France Digitale welcomes the ambitions of the European Health Data Space (EHDS) but is concerned about its interaction with existing legislation

Paris, December 2022

On 3 May 2022, the European Commission presented its proposal for a Regulation on the European Health Data Space (EHDS), a piece of legislation that will act as lex specialis of the Data Act, currently under discussion in Brussels.

France Digitale welcomes this proposal as it aims to facilitate access to and exchange of electronic health data to support, among others, the provision of care, medical research and personalized medicine.

However, we are concerned about its implementation, in particular regarding the interaction with existing national and European legislation, notably the GDPR, as well as the calculation of fees and the definition of standards.

The priority for French startups is to preserve patients’ trust in medical research as well as to establish clear and harmonized compliance obligations in the 27 Member States.

Therefore, France Digitale calls on the European Parliament and the Council to:

1. Consult the industry at all stages of the legislative process:
2. Manage intellectual property and trade secrets safely and consistently
3. Establish a fair fee system
4. Ensure consistency with the RGPD
5. Harmonize compliance obligations and relevant sanctions

—

1. Consult the industry at all stages of the legislative process: several elements of the proposal, in particular technical specifications and standards, are postponed to a later stage (the establishment of a national body, the adoption of an implementing act). While these are the provisions that will have a more direct impact on business, it is striking how little companies are involved in the process. Indeed, the advisory procedure in Art. 68(2) is wholly unsatisfactory, as it provides no details on the appointment of experts, the composition of the group or their powers. In order to ensure the relevance, effectiveness and feasibility of the technical provisions envisaged in the text, the health industry should be consulted in a regular and consistent manner on the following issues:
   - The establishment of data access services and proxy services;
   - The definition of data formats, interoperability standards and data exchange protocols;
   - Any changes to the list of primary use data.

The consultation process should be open to all stakeholders, regardless of their size, and their input should be taken into account before the adoption of any implementing acts. One or more industry experts should also be systematically (rather than occasionally) invited to the EHDS Board meetings (Art. 64).
2. **Manage intellectual property and trade secrets safely and consistently:** Chapter IV of the proposal sets out the rules for the secondary use of health data. This includes the obligation to share trade secrets and intellectual property (IP) rights, as well as the publication of the results of secondary use of data. However, the text does not specify what measures will be taken to protect the confidentiality of this information or the remedies available. It is also unclear whether health data access bodies will return IP rights and trade secrets to the data holders once the data permits have expired.

3. **Establish a fair fee system:** the compensation system envisaged in the proposal is entirely based on the costs of collecting and making data available. While this system is relevant for raw data, it is not at all appropriate for derived data, i.e. data which have been processed by the company and thus required an investment in human, financial and technical resources. Pricing rules should therefore be established to allow companies, including startups, to calculate a fair and adequate compensation.

   Another problematic aspect is the exclusion of public funds from the calculation, as this does not take into account the fact that not all public funds are subsidies. Indeed, some public loans such as recoverable advances from Bpifrance have to be repaid by startups with interest and therefore should be taken into account in the compensation for making data available.

4. **Ensure consistency with the RGPD:** The proposal grants health data access bodies significant powers and exemptions from data protection obligations. These provisions appear to be in contrast to the GDPR, which states that only the data holder should have the information necessary to undo pseudonymisation and that individuals have the right to always be asked for their consent. Indeed, this function can nowadays be easily automated even for a large number of consent requests. In this context, it would be useful to specify the conditions under which patient information would be considered sufficient, following the example of the provisions set out in the CNIL EDS Guidelines, in addition to the notion of altruism present in the proposal.

   It is also unclear how the health data access bodies would proceed with the anonymisation/pseudonymisation of data and which technique they would apply, given that these bodies will have access to patients’ real identities as well as information on rare diseases. Similarly, it seems difficult to guarantee complete anonymisation when publishing the results of the secondary use of data if sources are known to the users and made public.

   Another question concerns the designation of the data access body as a joint controller. In the light of Art. 26 GDPR, this does not seem necessary. Only the user should determine the purposes and means of the data processing, the body should authorize the processing under EHDS criteria, and provide the data without determining the purpose and means of the processing. Indeed, in the case of research projects and data requests to hospitals, the user is usually not considered as a joint controller with the institution, rather, as an individual controller. In its current form, Art. 26 EHDS dilutes responsibility among several actors, adding further complexity to data processing, without providing patients with any additional guarantee on the respect of the GDPR.
Lastly, there seems no way to hold data access bodies accountable in the case, for example, of negligence or conflicts of interest (in particular when issuing of data permits). Taken together, these provisions could seriously undermine patient trust, leading to large-scale denials of consent for the secondary uses of data, which in turn would slow down medical research.

5. **Harmonize compliance obligations and relevant sanctions:** businesses, especially startups, need legal certainty to operate. With the proliferation of digital regulation at EU level, it is essential to make compliance simple and harmonized across Member States. A simple but crucial first step would be the introduction of a standardized and digital self-assessment form that would allow businesses, including startups, to fulfill their reporting obligations regardless of where they are based in the EU. Another important point to increase predictability would be to clarify the modalities, frequency and nature of the controls to which businesses will be subject. It should also be clarified whether a control by a national authority exempts offices of the same company located in other European countries from such control. Lastly, to avoid the fragmentation seen with the implementation of the GDPR, national authorities should be required to follow the same criteria for assessing and determining sanctions so that enforcement is consistent across Member States.

Contacts:

**Agata Hidalgo**, European Affairs Manager - [agata@francedigitale.org](mailto:agata@francedigitale.org)

**Marianne Tordeux Bitker**, Public Affairs Director, [marianne@francedigitale.org](mailto:marianne@francedigitale.org)