EU HEALTH DATA SPACE

Proposal COM(2022) 197 of 3 May 2022 for a **Regulation** of the European Parliament and of the Council on the **European Health Data Space.**

cep**PolicyBrief** No. 13/2022

SHORT VERSION [Go to Long Version]

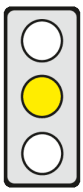
Context | Objective | Interested Parties

Context: The EU-wide use of health data has so far been carried out on a voluntary basis due to the fact that Member States are responsible for healthcare. Now, a "European Health Data Space" (EHDS) is to be created, which will improve individual healthcare and accelerate the processing of health data, especially for research, policy making and regulation. The Commission needs to strike a balance between exploiting the gains in value creation and innovation and protecting highly sensitive data.

Aim: The EHDS aims to allow health data to be used as a resource both (1) for individual healthcare and (2) as a database for policy decisions and research and development. Two data infrastructures are being set up for this purpose: "MyHealth@EU" (1) and "HealthData@EU" (2).

Affected parties: All EU citizens, healthcare stakeholders, private and public companies.

Brief Assessment



Pro

- Citizens will have the EU-wide right to access their own health data in the area of individual healthcare and to restrict third-party access to it. This will strengthen the fundamental freedoms of the individual.
- The EHDS will give the Member States a necessary "incentive to digitalise" and may also promote competition and increase quality in the health sector.
- The Commission has basically found a sensible solution to the conflict of interests between the increased use of data, which is in the public interest, and the need to protect the individual when using sensitive health data.

Contra

- When it comes to using data for policymaking, regulation, research and development, individuals have no freedom of choice about how their data is used.
- Nor, so far, is any individual "opt-out" envisaged. This would, however, safeguard individual freedom of choice without preventing the general use of data for research purposes and health policy, and should therefore be introduced.
- The timetable for implementation of the project is too short to create the necessary conditions throughout the EU; implementation deadlines should be extended appropriately.
- Two of the numerous delegations of power to the Commission to adopt delegated acts, in this case defining the data covered by the EHDS, go too far - they should be withdrawn.

Rights of the individual [Long Version A.2.1, C.1.4]

Commission proposal: Individuals will have the right to access health data from their healthcare immediately and free of charge [Art. 3 (1)] as well as to receive electronic copies, at least of health data in what are defined by law as the "priority categories" [Art. 3 (2)]. In addition, individuals will be able to insert their health data into electronic health records [Art. 3 (6)], have it rectified [Art. 3 (7)] and restrict access to it, in whole or in part, by doctors and other health professionals [Art. 3 (9)].

cep-Assessment: Currently, the health data of EU citizens is unsystematic and scattered among the various healthcare providers. The EHDS will allow individuals to access and control their health data, thereby strengthening the fundamental freedoms of EU citizens in the area of cross-border healthcare.

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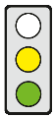
Digitalisation and competition in the health sector [Long Version A.2.3, C.1.3]

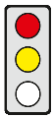
Commission proposal: The (already existing) data infrastructure for the use of health data for individual, cross-border healthcare ("MyHealth@EU") is intended to facilitate and expand the exchange of health data between Member States [Art. 12]. Member States and the Commission will also establish another data infrastructure allowing the use of health data for policymaking, regulation, research and development ("HealthData@EU") [Art. 52 (8)].



cep-Assessment: The digitalisation of healthcare in the Member States has progressed at very different rates. In this respect, the EHDS will give the Member States a (much needed) "incentive to digitalise". Furthermore, it may promote competition in many areas of the health sector, such as pharmacies, and support innovation. It will be crucial to create a data infrastructure that guarantees secure cross-border use of data.

Control over health data [Long Version A.5.2, C.1.4]

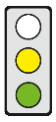
Commission proposal: Health data may only be used by third parties - outside of healthcare - for legally defined purposes, e.g. policymaking, regulation, and also for research and the development of products or services to ensure high standards of quality and safety in relation to healthcare, medicines and medical devices [Art. 34 (1), (f)]. There is no requirement to obtain the consent of the individual for this.



cep-Assessment: When health data is used for an individual's own healthcare, the individual has control over who can access their data. This is not the case, however, when data is used for additional purposes, e.g. research and development. The use of health data for policy/regulation, research and development is very important. EU citizens should, nevertheless, be given the possibility to opt out. It will ensure freedom of choice without standing in the way of health research.

Anonymisation and pseudonymisation [Long Version A.5.1 and 5.3, C.1.6]

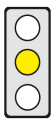
Commission proposal: Health data is generally made available in anonymised format for policymaking, regulation, research and development. If the purpose of processing cannot be achieved by this, the health data may be provided in a pseudonymised format. Only the public access body, which has yet to be established for this purpose, will have the necessary information to reverse the pseudonymisation. Data users are generally prohibited from doing so, on pain of penalties [Art. 44 (3)].



cep-Assessment: There is a conflict of interests between the increased use of data, which is in the public interest, and the need to protect the individual. The conflict itself cannot be resolved. It will always be necessary to examine each individual case using the instruments provided - use of data only for legally defined purposes, and penalties. This is the right approach. It is not clear how pseudonymisation will be technically carried out. Various procedures are conceivable.

Ambitious timetable [Long Version A.1, C.1.7]

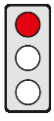
Commission proposal: In principle, the legislation will apply twelve months after its adoption. There are, however, special features that will delay the application of certain provisions by a further one to three years [Art. 72].



cep-Assessment: The Commission aims to ensure that EU citizens gain access to and control over their health data as quickly as possible, that healthcare and research are improved using data, and that a single market for health data is created. However, when it comes to such large-scale projects, EU-wide implementation is a challenge. Since some Member States have a lot of catching up to do in the area of digitalisation, the timetable here is too ambitious and should therefore be extended appropriately.

Delegation of powers to the Commission [Long Version C.2]

Commission proposal: The proposal provides for a plethora of delegations of power to the Commission. Most notably, the Commission will be empowered to adapt by means of delegated acts the list of health data collected by the EHDS for individual healthcare and for use by third parties, e.g. policymaking, regulation, research and development [Art. 5 (2) and Art. 33 (7)].



cep-Assessment: Delegations of power to adopt delegated acts are subject to the concept of "essential elements" [Art. 290 TFEU]. This means that "essential elements" are reserved for the legislator - decisions on them cannot be delegated. In this case, essential features of the EHDS are affected: thus, the Commission could determine which specific health data is collected. This is a matter for the European legislator itself - the delegations of power should be withdrawn.