Asociace inovativního farmaceutického průmyslu

AIFP POSITION PAPER

AIFP's Position on the Proposal for a Regulation on the European Health Data Space

28st November 2022

aifp
Asociace inovativního farmaceutického průmyslu

Introduction

The European Commission has prepared **a proposal for a Regulation on the European Health Data Space**, from now on referred to as the "EHDS Regulation", and submitted it for discussion to the EU Council and the European Parliament on 3 May 2022. The EHDS Regulation aims to set up an all-European ecosystem of collecting and sharing electronic health data for primary and secondary use.

Although digitalisation is now one of the EU's main healthcare topics, the digitalisation approach and implementation varies dramatically from state to state. Yet the digital transformation of health systems can accelerate the arrival of innovative technologies in healthcare, increase the productivity of the EU economy and support the EU's better competitiveness in innovations. Evidence shows that **while 48% of healthcare innovations take place in the USA, only 22% of global innovations take place in the EU**.[1]

The European Commission is trying to reverse this negative trend and is working, for these purposes, on a complete review of current pharmaceutical legislation. This review is expected to be presented in the first quarter of 2023 and, together with the EHDS Regulation, should help improve the European regulatory environment.

The EHDS Regulation sets for the first time a specific **legal framework for collecting and using health data across the European Union.** The aim is to establish **clear rules, common standards and practices, infrastructure, and governance.** All this is to facilitate the use of health data by patients, healthcare professionals, researchers, statisticians, ministries, and other regulators and thus increase the EU's level of innovations and competitiveness.[2]

1. The first aim of the Regulation **is to increase patients' control over their electronic health data**. The Regulation is intended to allow patients to fully exercise their rights to their electronic health data, including in the context of cross-border healthcare. Every EU citizen will be able to see their health data, share them in a single European format, add information to them, restrict access to them and know which healthcare professional has consulted them. Patients and physicians can easily access health reports, patient summaries, ePrescriptions, images (from imaging), laboratory results, hospital discharge reports, etc.[3]

2. The second aim of the Regulation **is to provide a consistent framework for**

[1] EFPIA's article for consultation on the review of general pharmaceutical legislation available here
[2] ICTandhealth.com interview EC available here
[3] ICTandhealth.com interview EC available here

using health data for research, innovations, government strategies and regulatory activities. Finally, the third aim is to facilitate the development of the data economy by creating a single market of digital health services and products (EHR system - electronic health record system).[4]

The recent "Covid" acceleration of online digital communication has made the topic of digitalisation, health data and access to them a key issue, which can also **significantly improve the efficiency of healthcare, both professionally and financially.**

The Czech Republic has already made progress in legally establishing the foundations of the digitalisation of healthcare by adopting Act no. 325/2021 of Coll. on the digitalisation of healthcare, which came into force in January 2022 and is expected to be in full effect in 2026. The EHDS Regulation gives the digitalisation of healthcare an international dimension, as it aims to go even further and to ensure the common standardised collection and sharing of electronic health data across borders.

European Health Data Space Regulation (a detailed view)

The proposal for an EHDS Regulation includes processes for accessing and using data for primary and secondary purposes. It also includes procedures to ensure cross-border data sharing, data access and the EHDS control and governance system, including establishing a system of control and support bodies.

In terms of **the primary use of electronic health data**[5] (i.e., the use of a particular patient's data by a specific physician to provide healthcare), the EHDS Regulation gives patients better access to and control over their electronic health data. Also, the attending physician will have information on the patient's health condition, which will be easy to search for in one place, even if the patient was treated in another EU Member State. **The European Commission estimates that the EHDS Regulation can save hospitals up to 15% of costs, and the healthcare sector up to 10% of costs, of sharing imaging results, a total of 11 billion EUR per year in the EU.**[6]

The primary use of data will:

- Reduce healthcare costs.
- Increase patients' awareness,
- And improve the overall quality of healthcare.

[4] ICTandhealth.com interview EC available here
[5] Primary use of electronic health data means the use of health data to provide healthcare, i.e., for physicians as well as for patients as it emphasizes the patient's right of access to his or her electronic health data, immediately, free of charge and in an easily readable, consolidated, and accessible form.
[6] ICTandhealth.com interview EC

The essential requirement for using data for primary purposes is the maximum possible data protection and security level. Misusing patients' sensitive data would compromise patients' trust in such a system.

Regarding the **secondary use of health data**, the proposal for an EHDS Regulation specifies the type of data that a Member State must make available for secondary use (Article 33). Article 34 provides an exhaustive list of purposes for which data will be made available to the applicant for secondary use (public interest, health threat, statistical data, education, scientific research, development, innovation activities, etc.). Article 35 specifies the purposes for which it is prohibited to provide data for secondary use (decisions detrimental to patients, advertising and marketing activities towards healthcare professionals or patients, provision of data to a third party not mentioned in the application, etc.). The Regulation also regulates the process for granting permission to provide data for secondary use based on an application (Article 44), whereby the successful applicant must disclose the result in which they used the data (e.g., study, analysis, etc.) within 18 months.

The Regulation also lays down rules for the cross-border provision of health data for secondary use, for which the national contact point will be responsible. The Regulation also establishes the European Health Data Space Board (EHDS Board), a new body of the European Commission that will play a unifying role in an otherwise relatively decentralised system.

The EHDS Regulation will come into force in three waves after adopting this directly applicable regulation. The EHDS system is expected to be operational within three years of the adoption of the Regulation, which may be **around the year 2027**.

AIFP's position

AIFP welcomes the proposal for an EHDS regulation and sees it as an unprecedented opportunity to set up the future data and digital ecosystem in healthcare. We believe that the EHDS if set up well, interpreted and implemented consistently in all EU Member States, can achieve the goals we support.

However, as part of our assessment of the proposal for a Regulation, **we have also identified areas that could significantly impact the complex operating model of the innovative pharmaceutical industry and thus negatively affect our ability to develop and market new medicines.** We also see some **untapped opportunities** in the proposal. We have prepared specific proposals for these areas as described below.

In discussion with authorised institutions, we want to ensure that the EHDS Regulation will not ultimately reduce the volume of innovation in the EU, the attractiveness of the EU for R&D and the relevance for clinical trials, which is the opposite of the aims set out by the EHDS Regulation.

Three areas where we call for clarification and improvement of the current proposal:

1. **Secondary use of health data**
2. **Rights and obligations of data holders**
3. **Protection of intellectual property rights (patents) and trade secrets**

1. Secondary use of health data

We welcome **the definition of minimum categories of data** to be provided in an anonymised and aggregated form as "data for secondary use" (Article 34). However, we are concerned that **the list of purposes for which "other applicants" may request data does not cover all legitimate needs of all participants in the healthcare system.** "Other applicants" include pharmaceutical companies, patient organisations, data processing institutions (analytical, statistical), pharmacoeconomists, etc.

In compliance with the basic principles of public administration digitalisation, we believe that the digitalisation of health systems should serve to collect, use, analyse and evaluate data. **Health data for secondary use are fully anonymised and aggregated, and there is no risk of misuse of an individual's disclosed sensitive personal data**. Access to such health data, particularly data collected by public authorities, must be systemically open. All their users will have a legitimate reason to use such data. This will establish a fair and non-discriminatory environment in terms of access to data.

- **The legitimate reasons for accessing data for secondary use** by the pharmaceutical industry are mentioned above. However, the reasons for requesting data for secondary use under the EHDS Regulation are limited. Unfortunately, the list of permitted data use purposes (Article 34 (1) (d)-h))[7] does not include the possibility of obtaining data for secondary use to fulfil a legal obligation (e.g., to submit a cost-effectiveness analysis and other similar compelling reasons on which the availability of medicine for Czech patients depends). **We recommend adding to these purposes** *"other legitimate purposes where the applicant is obliged to use the obtained data to prepare an output required by national legislation or requested by a national or European public administration."*

[7]Article 34 (1) (d)-h)) of the Regulation: d) education, e) scientific research, f) development of innovative products or services, g) teaching, testing, and evaluating of AI and other algorithms, h) providing personalized healthcare to a natural person.

- We also propose to clarify Article 34 (1) (d), i.e., **the purpose of the permitted data provision** *"education or teaching activities in health or care sectors."* It is not clear what kind of the **scope of "education"** it concerns. Education can take place in the classroom or nationally through an educational campaign. It is essential to clarify that the proposal refers to education in the broadest sense. Moreover, health data for secondary use cannot be used only for health and care education. Such data are also needed by psychologists, sociologists, journalists, social care organisations, aftercare, preventive care, etc. Their demands for such data are entirely legitimate, and their access to such data will help meet the aims of the Regulation. We, therefore, recommend adding to (d) the following text*: "education or teaching of individuals, groups and the general or professional public, in any field as part of which the applicant has a legitimate reason to carry out such education or teaching."*
- The third specific proposal in terms of data for secondary use concerns **the prohibition of providing data for secondary use for the purposes of "advertising or marketing activities towards healthcare professionals, healthcare organisations or individuals"** (Article 35 (c)). It is necessary to consider that any information that a pharmaceutical company provides to physicians about its products - the latest medicines about which physicians must be sufficiently informed - is considered, by the Advertising Regulation Act, to be advertising and is assessed and approved as such. It is, therefore, necessary to clarify or **cancel** this provision.

Article 35 (c) may be clarified by defining "advertising" and marketing activities," particularly in light of the current regulation of "advertising" of medicinal products and the restrictions that they already meet concerning advertising towards healthcare professionals.

The cancellation of Article 35 (c) of the EHDS Regulation should also be seriously considered since it contradicts the obligations under Directive 2001/83 on medicinal products for human use (the HMP Directive). This Directive has established that marketing and advertising to physicians is a legitimate activity. Therefore, there is no reason not to use correct data (from the EHDS Regulation) in advertising; however, advertising must be based on such data.

The HMP Directive establishes criteria for such advertising and specifies that the information provided to the physician must be "*accurate, up-to-date, verifiable and sufficiently complete".*[8] The HMP Directive further specifies that "the advertising of medicinal products to persons authorised to prescribe or dispense medicinal products

[8] Dir 2001/83, Article 92/2

helps to inform such persons".[9]

Thus, the advertising of medicinal products towards healthcare professionals has been tightly regulated and monitored for over 30 years. There is no reason not to provide pharmaceutical companies with access to data for secondary use for such advertising. Especially since another applicable EU regulation stipulates the obligation of the manufacturer to be up-to-date, complete, and balanced, and it is, therefore, necessary to base advertising not only on the current SPC but also on up-to-date data concerning the therapeutic area (e.g., epidemiological data, prevalence, data from actual clinical practice, etc.). Not to mention that such limitation in the use of data creates a significant inequality among data applicants.

2. Rights and obligations of data holders

- Regarding the provision of data by the data holder (Article 41), **it is necessary to clarify who the "data holder" is**. For example, in the case of pharmaceutical companies, it is not clear whether a company whose headquarters are located outside the EU will also be considered a data holder. A global pharmaceutical company has branches in many EU Member States. However, research and development, clinical trials and other activities during which health data are collected are usually centralised, and individual units in the EU Member States do not have access to such data.

In the case that an EU branch of such a non-European company is considered a "data holder" under the EHDS Regulation**, it will be necessary to clarify how to proceed in case of a conflict between the non-European rules for the protection and sharing of health data and the European laws under the EHDS Regulation.**

- **Another big question remains unanswered: which data will have to be provided to the applicant?** The category "European health data" is vast and includes personal and non-personal data. Moreover, **the proposal does not deal at all with specific situations**. It is thus unclear how the data holder should proceed if there is a justified reason for refusing to provide the data (e.g., the protection of the trade secret or sensitive commercial information) or if the scope of the requested data needs to be further consulted**.**

And the case that such a data holder was to be fined, the proposal does not include any defence (appeal) process. Also, the proposal does not specify how to proceed in case of any doubt as to whether the data permit was actually issued for the requested data or the requested purpose. **The permit issuance system totally lacks the option of an appeal or a suspensory period** (not to provide data until the situation is resolved). In

[9] Dir 2001/83 Preamble (47)

other words, there is no guarantee of legality and reviews of administrative decisions. The data permit decision will be a public-law decision, which must be the subject of remedial measures. Otherwise, the principle of the legality of public administration will not be applied. The Regulation should include such procedures. Otherwise, its implementation will create many unclear situations, where different regulators or organisations may start making their own process, which will be different in each EU Member State. And this is not in line with the aims of the Regulation.

- **The third issue to be clarified is the administrative burden and the compensation of costs** charged to data holders upon fulfilling the new obligations under the EHDS Regulation. This concerns, in particular private entities. The data holder will receive an approved data acquisition permit from the applicant and be required to hand the data to the applicant within two months and in a single European format. **Firstly, the regulators should set technical requirements to allow data holders to comply with these requirements without laboriously converting all data** (including imaging) into the required format and within a brief period of two months. The fact is that many companies present in the EU are essentially foreign companies whose data the EU law does not govern collection processes. These companies do not have to collect and archive data in the European format and will have to convert the data at a high cost. Secondly, clarifying the compensation for the data holder's higher costs is necessary**.**

The pharmaceutical industry is in favour of standardised fees in the entire EU. However, we understand that actual costs vary in each EU Member State. The fee should be in proportion to the costs incurred. EU Member States should also consider the following option. If data users are also data holders, they should pay reduced fees to compensate for their financial costs and motivate them to share data.

3. Protection of intellectual property rights (patents) and trade secrets

Protecting intellectual property rights (IPR), **i.e., patents, trademarks, trade secrets and copyrights, and regulatory data protection (RDP) facilitate the development of new technologies and support a robust knowledge-based European economy.**

- Unfortunately, **the protected data area is a crucial concern for data holders**. According to the Regulation (Article 33 (4)), private enterprises, which are data holders, must also provide data protected by intellectual property rights and trade secrets. In such a case, the Regulation suggests that "all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken." However, this provision is very vague and does not provide any necessary answers as to how IP rights and trade secrets will be protected, nor does it provide any guarantees that IP rights and trade secrets will be protected.

Protecting IP rights is critical for maintaining the competitiveness of the innovation ecosystem in the EU. IP rights allow the pharmaceutical industry to invest in R&D and, thus, to advance technological development and innovations.

- We have also defined another critical concern in this area. **The EHDS Regulation does not address the protection of commercially confidential information (CCI).** However, the EU Data Governance Act regulates exceptions for CCI protection. We believe that the EHDS Regulation should completely prevent the sharing of protected data. If not, EU Member States should at least be authorised to assess whether a particular data set falls under the protection of IP rights, trade secrets or CCI and to exclude such data from disclosure. The risk of this more lenient approach will be the "shopping" of applicants fishing for protected data and focusing on EU Member States with more lenient assessments.
- **It is also unclear under which conditions data holders should share data from clinical trials**. It is essential to point out that the pharmaceutical industry has already been subject to requirements for clinical data transparency and standardised sharing[10] that balances out the need to make data public while protecting ongoing clinical trials and IP rights. It is crucial that the EHDS does not upset this balance. **We consider the current conditions for disclosing clinical trial results to be well thought out, sufficient and well-proven,** and we see no need for the provision of such data to be regulated by the EHDS Regulation as well.
- It is also essential to address the fact that **the EHDS Regulation makes it mandatory to disclose the results of secondary data use within 18 months**. However, it is unclear how the protection of protected data and newly created intellectual property rights would be ensured.

We trust that those, who will be deciding on the final text of the EHDS Regulation in the upcoming months, will support the value of innovations and the pharmaceutical industry's track record **by not supporting mandatory transfers of protected data**.

Any disclosure of such data would significantly affect not only the specific data holder. Such a situation would limit the ability to maintain a sustainable and competitive research ecosystem for the entire EU, which would no longer be a credible partner for global investors. Also, these datasets could be placed outside the EU jurisdiction. This, especially considering data protection under the GDPR, raises additional uncertainty.

[10] Sharing clinical trial information (efpia.eu)

aifp
Asociace inovativního farmaceutického průmyslu

Conclusions

In the end, we would like to say that the innovative pharmaceutical industry has a long history of transparent handling of patient data based on respecting the protection of privacy and sensitive data. It also has a long history of working with Real-World Evidence (RWE) generated from other sources and requiring new research methods, including surveillance and ethical and legal implications.

We are, therefore, ready to use our expertise to help improve public understanding of the value of health data and increase confidence in how data are collected and used to support health innovations.

The success of the EHDS Regulation depends on the availability of and access to a wide range of high-quality, interoperable data suitable for public sharing.