Summary of key points

Proposal for a regulation of the European Parliament and of the Council on the European Health Data Space
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The European Commission has presented a draft regulation for a European Health Data Space (EHDS). With this summary of key points, we would like to submit an initial assessment of the measures it sets out. Bitkom welcomes the chosen route of collating health data and ensuring their cross-border usability. Interlinkage of individual national health systems by creating common standards, infrastructures and procedures offers great potential for all concerned parties as well as users of a digital health system. The right of European citizens to digital access to their health data collected as part of the care process strengthens their individual capability to act. The future possibility to retrieve health data also across borders, the European patient summary and the electronic prescription that can be dispensed cross-border offer European citizens additional flexibility and mobility. Patients and society as a whole alike benefit from better diagnostic options, more continuity in care and efficient, data-based decision-making possibilities.

We expressly endorse the envisaged access to reusable health data for questions linked to health research by public applicants and for players in the health sector. Access to and use of data should in future depend on the established purpose instead of being restricted to a list of institutions. Scientific research, development and innovation activities should also be included. This newly created right to use data would accelerate medical research and foster a learn-as-you-go health system. A reliable and innovation-friendly legislative framework for the secondary use of European health data would make an important contribution to the further development and improvement of patient care. This applies equally for research into novel and individual treatment possibilities and for improvement of patient care through artificial intelligence.

Unfortunately, the plans for a European Health Data Space as currently drafted do not yet put in place the necessary preconditions for this potential to unfold. In an initial assessment, we would like to highlight a number of points which prompt criticism:

Consistency with other legislative provisions

One objective of the proposal for a regulation is to create a uniform and coherent sectoral legislative framework for the use of health data. Yet there remain unclear areas in relation to the interplay between EHDS provisions and those on the AI Act, Data Governance Act, Data Act, GDPR and MDR/IVDR. Additional guidance and more precise indications are therefore indispensable. It is essential to avoid superfluous efforts by those generating or using the data as a result of ambiguous or duplicate rules. To this end, a central lever is coherent definitions of core concepts such as "interoperability" or "data holder" (cf. article 2.2 points f and y). Furthermore, the negotiations must take into account that interactions between various legislative acts (e.g. AI Act – EHDS – MDR/IVDR, EHDS – eIDAS, Data Act – DGA – EHDS) have to be considered in the light of ongoing legislative procedures (cf. AI Act, Data Act and eIDAS regulation).

Moreover, we would like to underline that uniform interpretation and application of GDPR in the Member States is crucial for the workability of the data use objectives outlined. Divergent interpretations which limit data use within a country as is still the case in Germany constitute a considerable obstacle.

Infrastructure for data use

Further details and more concrete proposals enshrined in implementing acts are needed regarding the infrastructure that has to be created for the secondary use of health data. The structure of governance for the use of secondary data should be streamlined, non-bureaucratic and must guarantee secure and confidential handling of health data. To this end, more precise formulations on the design of a "secure processing environment" are needed (cf. article 50).

Development of institutions

The proposal for a regulation leaves it to the Member States to decide on whether one body should handle both primary and secondary data or whether these tasks should be assigned to separate institutions. This decision-making discretion can lead to fragmentation and considerable additional effort for all concerned. Instead, a uniform structure should be created. With a view to simple and efficient processes, the provisions on mutual recognition of data authorisations in all Member States should be strengthened in order to do justice to the notion of a single access point and uniform access authorisation (cf. articles 53 and 54).

Primary use of electronic health data

- Bitkom welcomes the fact that the proposal for a regulation lays down rights and mechanisms for European citizens in relation to their electronic health data. Nevertheless, the legislator is encouraged to exercise restraint in the requirements placed on data holders and not to create disproportionate burdens (Art. 3 para. 8).

- The proposal envisages that priority should be given to certain data categories for integration in EHDS. The information to be provided in this regard is still formulated in unduly general terms. For instance, sequenced genetic information is not yet explicitly included in the information to be provided, yet the underlying procedure entails a considerable financial cost. It should therefore be made possible to use these data in a structured format in order to avoid unnecessary resequencing.
- Regarding the availability of health data for secondary use and realisation of the resulting possibilities, a clear and unambiguous basis for authorisation of processing is needed. This will build trust and create predictability. The proposal for a regulation does not yet set out measures or provisions on how a commitment is to be generated among patients and members of the caring professions in the Member States. An important element for this consent will be how easy users find it to handle their health data. Accordingly, manufacturers should be given as much leeway as possible to incorporate user experience in data administration. Thanks to their wealth of experience and technical knowhow, they can ensure that the use environment is user-friendly. The extent of specifications stipulated by the legislator should be kept to a minimum.
- To enhance the benefit of participation for patients, it is necessary to be able to exchange electronic health data and electronic prescriptions across borders, also in foreign languages, with healthcare providers and (online) pharmacies. In this way, access to quality care will be improved, wherever the patient is located. We therefore welcome the obligation on EU Member States to introduce the digital health infrastructure of MyHealth@EU. It would be better if a fixed date (1 January 2025) for implementation in the Member States were attached to this obligation.

Requirements for electronic health records

- Chapter III of the draft proposes binding provisions for self-certification of electronic health records. However, the current definition is disproportionately widely framed. As it is drafted, not only basic health records would fall within the scope but also patient-related files within clinical studies and virtually every medical product and wellness app. This would also include products and applications which collect and process data prior to inclusion in the health record, even without access to an online connection. Such a broad definition does not serve the purpose of securing compatibility and simple transmission of electronic health records between systems. Instead, there is a risk of non-relevant obligations and a high effort for manufacturers and researchers. Hence, application of the requirements should be restricted to EHR systems which are used as patients' main record.
- Products may fall within the requirements of not only EHDS but also EU-MDR, the AI Act or the Data Act. This poses a risk of over-regulation. Without a tighter definition of the scope, manufacturers would have to carry out a detailed and elaborate assessment of which regulation is applicable on a case-by-case basis for each of their products. Such an inefficient process runs counter to the overarching objective of EHDS.

- The legislator should have a concern to ensure that the standardisation requirements are compatible with ongoing standardisation activities around the world and existing standards (cf. recital 17; article 23.3 point b; annex II). The introduction of EU specifications alongside existing, internationally accepted standards can be a barrier to innovation and leads to considerable additional burdens for manufacturers which address both EU and non-European markets.

Secondary use of electronic health data

Chapter IV of the proposal for a regulation sets out conditions for the secondary use of electronic health data. Unfortunately, large parts of these conditions are still too imprecise and leave considerable discretion for interpretation. To create certainty about the legality of action and to allow a concrete assessment of effects on data users and holders, the formulations need to be comprehensively tightened. The following provisions on the rights and obligations of data holders are good examples of this need for more specific language:

- It is urgently necessary to clarify what secondary data can be used for. The purposes listed in the proposal for a regulation in relation to industrial use are unclear:
  - For example, how can it be demonstrated that “development and innovation activities for products or services” contribute to “social security”? If this were to be based on a discretionary decision by a Member State, there would be a risk of intra-European fragmentation with regard to data access (inter alia article 34.1 point f)
  - With an eye to realising the full potential of a European Health Data Space, it is important to clarify that secondary use of health data for research and development of new, innovative products and solutions also encompasses the related obligatory regulatory market access, reporting and post-market surveillance procedures.
- There is a lack of clarity as to when certain data categories, often generated using considerable private resources, must be shared by whom and with whom. The conditions broadly point to very wide-ranging availability obligations (cf. articles 33 and 34). Similarly, the obligation to make results available for secondary use leaves too much room for interpretation with the blanket inclusion of “information relevant for the provision of healthcare” (cf. article 46.11).
- These wide-ranging availability obligations are not qualified with adequate guarantees for protection of intellectual property and trade secrets (cf. article 33.4; article 34.4; article 37.1 point f). Even the risk of having to disclose trade secrets could lead to businesses neglecting to collect certain data in the first place – with potentially far-reaching consequences for data-driven healthcare innovations.
- It is envisaged that access to additional categories of electronic health data should be enabled on the basis of voluntary cooperation, in particular access to electronic health data “held by private entities in the health sector” (article 33.8). Yet it remains unclear how such an exchange of data can be encouraged, e.g. through an incentive system.

- The obligations envisaged for data holders remain imprecise at many points. For instance, this applies regarding the obligation on a data holder to "cooperate in good faith with the health data access bodies, where relevant" (cf. article 41.1) or regarding the extent of the obligation on the data holder to communicate data to the health data access body (cf. articles 41.1 and 41.2). Not least against the background that resources must be deployed and financial costs incurred in businesses for the obligations envisaged here, the cost-benefit ratio of data use should be proportionate. Also missing is a concrete indication of what constitutes sufficient documentation on data quality (article 41.3) or the conditions under which an enriched dataset is considered to be unsuitable (article 41.5). Legally uniform and legally certain implementation by authorities and data holders in the Member States is of decisive importance for the success of the European Health Data Space. Inasmuch as the proposal for a regulation provides that national data access bodies add an explanation of natural persons' rights in accordance with GDPR to a secondary use authorisation, this cements the existing disparities in interpretation and implementation of GDPR in the area of research with health data. These disparities are the cause of innovation obstacles in the single market. Bitkom therefore urges the European legislator to explore how a uniform EU-wide basis for involved parties to exercise their rights in the European Health Data Space can be developed and enshrined in the framework of HealthData@EU (article 38.1).

  Furthermore, the intention and reach of the provision in article 33.5, which relates to consent arrangements under national law, is unclear. It should at least be clarified that Member States must not have consent requirements which one-sidedly restrict data categories, the privileged purposes of data use or the application rights of individual groups.

As a proactive player, it is our objective that the large volume of data generated in the European Union on a daily basis is used to the best possible effect in terms of patient safety as well as the quality of and access to innovative forms of healthcare. We are convinced that a uniform European Health Data Space with transparent, efficient and innovation-promoting conditions is the central component of a connected and learn-as-you-go health sector. As the process continues to unfold, technical implementation of the European Health Data Space will be of essential importance. An efficient system will require the full support of all Member States. Moreover, a complete picture of the possibilities and potential stumbling blocks for implementation contributes greatly to the success of the initiative. It should therefore be ensured that the assessments of all interested parties feed into the deliberations of decision-making bodies.

We look forward to contributing to the ongoing dialogue with the cross-sectoral professional and technical expertise brought together under the umbrella of Bitkom.