to the insurer, while others would pay too little.
    - Insurers would need to increase premiums significantly to compensate for uncertainty about what claims to expect.
    - Insurance would become less attractive to the consumer, or even unaffordable, ultimately leading to insurers offering fewer products.

Finally, Article 35(b) may also impede insurers in receiving access to anonymised health data for one of the compatible purposes under the proposal, such as facilitating access to care. For insurers, in fact, greater availability of anonymised or pseudonymised data could lead instead to improved and more effective risk monitoring and assessment. This can enable insurers to offer more affordable rates or to offer insurance for risks that were previously uninsurable, due to information gaps that today can be filled in by the increased availability of data. For example, the increasing availability of data together with medical progress has made it possible, under certain conditions, to provide more affordable insurance cover to individuals with HIV. Insurer's access to new types of health data can therefore facilitate access to care, improve health outcomes and reduce overall healthcare costs in the society.

[2] Article 82 and Article 84 of the 2 Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II Directive).