Amendments to the proposal for a European Health Data Space - by the European Patients' Forum (EPF)

November 2022

Amendment 1

Article 2 – paragraph 2 – point af (new)

Text proposed by the Commission	*Amendment*
	(af). 'innovation activities' means new products, services and models foreseen to improve health outcomes, cost efficiency and any other areas as recognised by the end-users of the innovation such as patients, healthcare professionals and health administrators.

Justification:

If patients agree to share their data, it should always be in their interest, whether it is to support research or improve their quality of life. As pointed out by the European Data Protection Board and the European Data Protection Supervisor, 'Innovation activities', which constitute a purpose for re-use, are not properly delineated in the draft regulation, which opens the door to interpretation and creates new bases for the secondary processing of health data, such as for commercial purposes that do not add value for patients or society[1]. Although there is no universally accepted definition of 'innovation', we feel that health innovation should refer to the extent to which the activity makes a tangible and positive difference to patients. Identifying this benefit is only possible in partnership with patients.

Amendment 2

Article 3 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health	9. Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health

[1] See EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, p.22. Available at https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf

data. *Member States* shall establish the rules and specific safeguards regarding such restriction mechanisms.	data. ***The European Commission*** ~~*Member States*~~ shall establish the rules and specific safeguards regarding such restriction mechanisms ***through a delegated act.***

Justification:

The specific rules and safeguards to ensure the right to restrict access by health professionals to all or part of patients' electronic health data should be established at European level, not at national level. Firstly, access to records will take place between Member States in the framework of the cross-border infrastructure MyHealth@EU, which will therefore require harmonised rules between Member States. Secondly, a definition at national level risks creating inequalities between citizens and ultimately hindering their right to restrict access, as Member States may apply different rules and specific safeguards to this right.

Amendment 3

Article 6 – paragraph 1 - point a

Text proposed by the Commission	*Amendment*
1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:	1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:
(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the content representation of clinical content and other parts of the electronic health data;	*(a)* ***harmonised*** datasets containing electronic health data and defining structures, such as ***minimum*** data fields and data groups for the content representation of clinical content and other parts of the electronic health data***, that can be enlarged to include disease-specific data****;*

Justification:

The European Health Data Space is a unique opportunity for patients to be empowered to make the best use of their personal health data individually and in partnership with healthcare providers, not only in a cross-border scenario but also to manage their inter-provider care and self-management. This is in line with the Commission's stated priority that citizens should be empowered with data and digital tools for person-centred care, prevention,

and self-care as well as interaction between users and healthcare providers.[2] *All patients should receive a minimum set of data in a common format that can be enlarged to include disease-specific data, if necessary. Patient organisations will play a key role as capacity-builders by providing their patients with targeted educational materials and activities on the disease-specific dataset.*

Amendment 4

Article 10 – paragraph 5

Text proposed by the Commission	*Amendment*
4. In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest.	4. ***Essential health stakeholders' representatives, including patient organisations, shall be present in the governance and decision-making structures of the digital health authority.*** In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest. ***The Commission shall be empowered to adopt delegated acts setting out what is likely to constitute a conflict of interests together with the procedure to be followed in such cases.***

Justification:

Digital health authorities (DHA) will be responsible for monitoring patients' and citizens' rights and for ensuring that they are properly protected. The regulation must involve the main actors who will be impacted and who will be essential to its achievement: the health stakeholders. Concrete and meaningful involvement of patients' representatives in the governance and decision-making structures of the DHA will be essential to ensure transparency, build a high level of trust and make sure patients' needs are fully taken into consideration. In addition, the Commission should define more precisely what constitutes a conflict of interest, as unclear criteria lead to unpredictable engagement.

[2] See the Communication from the Commission to the European Parliament and the Council; A European Health Data Space: harnessing the power of health data for people, patients and innovation, COM(2022) 196/2, 3 May 2022. Available at https://health.ec.europa.eu/publications/communication-commission-european-health-data-space-harnessing-power-health-data-people-patients-and_en

Amendment 5

Article 33 – paragraph 5a (new)

Text proposed by the Commission	*Amendment*
	4b. Health data access bodies shall provide for an accessible and easily understandable opt-out mechanism, whereby natural persons must be required to explicitly express their wish not to have their personal electronic health data processed for secondary use.

Justification:

Patients are generally willing to share their health data provided that appropriate and informed consent is given, in particular in view of the large number of categories of health data made available in the context of the EHDS. An opt-out mechanism would give patients and citizens the choice to control their own health data, which is the objective of the Regulation as described in Article 1(2)(a), namely, to strengthen the rights of individuals with regard to the availability and control of their electronic health data. Opt-out mechanisms for processing health data are already in place in several Member States. Belgium, for example, has an opt-out system for tissue research, while France has an opt-out mechanism for the collection of personal health data in registries.[3] In addition to being described as a trust-building option[4], various studies have shown that an opt-out system is to be preferred to consent for each use of personal data, which places a disproportionate burden on patients, or to an opt-in mechanism, which is more likely to result in a less representative study population.[5]

Amendment 6

Article 34 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) development and innovation activities for products or services contributing to public health	(f) development and innovation activities for products or services contributing to public health

[3] See DG Health and Food Safety, "Assessment of the EU Member States' rules on health data in the light of GDPR", 2021, p. 116. Available at: https://health.ec.europa.eu/system/files/2021-02/ms_rules_health-data_en_0.pdf

[4] See DG Health and Food Safety, "Assessment of the EU Member States' rules on health data in the light of GDPR", p. 116 ; and this was identified in the discussions at the EPF 2022 Congress. Replay available at: https://epfcongress.eu/

[5] See National Data Guardian for Health and Care, "Review of Data Security, Consent and Opt-Outs", 2016. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF; and Henshall, C. & Potts, J.& Walker, S. & Hancock, M. & Underwood, M. & Broughton, N. & Ede, R. & Kernot, C. & O'Neill, L.& Geddes, J. & Cipriani, A., "Informing National Health Service patients about participation in clinical research: A comparison of opt-in and opt-out approaches across the United Kingdom", Australian & New Zealand Journal of Psychiatry, 21 November 2020.

or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;	or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices, ***and ensuring benefit to the end-users of the innovation, such as patients, healthcare professionals and health administrators, which is defined in partnership with them.***

Justification:

As pointed out by the European Data Protection Board and the European Data Protection Supervisor in their joint opinion[6], the purposes for re-use are not properly delimited and could include any form of development and innovation activities for products or services contributing to public health or social security. Patient data should be used for the benefit of providing better healthcare to patients and to improve public health. Data used to drive advancements in treatments, medicines, devices and services should, for instance, lead to innovation bringing better health outcomes to patients, including answering the patients' unmet needs.

Amendment 7

Article 34 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;	(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices; ***and ensuring benefit to the end-users, such as patients, healthcare professionals and health administrators, which is defined in partnership with them.***

Justification:

As pointed out by the European Data Protection Board and the European Data Protection Supervisor in their joint opinion[7], the purposes for re-use are not properly delimited and could include any form of training, testing and evaluation of algorithms, including in medical devices, AI systems and digital health applications,

[6] See See EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, 12 July 2022, p.22.

[7] Ibid.

contributing to public health or social security. The use of patient data should bring benefit to patients, otherwise, it risks undermining acceptance and trust in the sharing of their health data.

Amendment 8

Article 35 – point f (new)

Text proposed by the Commission	*Amendment*
	(f). automated individual decision-making, including profiling, in accordance with Article 22 of the Regulation (EU) 2016/679

Justification:

Personal health characteristics should not be used to make automated decisions, such as employment, loan and insurance decisions, and to profile an individual. Patients with chronic diseases are particularly vulnerable to automated individual decision-making and profiling, as their chronic condition could be used to make decisions against them or categorise them and lead to discrimination based on predictive and not factual health data [8]

Amendment 9

Article 36 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.	3. ***Essential health stakeholders' representatives, including patient organisations, shall be present in the governance and decision-making structures of the health data access bodies.*** In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies

[8] See Favaretto, M., De Clercq, E. & Elger, B.S." Big Data and discrimination: perils, promises and solutions. A systematic review", *J Big Data* 6, 12, 2019. Available at: https://doi.org/10.1186/s40537-019-0177-4

	shall not be bound by any instructions, when making their decisions.

Justification:

The health data access bodies are responsible for the secondary use of data, including granting permits. They will be the decision-makers on behalf of society. The involvement of patient organisations is therefore crucial, not only to ensure that the needs of patients are fully taken into account, but also to ensure transparency, democratic and inclusive governance. This is already the case in the French health data access body, the Health Data Hub, where the vice-president is the president of the national platform of patient and health system user organisations.[9]

Amendment 10

Article 38 – paragraph 1 – point ea (new)

Text proposed by the Commission	*Amendment*
	(ea) The record on who has been granted access to the data, the legal basis and the purpose, in accordance with Union and national law.

Justification:

Currently, the proposal states that the health data access bodies are not required to provide specific information to each natural person about the use of their data. While most patients agree that their health data should be used in the public interest, they also want information on who is using their data and how. This exemption from Article 14 of the General Data Protection Regulation (GDPR) may also have unintended consequences for patients' fundamental rights and freedoms, including their right to information. Therefore, in line with GDPR exemptions, patients should be informed about who has had access to their data, on what basis and for what purpose.

Amendment 11

Article 38 – paragraph 2

[9] See the Health Data Hub, https://www.health-data-hub.fr/notre-organisation

Text proposed by the Commission	*Amendment*
2. Health data access bodies shall not be obliged to provide the specific information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.	2. ***At the request of a natural person or a group representing natural persons***, health data access bodies shall ***~~not~~*** be obliged to provide the specific information under Article 14 of Regulation (EU) 2016/679 concerning the use of their health data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.

Justification:

This amendment is linked to Amendment No 9 and echoes the joint opinion of the European Data Protection Board and the European Data Protection Supervisor, noting that this exemption to Article 14 of the GDPR may have "unintended consequences for the fundamental rights and freedoms of patients, due to the lack of concrete conditions under which such an exemption would be applicable"[10]. They recommend amending the provision accordingly, taking into account that the requirements set out in Article 14 of the GDPR cannot be systematically set aside without a proper and relevant assessment and justification of the need for such an exemption. Moreover, a natural person or a group representing natural persons, such as patient organisations, should be entitled to request data.

Amendment 12

Article 38 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.	4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies, ***the risks and consequences linked with individual and collective digital health data rights arising from this Regulation.***

Justification:

Informed consent requires clear, transparent, easily accessible information on the use of patients' data. As the right to information under Article 14 of the GDPR is challenged in the Regulation, it is essential that Member States conduct extensive information campaigns not only on the role and benefits of health data access bodies,

[10] EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space, p. 24

but also on the potential consequences of sharing health data and on the individual and collective digital rights arising from this Regulation.

Amendment 13

Article 43 – paragraph 4

Text proposed by the Commission	*Amendment*
4. [..] In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the data user from any access to electronic health data for a period of up to 5 years.	4. [..] In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the data user from any access to electronic health data for a period of up to 5 years, ***and fines shall be imposed in accordance with Article 83 of the Regulation (EU) 2016/679.***

Justification:

The draft regulation only mentions the revocation of permits for a maximum of 5 years. In order to build trust, misuse of health data must be accompanied by strong sanctions that deter data users from violating the licence, including, but not limited to, fines. Fines should be transparent, proportionate, effective, and harmonised between Member States to ensure the same level of protection for all patients.

Amendment 14

Article 43 – paragraph 4a (new)

Text proposed by the Commission	*Amendment*
	4b. Any natural person affected by a breach of the data permit issued pursuant to Articles 35 and 46 should have the right to an effective judicial remedy before a tribunal in accordance with Article 47 of the EU Charter of Fundamental Rights.

Justification:

The draft Regulation undermines the right to information of patients, with at least one explicit derogation from the provisions of Article 14 of the GDPR regarding the information to be provided to data subjects. As highlighted

in the joint opinion of the European Data Protection Board and the European Data Protection Supervisor, such a derogation undermines the possibility for data subjects to exercise effective control over their personal data. In the absence of the right of information being upheld, it cannot reasonably be expected that natural persons, especially vulnerable groups such as patients, have the knowledge, resources, and capacity to ensure the protection of their data. The Regulation should therefore include provisions on effective access to justice in cases of misuse of health data.

Amendment 15

Article 45 – paragraph 2i (new)

Text proposed by the Commission	*Amendment*
	(i) a communication plan defining audiences and tools to publicly inform on the results or outcomes of the access to the data in accordance with article 46 (11).

Justification:

This amendment is an additional safeguard to ensure that patients are informed about the results or findings of projects for which electronic health data have been used. While most patients agree that their health data should be used for the public benefit, they also want access to the results of research that uses their data. Under Article 38(1)(e) of the draft Regulation, data users are required to make these results publicly available. However, in their requests for access to the data, data users are not obliged to indicate how they will communicate these results.

Amendment 16

Article 46 - paragraph 11

Text proposed by the Commission	*Amendment*
11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than *18* months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those	11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than ***12*** months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those

results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS.	results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public ***in lay summaries*** on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS.

Justification:

Simply providing the results or output of secondary use of electronic health data is not enough if the information provided is not easily understandable by patients. Data users should therefore ensure that information is communicated in a way that facilitates understanding, by for example using a lay language. Effective and patient-friendly communication is of utmost importance, and it contributes to the health and digital health literacy of patients. Not having clear information on how their data has been used could undermine the willingness of patients to share their data, which however is indispensable for the effective deployment of the EHDS.

Amendment 17

Article 64 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of the high level representatives of digital health authorities and health data access bodies of all the Member States. [...]	1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of the high level representatives of digital health authorities and health data access bodies of all the Member States, ***as well as representatives of health stakeholders, including patient organisations. [...]***

Justification:

The participation of patient representatives in the meetings of the EHDS Board should not be conditional on the topics discussed and their degree of sensitivity. The unique experience that patients can bring is fundamental to driving the implementation of the EHDS, building a high level of trust and ensuring that patients' needs are fully taken into consideration. In shaping the governance of the EHDS at European level, inspiration could be taken

from the European Medicines Agency (EMA), which has a long-standing commitment to and appropriate structures for engaging with civil society stakeholders. Patient representatives are present in most scientific committees of the EMA as well as the Management Board. Patients, consumers and healthcare professionals' organisations have a dedicated forum for regular dialogue.[11]

Amendment 18

Article 64 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.	4. ***Health*** stakeholders, ***including patients' representatives***, and relevant third parties, ~~***including patients' representatives,***~~ shall ~~***be invited to***~~ attend meetings of the EHDS Board and participate in its work~~***, depending on the topics discussed and their degree of sensitivity.***~~

Justification:

The participation of patient representatives in the meetings of the EHDS Board should not be conditional on the topics discussed and their degree of sensitivity. The unique experience that patients can bring is fundamental to driving the implementation of the EHDS, building a high level of trust, and ensuring that patients' needs are fully taken into consideration.

Amendment 19

Annex I – paragraph 1

Text proposed by the Commission	*Amendment*
1. Patient summary Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and	1. Patient summary Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and

[11] See the EMA Framework for engaging patients and consumers, updated in January 2022: https://www.ema.europa.eu/en/documents/other/engagement-framework-european-medicines-agency-patients-consumers-their-organisations_en.pdf ; and the EMA Stakeholder engagement report 2020-21: https://www.ema.europa.eu/en/documents/report/stakeholder-engagement-report-2020-2021_en.pdf

efficient healthcare to that person. The following information is part of a patient summary: [..]	efficient healthcare to that person. ***The patient summary shall be harmonised across Member States and include a minimum data set that can be expanded to include disease-specific data***. The following information is part of a patient summary: [..]

Justification:

This amendment is linked to amendment No 3 and aims to promote patients' understanding and control of their personal health data.