



Amendments to the European Health Data Space (EHDS) proposal

I EPSU Amendments

These are amendments that are proposed directly to the Commission's texts as they involve issues not addressed by the rapporteurs' report.

Amendment 1:

Commission's original proposal:	EPSU amendment:
<p>Article 1: 2. In addition, for the purposes of this Regulation the following definitions shall apply: (d) 'primary use of electronic health data' means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or <i>reimbursement</i> services;</p>	<p>Article 1: 2. In addition, for the purposes of this Regulation the following definitions shall apply: (d) 'primary use of electronic health data' means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security <i>and</i> administrative services;</p>

Justification:

Reimbursement services do not fall under the scope of the EHDS, especially of primary uses of health data.

Amendment 2:

Commission's original proposal:	EPSU amendment:
<p><u>Article 3</u> 5. Member States shall: (a) establish one or more electronic health data access services at national, regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2; (b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.</p> <p>The proxy services shall provide authorisations free of charge, electronically or on paper. They shall enable guardians <i>or other representatives</i> to be authorised, either automatically or upon request, to access electronic health data of the natural persons whose affairs they administer. Member States may provide that authorisations do not apply whenever necessary for reasons</p>	<p><u>Article 3</u> 5. Member states shall (a) establish one or more <i>public</i> electronic health data access services at national, regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2; (b) establish one or more <i>public</i> proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.</p> <p>The proxy services shall provide authorisations free of charge, electronically or on paper. They shall enable <i>legal</i> guardians <i>as recognised by national law</i> to be authorised, either automatically or upon request, to access electronic health data of the natural persons whose affairs they administer. Member States may provide that</p>



related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.	authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.
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Justification:

The bodies that act as intermediaries for health data must be in public hands, both for the sake of transparency and for security reasons. In order to protect vulnerable people and their health data, only legal guardians who have been properly recognised by law should be able to have access to personal health data. The risk of abuse of the right to access health data is extremely high in the Commission’s original proposal as it does not contain any safeguards.

Amendment 3:

Commission’s original proposal:	EPSU amendment:
<p><u>Article 3:</u> 8. Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.</p> <p>Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6 and the data recipient shall read and accept it.</p> <p>By way of derogation from Article 9 of Regulation [...] [Data Act COM/2022/68 final], the data recipient shall not be required to compensate the data holder for making electronic health data available.</p> <p>Natural persons shall have the right that, where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.</p>	<p><u>Article 3:</u> 8. Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.</p> <p>Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to in Article 6 and the data recipient shall read and accept it.</p> <p>By way of derogation from Article 9 of Regulation [...] [Data Act COM/2022/68 final], the data recipient shall not be required to compensate the data holder for making electronic health data available.</p> <p>Natural persons shall have the right that, where priority categories of personal electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.</p> <p><i>The Commission shall, by means of implementing acts, determine the requirements for the</i></p>



	<i>interoperable, cross-border mechanism for identifying data recipients and authenticating the receiving entity's belonging to the health or social security sector.</i>
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Justification:

There needs to be an effective way of confirming that any entity potentially receiving health data is a legitimate data recipient in the health and social security sector.

Amendment 4:

Commission's original proposal:	EPSU amendment:
<p><u>Article 5:</u> 2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data and indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria:</p> <ul style="list-style-type: none"> <i>(a) the category is relevant for health services provided to natural persons;</i> <i>(b) according to the most recent information, the category is used in a significant number of EHR systems used in Member States;</i> <i>(c) international standards exist for the category that have been examined for the possibility of their application in the Union.</i> 	<p><u>Article 3:</u> <i>deleted</i></p>

Justification:

The Commission should not be able to modify the list of categories of personal data subject to mandatory availability for primary use so easily as change might require a re-evaluation of the risks to the fundamental rights and interests of the concerned individuals. These issues amounts to substantive matters that should be considered as essential elements, pursuant to Article 290 of the TFEU.

Amendment 5:

Commission's original proposal:	EPSU amendment:



<p><u>Article 8:</u> <i>Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.</i></p>	<p><u>Article 8:</u> <i>deleted</i></p>
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Justification:

Article 8 risked further marketisation and commercialisation of the health sector and hence must be removed. It is also entirely unworkable as it does not address any of the many issues with cross-border telemedicine such as medical liability

Amendment 7:

Commission's original proposal:	EPSU amendment:
<p><u>Article 33</u> 1. Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter: (f) person generated electronic health data <i>including</i> medical devices, <i>wellness applications or other digital health applications</i>; (n) electronic data related to insurance status, professional status, education lifestyle, <i>wellness and behaviour</i> data relevant to health;</p>	<p><u>Article 33</u> 1. Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter: (f) person generated electronic health data <i>from</i> medical devices; (n) electronic data related to insurance status, professional status, education <i>and</i> lifestyle data relevant to health;</p>

Justification:

Wellness and other digital health applications collect personal data that are not related to health such as location, meaning they should not be included. Wellness and behaviour data may indirectly reveal sensitive information.

Amendment 8:

Commission's original proposal:	EPSU amendment:
<p><u>Article 33</u> <i>7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic health data.</i></p>	<p><u>Article 33</u> <i>7. deleted</i></p>

Justification:

The Commission should not be able to modify the list of categories of personal data subject to mandatory availability for secondary use so easily as change might require a re-evaluation of the risks to the fundamental rights and interests of the concerned individuals. These issues amounts to substantive matters that should be considered as essential elements, pursuant to Article 290 of the TFEU.

Amendment 9:



Commission's original proposal:	EPSU amendment:
<u>Article 35</u> Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited: (f) <i>(new)</i>	<u>Article 35</u> Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited: (f) calculating reimbursement, costs or expenditures relating to healthcare provision to be borne by natural persons, private or public insurance, or public bodies, including, but not limited to, the development and amendment of healthcare provider payment systems.

Justification:

Health data should be used to improve healthcare provision and research. Healthcare provider payment systems should not fall under the scope of the proposal.

Amendment 10:

Commission's original proposal:	EPSU amendment:
<u>Article 42</u> 5. <i>(new)</i>	<u>Article 42</u> 5. <i>The profits generated from the collection or use of health data should benefit Member States' health systems. This requires transparent and robust regulations to ensure that profits from using data are shared fairly and that the general interest takes precedence over private profit.</i>

Justification:

It is only just that the returns from the secondary uses of health data are adequately reinvested into the healthcare systems that allowed for this data to be collected.

Amendment 11:

Commission's original proposal:	EPSU amendment:
<u>Article 55</u> 2. The data access application shall include (i) <i>(new)</i>	<u>Article 55</u> 2. The data access application shall include <i>(i) a signed agreement pledging to respect the common code of ethical conduct for the secondary uses of personal health data as developed by the EHDS Board per Article 65(2)(g).</i>

Justification:

Data users should also pledge to follow ethical as well as legal rules.

Amendment 12:

Commission's original proposal:	EPSU amendment:
Article 65:	Article 65:

<p>2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV: (g) <i>(new)</i></p>	<p>2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in accordance with Chapter IV: (g) to elaborate and monitor the implementation of a common code of ethical conduct for the secondary uses of personal health data.</p>
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Justification:

A legal secondary use of health data may not be ethical. It is therefore important to have a clear and common standard of conduct for the use of health data across the EU

II Amendments in the rapporteurs' report that EPSU is against

The provisions of these amendments are worse than in the Commission's original proposal and so the Commission's wording should be maintained.

1 Amendment 32¹:

Commission's original proposal:	Rapporteur's amendment:
<p><u>Article 2</u> 2. In addition, for the purposes of this Regulation the following definitions shall apply: (q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, <i>might have</i> led or <i>might</i> lead to any of the following:</p>	<p><u>Article 2</u> 2. In addition, for the purposes of this Regulation the following definitions shall apply: (q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, <i>has led or is likely to lead</i> to any of the following:</p>

Justification:

The rapporteurs' amendment waters down the definition of a serious incident, hence why the Commission's original wording should be maintained.

2 Amendment 86²:

Commission's original proposal:	Rapporteur's amendment:
<p><u>Article 34</u> 1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with: (a) activities for reasons of public interest in the area of public and <i>occupational</i> health, such as protection against serious cross-border threats to health, public</p>	<p><u>Article 34</u> 1. Health data access bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with: (a) activities for reasons of public interest in the area of public health, such as protection against serious cross border threats to health, public health</p>

¹ https://www.europarl.europa.eu/doceo/document/CJ43-PR-742387_EN.pdf, p.36

² Ibid, p.56

health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;	surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;
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Justification:

The rapporteurs' amendment removes the ability of public bodies to use health data in the area of occupational health. This could have serious impacts into research, policymaking and other activities regarding important issues such as long Covid as an occupational disease or asbestos exposure.

3 Amendment 113³

Commission's original proposal:	Rapporteur's amendment:
<p><u>Article 42</u></p> <p>4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update that dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees <i>proportionately to their size or budget</i>.</p>	<p><u>Article 42</u></p> <p>4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update that dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees <i>according to a predefined percentage of deduction based on the importance of the research to the society and the level of sensitivity of data requested and thus implied technical obligations to ensure maximum personal data protection.</i></p>

Justification:

The rapporteurs' amendment unjustifiably restricts the ability of organisations and bodies with fewer resources to access health data for secondary use. The unclear definition of "importance of the research to society", as well as questions as to who is to evaluate the importance of this research, could lead to large private companies getting discounts to fees.

II Rapporteurs' amendments that should be included but changed

These amendments by the rapporteurs are a step in the right direction but can be improved.

³ Ibid, p.68

Justification:

The EHDS will involve significant changes in workplaces across the HSS sector. It is vital that social partners are consulted.

4 Amendment 97⁴:

Commission's proposal	Rapporteurs' original amendment	EPSU addition to rapporteurs' amendment
<p><u>Article 36</u> 2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers.</p>	<p><u>Article 36</u> 2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers, <i>including for the pseudonymization of the electronic health data.</i></p>	<p><u>Article 36</u> 2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure, <i>including the availability of sufficient legal expertise</i>, necessary for the effective performance of its tasks and the exercise of its powers, including for the pseudonymization of the electronic health data.</p>

Justification:

Assessing whether access requests for secondary uses of health data will involve a keen understanding of the provisions of multiple overlapping pieces of European and national legislation. Health data access bodies must have sufficient legal expertise to resist regulatory capture by large companies able to hire expensive lawyers.

5 Amendment 119⁵:

Commission's proposal	Rapporteurs' original amendment	EPSU addition to rapporteurs' amendment
<p><u>Article 45</u> 2. The data access application shall include</p> <p>(a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1), access is sought;</p>	<p><u>Article 45</u> 2. The data access application shall include</p> <p>(a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in <i>Article 9(2) of Regulation (EU) 2016/679, combined with Article 34(1)</i>, access is sought;</p>	<p><u>Article 45</u> 2. The data access application shall include</p> <p>(a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 9(2) of Regulation (EU) 2016/679, combined with Article 34(1), access is sought <i>and, for purposes referred to in points (d) to (g) of</i></p>

⁴ Ibid, p.60-61

⁵ Ibid, p.71



		<i>Article 34(1), a demonstration of the intended use's genuine connection to the health or care sectors;</i>
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Justification:

Brings the proposal in line with GDPR. There is a danger that health data is used for purposes such as research that is only incidentally related to public health.