European Federation of Pharmaceutical Industries and Associations

EFPIA position on the Regulation on the European Health Data Space (EHDS)

Executive summary

Given the importance of health data sharing - to patients, healthcare professionals, public and private health researchers and health systems as a whole - EFPIA recognises the final agreement on the European Health Data Space (EHDS) Regulation, acknowledging that it is a pivotal moment to create long-term benefits for patients around Europe. Health data is a major catalyst for driving the discovery of innovative therapies, particularly in areas where therapeutic options are non-existent or unsatisfactory. Access to health data is therefore vital to facilitate research and improve patient outcomes.

The EHDS will require the public and private sectors to work together in new and innovative ways. We look forward to working with the EU institutions and Member States to address critical aspects that require further clarification within the implementation phase. We are committed to working constructively to resolve a number of issues that require particular attention:

Data in scope for secondary use remains unclear in important areas: data sets in scope for sharing for secondary purposes are too broadly defined. The absence of agreed vocabulary and definitions for these data sets will create confusion for data holders in assessing which data sets are in scope for sharing vs those which are not, and this will be compounded by the fact each data holder may assess this differently.

The absence of a provision on territorial scope of the EHDS needs to be addressed. The Regulation raises a number of complex legal and operational issues for companies operating globally. It is of high importance to clarify that the Regulation does not apply to sponsors/data controllers established outside of the EU and to clarify how the Regulation applies to entities in the EU processing data of data subjects outside of the EU.

The terms for the sharing of IP protected data reduce Europe's attractiveness for health research: we believe highly specific knowledge and expertise is necessary to assess the economic impact and serious economic risk of sharing a dataset containing IP rights, including Trade Secrets.

Despite the fact that the Health Data Access Bodies (HDAB) will be asked to build knowledge, capability and experience over time in making such assessments, only the Data Holder can fully know and understand the economic impact on a case-by-case basis. It was for this reason that Industry proposals included a final right of refusal to share data (as provided in the Data Act).

The creation of an opt-out mechanism diminishes data diversity for medical research: It is critical that patients understand this when taking the important decision to have their data enter the EHDS or to instead opt-out. The patients should be aware of a risk of fragmentation in data availability, in addition to the risk of bias in future healthcare research, ultimately impacting evidence-based decision making. While the agreed text allows for the Member States to provide their own mechanism for the opt-out, standardization and harmonization nevertheless should be a key consideration.

Conditions for international transfer of data create ambiguity: the provision allowing Member States to introduce further conditions in the context of international access and transfer of personal health data may fuel fragmentation. This would run contrary to the drive for harmonisation of the European health data ecosystem. These provisions may create further ambiguity in an already complex data environment, and are contrary to the objective to harmonise data flows and free movement of electronic health data.

EFPIA members have a wealth of experience and knowledge in generating and sharing health data, and they commit to contributing this expertise to the timely development and adoption of secondary legislations to provide greater legal certainly on interpretation of key provisions and to guide harmonised implementation. It will take all of us to realise the potential of the EHDS.

In this paper, we provide a detailed view on how to ensure the EHDS achieves all of its objectives: making European health systems more efficient; contributing to better health outcomes; and strengthening public health, research and innovation activities in the EU.

Detailed comments

EFPIA recognises the importance of the EHDS, the pharmaceutical industry wants to take part in the EHDS ecosystem, with the paramount objectives of unlocking the huge potential of health data to improve care and treatment, foster innovation and support the economy.

The research-based industry has an important role in building a well-functioning data and digital ecosystem and should be actively included in the pilot projects and the broader implementation phase. Clear and applicable measures are essential for ensuring the effectiveness and inclusivity of the EHDS, enabling the industry - as future data holders and users - to contribute fully to its success and advancement. We are looking forward to collaborating with the European Commission (EC), Member States and responsible authorities in order to achieve this, ensuring that our expertise is leveraged to the fullest extent for the benefit of all stakeholders involved.

Challenges and areas to focus on for secondary legislation

After the adoption of the core text of the EHDS, we move to the critical phase of its implementation with many aspects to be further addressed in implementing and delegated acts. **EFPIA has concerns about some of the key provisions and requirements in the text.** Throughout the last two years of dialogue with the co-legislators, EFPIA and other stakeholders expressed important considerations for the creation of a well-balanced ecosystem. These considerations are not fully reflected in the EHDS.

EFPIA has identified key concerns in the final text, with a focus on provisions primarily laid out in Chapter IV related to the secondary access and use of health data:

- **Definitions and scope of the legislation remain unclear in important areas**

1. Definition and scope of “Data Holder”

The broadly defined term of “data holder” and the absence of a provision on the territorial scope of the EHDS raises many questions, in particular to clarify that the Regulation does not apply to sponsors/data controllers established outside of the EU, and to understand whether the Regulation applies to data sponsors/controllers in the EU processing data of data subjects outside of the EU. It is also unclear how datasets containing data from multiple countries, including those outside of the EU would fall within the scope of the EHDS. A clarification of the territorial application of EHDS for both personal and non-personal data is needed as this currently raises a number of complex legal and operational issues for companies operating globally.

For example, in many countries outside the EU there are legal and/or ethical restrictions on how pseudonymised clinical trial data may be used for secondary purposes. Data holders established in the EU would not be permitted to share data collected from non-EU sites with EU regulators, third party researchers, etc. for the broad range of secondary purposes under EHDS. Similarly, EU based biobanks may hold samples and associated data from non-EU donors, who have not provided their consent for the broad data sharing envisaged by EHDS in accordance with local laws/ethical principles. Under this scenario, data holders could find themselves in breach of non-EU laws.

2. The definition of "non-personal data"

We support greater consistency and coordination between existing and emerging rules. It appears that the definition of non-personal data aligns with the Data Act. However, no references are made or annexes provided with further explanations as to what constitutes non-personal data. Further clarity on this definition is needed.

3. Broadly defined minimum categories of health data for secondary access

The absence of an agreed vocabulary and more detailed definitions for the relevant data categories will create confusion for data holders in assessing which data sets are in scope of their EHDS secondary use obligations. This will be compounded by the fact each data holder may assess the definition differently.

We are concerned that there is no plan for any secondary legislation (implementing acts) to provide further clarity on these definitions. This is aggravated by the fact that Member States have the power to expand the list of minimum data categories which, if done in an uncoordinated way, will further fuel fragmentation across the EU.

4. Other Definitions

Beyond these definitions, there are other terms and concepts which remain ambiguously defined, including 'aggregated data', 'electronic data', 'health data', 'healthcare-related data'. We strongly recommend that greater clarity on such terms be a key focus of upcoming secondary legislation.

Lastly, while the EHDS sets out a long list of electronic health data types to be made available for secondary use, there is **no specification regarding the data format**. Expectations on data formats must be clarified in secondary legislation to enable data holders and Health Data Access Bodies (HDAB) to understand their responsibilities in processing and anonymizing health data for research purposes within the EHDS. It is important to consider that clinical trials data are already developed under standards required to fulfil regulatory submissions requirements. Data requirements for EHDS should be in line with those established formats to minimise required data transformations. However, many of the other types of data specified in the EHDS have no such agreed data standards.

- **Rules on IP Protection as described will reduce Europe's attractiveness for health research, development and clinical trials**

During the legislative process, EFPIA stressed the importance of setting workable provisions on the protection of data containing Intellectual Property (IP). The adopted language would be in direct contradiction with the existing frameworks for the protection of IP rights and trade secrets by giving the responsibility to the HDAB to act as a gatekeeper for assessing what constitutes commercially confidential information (CCI) and for protecting IP rights. Despite this inconsistency, **the data holders in the EHDS are deprived of the final right to refuse sharing of data (if it is likely to suffer serious economic damage through the disclosure of trade secrets), as provided in the Data Act**. Additionally, in further consistency with the Data Act, it should be stated that the commercially sensitive data should not be used to develop a competing product. The Data Holder should be involved in any decision made by the HDAB and, consistent with the EU Trade Secret Directive, remain in control of the trade secret.

We believe very specific knowledge is necessary to assess the economic impact and serious economic risk of sharing a dataset considered commercially confidential information. Despite the fact that the HDABs will be asked to build knowledge, capability and experience over time in making such assessments, only data holders can fully determine and understand the economic impact of disclosure on a case-by-case basis.

In addition, since **there is no patent protection or regulatory data protection (RDP) available for early research datasets as innovators rely on confidentiality and trade secret protection to protect these valuable assets**. Consequently, without adequate control over their trade secrets (by way of an overriding right to refuse and/or to determine appropriate measures to protect trade secrets), innovator companies would not be able to sustainably and reliably continue to invest in data generation within the EU for the purposes of developing new treatments for patients in need driving the innovation of tomorrow. **Companies would be deterred from establishing and continuing early research activities in the EU such as the establishment of biobanks, exploratory research studies in collaboration with EU universities, AI/ML and genomic research.**

Looking ahead to the development of secondary legislation, including implementing acts, we highlight again the critical need for **data holders to remain involved at all steps of the decision-making process. Furthermore, data holders should retain control on their IP and should have the right to refuse access to data,** if it is deemed that it can jeopardise its IP rights or trade secrets, and also have the right to defer sharing of data until no economic damage is expected. The EHDS cannot take precedence over the TRIPS agreement or regulatory data protections.

Finally, it must be specified that where there is disagreement between a HDAB and a Data Holder in this process, a HDAB decision cannot take precedence over the assessment of the Data Holder without being subject to judicial review, and during such a review HDABs cannot provide relevant data to Data Users. When a complaint is lodged, the data sharing shall be suspended until the complaint has been addressed.

- **Requirements to share data from clinical trials will disincentivise clinical development and clinical trials in the EU**

We welcome the reference to the Clinical Trial Regulation (CTR) for greater consistency with well-established rules defining the requirements governing sharing of data from clinical trials. However, the lack of specification that it applies to 'fully completed trials' in accordance with definitions in Article 2(2) and Article 2(26) of Regulation (EU) No 536/2014 and in the format as outlined in Annex IV in Regulation No 536/2014, with raw data being shared only voluntarily as outlined in Article 37(4) **will create confusion and ultimately undermine the scientific integrity of a trial and disincentivise clinical developments in the EU, and further reduce the number of clinical trials being conducted in the region. At a time when the EU is already losing clinical research competitiveness relative to other regions and countries. This would undermine one of the main purposes of the EU's Accelerating Clinical Trials (ACT-EU) initiative: supporting clinical trial development and enabling innovation in Europe.**

Data holders will also be required to communicate to HDABs, on a systematic and proactive basis, a description of the datasets they hold, that will be shared with the general public via national dataset catalogues. Through implementing acts, the EC will set out the minimum elements health data holders are to provide for datasets and their characteristics. It is unclear, at this stage, what will be the content of these summaries, meaning the datasets in scope, and the potential burden on data

holders. We would therefore appreciate stakeholders' direct involvement in the development of related guidelines.

- **An opt-out mechanism that will create fragmentation and data biases across European health data sets**

While the agreed text allows for the Member States to provide their own mechanism for the opt-out, standardization and harmonization nevertheless should be a key consideration. If not, all stakeholders will face significant challenges in navigating varying opt-out systems across different Member States. Lack of harmonisation will ultimately lead to fragmentation of the EU regime for secondary use and of the availability of data sets, as well as complicate the combination of data sets from different Member States, undermining one of the primary objectives of the EHDS.

The resulting text, which enables an opt-out mechanism for patients for private sector access, will have numerous effects on Europe's healthcare research ecosystem, as providing an opt-out will mean less data available to data users attempting to conduct research. It also entails a risk of fragmentation in data availability, impacts on private-public partnerships, in addition to the risk of bias in future healthcare research, ultimately impacting evidence-based decision making. EU **citizens should understand the consequences of opting out, including the missed opportunity for scientific progress.** The process could be developed in collaboration between stakeholders such as patient organisations, academia and industry. Efforts to promote health data literacy for the public are needed to ensure that decisions to opt-out are well informed.

- **Consistency with GDPR and harmonisation**

We welcome the attempt to recognise the interplay between the EHDS and GDPR by providing that the necessary safeguards required under Article 9(2) of the GDPR are offered by the EHDS itself as stated in Recital 37. This means that data users will not have to find those safeguards under national law, allowing for better harmonisation. Nevertheless, we regret the absence of similar provisions in the enacting terms (i.e. the articles) of the EHDS. We would also like to raise concerns over Article 33(5), allowing Member States to impose stricter conditions on some specific categories of data, considered highly sensitive. EFPIA would appreciate better specification as to the meaning of "stricter measures" to avoid divergent approaches across Member States.

Regarding the additional conditions for the transfer of personal electronic health data to a third country or an international organisation, we are concerned about the possibility for Member States to maintain or introduce further conditions for access and transfer of these data. While consistent with GDPR, this provision could fuel fragmentation and further hinder transatlantic data flows.

The implementation phase of EHDS should also be used to clarify the anonymisation requirements, both in terms of the standards to be applied and their practical application (who will do what and when). In terms of the standard, an anonymisation approach should strike a balance between protecting patients' privacy and maintaining the data utility of a dataset. A dogmatic approach, on either side of the spectrum, would leave data protected too poorly to safeguard patients' privacy or lead to data being transformed so heavily that it has no meaningful research value which, in the end, would be detrimental to patients, industry, and society. Maintaining data utility also reduces the burden on patients generally as they will not have to provide additional data for research that could have been performed on the basis of existing data sets. Thus, when anonymising datasets, control

mechanisms need to be applied in a manner that reaches the objectives of privacy protection, usability for research and regulatory compliance. A balance needs to be struck between the different types of controls to enable both objectives. EFPIA has developed key learnings based on current practices of anonymising datasets, and would gladly support discussions on this topic.

The way forward and EFPIA's commitment to realise the potential of the EHDS

- **EHDS: a key lever of strength for the EU internal market:**

As Enrico Letta pointed out in his report Much More Than a Market "[the] treasure trove of [health] information is indispensable for advancing R&D and enhancing healthcare planning" (p. 82). The report also warns that, to achieve the full potential of the EHDS, **a number of provisions adopted in the text will need to be carefully assessed, clarified and implemented.** This includes, for example, the implementation of the opt-out mechanism, the definition and design of contractual agreements between data users and data holders before sharing data and the minimum requirements that data holders must meet concerning dataset provisions.

- **Getting the complex secondary legislations right:**

More than 33 delegated and implementing acts, model/template and other guidelines have been introduced in the final text of the EHDS, and, for some of the provisions the implementation is not foreseen before 2030 (for example, the application of specific data categories for secondary use such as genomic data). The scope of all these secondary legislations will be very technical and complex in nature and will set the rules for future data sharing from new, continuously emerging data sources. Therefore, we call on all stakeholders, in particular the European Commission and national authorities to regularly consult with industry stakeholders to ensure that implementation measures are workable and future-proof. These consultations should continue throughout the implementation process and should be meaningful, i.e. taking the time to carefully consider the input from stakeholders.

- **Making the most of the Stakeholder Forum:**

Article 64a foresees the creation of a Stakeholder forum "for the purpose of facilitating the exchange of information and promoting cooperation with stakeholders in relation to the implementation of this Regulation". While the details of the scope and governance of this Forum are not yet defined, we call on this platform to become a truly consultative body with the necessary resources to maintain a long-term and granular dialogue with all stakeholders.

- **Industry commits to support the development of workable and a future-proof secondary legislation**

Recently, complex EU health legislation such as the Medical Devices Regulation and the In-Vitro Diagnostics Regulation had their implementation periods extended due to the transition to the new rules being slower than anticipated, creating bottlenecks and detrimental impact on healthcare systems and patients. We cannot afford this to happen with the EHDS, as the potential to improve patient outcomes, accelerate innovation and improve the competitiveness of the EU is too great. EFPIA members have a wealth of experience and knowledge in generating and sharing health data,

and they commit to contributing this expertise to the timely development and adoption of secondary legislation.

It will take all of us to realise the potential of the EHDS. Let's work together to secure the timely implementation of an EHDS that works for all.