EPSU POSITION ON THE EUROPEAN HEALTH DATA SPACE

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EUROPEAN PUBLIC SERVICE UNION

INTRO

The European Health Data Space (EHDS) is a proposal by the European Commission that is currently under consideration by the Parliament and the Council. The proposal aims to create a single, common integrated technical and regulatory system for electronic health data. While it is undeniable that access to large amounts of high-quality health data is vital for uses such as providing healthcare, health research and policymaking, the Commission's proposal lacks adequate provisions on social dialogue, the preservation of healthcare and health data as public goods, and the protection of data and privacy rights.

Considering that the EHDS is only the first of eight proposed data spaces, its final form and implementation will likely have significant influence on how the other seven European data spaces will be structured. It is vital that trade unions' concerns and interests are clearly communicated to the co-legislators as they shape the Commission's initial proposal. For this reason, EPSU has proposed a series of amendments to the proposal and the rapporteurs' report.

1. Social dialogue

Despite the Commission stating that social dialogue "helps to ensure social fairness and democracy at work, and boosts Europe's prosperity and resilience[1]", there is no explicit involvement of social partners in the governance of the EHDS proposal, and only limited involvement of stakeholders. This is problematic for two reasons.

Firstly, if the EHDS is implemented in a way that is indifferent to the needs and interests of workers, it will negatively impact already overstretched and understaffed health workers. The Standing Committee of European Doctors (CPME) warned that the EHDS proposal does not adequately address the expected changes to doctors' competences and work practices[2]. Other healthcare workers, such as nurses and administrative staff, face the same problem. Piling on new responsibilities related to the EHDS on workers (such as requiring medical staff to ensure data is properly updated) without adequate training and additional resources would further entrench the crisis of burn-out caused by understaffing in the health and care sectors[3]. The involvement of trade unions in the implementation of EHDS is therefore vital to protect the wellbeing of workers.

Secondly, as highlighted by a report by the European Parliament's research service, participation and "buy-in" of healthcare workers is crucial to the success of the EHDS[4]. It is therefore in the Commission and member states' interest to involve workers in the implementation of the EHDS.

EPSU amendment 6[5] tasks national digital health authorities with cooperating with social partners in the health and care sectors regarding

1 https://ec.europa.eu/commission/presscorner/detail/en/ip_23_290

2 https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-065.FINAL.CPME.position.EHDS.pdf

3 https://www.socialeurope.eu/health-and-social-care-staff-shortages-critical

4 https://www.europarl.europa.eu/RegData/etudes/STUD/2022/740054/IPOL_STU(2022)740054_EN.pdf

5 Page 4 of amendments doc

issues such as training and task organisation in the workplace in the implementation of the EHDS. Digital health authorities are the bodies charged with executing the provisions of the EHDS relating to the primary uses of health data and thus its interactions with frontline health and care workers. This makes it essential that an explicit obligation to cooperate with social partners be included in their modus operandi.

The rapporteurs' report strengthens the involvement of stakeholders within the governance of the EHDS. However, it does not explicitly list social partners as important stakeholders. EPSU's amendment to the rapporteurs' 60th, 98th and 142nd amendments[6] unequivocally includes social partners as key stakeholders to be consulted by digital health authorities, health data access bodies and the European Health Data Space Board. In the rapporteurs' original amendment 142, regarding the composition of the European Health Data Space Board (which is tasked with governing the EHDS at a European level), the Board is composed of, among other members, one member and one substitute representing healthcare professionals and one member and one substitute representing the health industry. These members are to be appointed by the Commission after having consulted the parliament. This is not social dialogue as, firstly, healthcare employers are absent and, secondly, the representatives are chosen by the Commission, infringing on the autonomy of the participants who are key to social dialogue. EPSU therefore proposes that these members are replaced by a pair of representatives appointed by the recognised European social partners in the hospital and healthcare sector.

2. Public ownership and governance

EPSU and its affiliates have been warning about the creeping privatisation and marketisation of health and care for many years, as well as the Commission's bias towards and encouragement of "market-based solutions" in these sectors[7]. This is in direct violation of the concepts of

6 Ibid, page 7, 9 and 11

7 See https://www.epsu.org/article/creeping-privatisation-health-care-european-union and https://www.epsu.org/article/fighting-and-challenging-privatisation-and-marke-

health as a public, common good; the right to access healthcare regardless of economic circumstances; and the Commission's competences as defined by the Treaties. The EHDS must represent a clean break from these tendencies, ensuring that health data is employed solely to improve healthcare services for citizens; alleviate workloads for health and care workers; and advance public-interest health research. It should not be an excuse to further commercialisation of the healthcare sector nor provide a publicly funded subsidy for private companies.

There are three aspects that EPSU addresses in this area with its proposed amendments: the governance of the EHDS, the principal of public interest, and preventing health data from being used for healthcare privatisation.

2.1 Governance

There are several aspects of the proposed governance of the EHDS that are problematic. The first, as explained by the European Data Protection Board (EDPB) and European Data Protection Supervisor (EDPS)[8], is the potential for fraud regarding the transmission of primary health data as envisaged by the Commission's proposal as there are limited safeguards through which vulnerable people's data rights can be protected and the integrity and legitimacy of actor's receiving health data ascertained. EPSU's amendment 2[9] stipulates that only public bodies will be allowed to enable patients to transmit their health data and authorise another natural person to act as health data proxies. This will prevent an out-sourcing of these vital functions to private companies motivated by profit rather than fundamental rights.

Amendment 2 only allows recognised legal guardians to act as data proxies, following the EDBP/EDBS' recommendation. EPSU's amendment 3[10] addresses the problem of authenticating whether receivers

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8 https://edps.europa.eu/system/files/2022-07/22-07-12_edpb_edps_joint-opinion_europeanhealthdataspace_en_.pdf

9 Amendment doc p. 1

10 Ibid, p.2

of health data are legitimate actors in the health and care sector by tasking the Commission with developing a cross-border identification mechanism.

Another EDBP/EDBS recommendation is implemented through EPSU's modification of the rapporteurs' amendment 97[11]. The new amendment charges member states with ensuring that health data access bodies (which are entrusted with regulating access to health data for secondary uses) are specifically provided with sufficient legal expertise, along with other necessary human, technical and financial resources. This is vital as these bodies will be evaluating the compatibility of data access requests with legislation such as GDPR and other data protection regulations, both national and European. Given that large companies with extensive and well-resourced legal departments will making data access requests, the ability of health data access bodies to effectively engage in legal disputes will be key to avoid regulatory capture of these bodies.

Finally, EPSU believes that the rapporteurs' amendment 32[12] should not be included in the final regulation as it waters down the definition of a ''serious incident'' in relation to electronic health record (EHR) systems in comparison to the Commission's original wording.

2.2. Public interest

Patients' and research stakeholders such as the European Patients' Forum (EPF)[13] and EURODIS – Rare Diseases Europe[14] highlighted the key issue of public interest. EURODIS noted that, as most health data is collected by public healthcare bodies, it is important that there is a public return on a public investment, especially if the health data is used to develop products that are then in turn sold to the public healthcare system. EPF stated very clearly that patients are generally happy to

11 Ibid, p.9

12 Ibid, p.6

13 https://www.eu-patient.eu/globalassets/news/20220720-ehds-call-for-feedback---final.pdf

14 https://download2.eurordis.org/EHDS_european_health_data_space_2022.pdf

share their personal health data for well-defined and societally useful research but are more wary of trusting nebulous and undefined ''innovation'', especially when private profit is involved. Furthermore, European Digital Rights (EDRi)[15] raised concerns regarding the too broad access to health data envisaged by the proposal, which may allow actors to access health data for purposes unrelated to the health and care fields.

To address these issues, EPSU's amendment 10[16] aims to ensure that the profits generated from secondary uses of health data are reinvested in public health systems, ensuring a public return to a public investment. Moreover, EPSU's modification of the rapporteurs' amendment 119[17] obligates entities making health data access requests to prove that the intended use of these data is genuinely connected to the health or care sectors.

Finally, EPSU believes that the rapporteurs amendments 86[18] and 113[19] should be excluded. The first unjustifiably removes the ability of public bodies to use health data in the area of occupational health, which could have serious impacts into research, policymaking and other activities regarding important issues such as long Covid as an occupational disease or asbestos exposure. The second removes the obligation for health data access bodies to reduce access fees proportionately to public bodies and research institutions' budget and instead provides for a system of deductions from fees based on an ill-defined ''importance of the research to society''. This amendment unjustifiably restricts the ability of organisations and bodies with fewer resources to access health data for secondary use and could lead to large private companies receiving de facto public subsidies.

15 https://edri.org/wp-content/uploads/2023/03/EHDS-EDRi-position-final.pdf

16 Amendment doc, p.5

17 Ibid, p.10

18 Ibid, p.6

19 Ibid, p.7

2.3. Preventing use of data for privatisation of health

The EHDS must not be a vehicle for further privatisation and marketisation of European health systems. To this end, EPSU's amendments 1[20] and 9[21] prevent health data from being used to calculate reimbursement or costs relating to healthcare. The EHDS should be a tool to improve patients' control over their health data, facilitate healthcare workers in providing high quality care and support public-interest research in health. This would align it with the value of healthcare as a social right and public service, as provided for by Article 35 of the Charter of Fundamental Rights. It should therefore be completely out of the scope of the EHDS to allow for health data to be used for reimbursement services, which are a key component of the marketisation of healthcare.

Finally, EPSU amendment 5[22] would remove Article 8 of the regulation which aims to regulate telemedicine services. This article has been criticised by stakeholders such as CPME for being unworkable due to outstanding issues such as medical liability and represents a creeping marketisation of healthcare provision.

3. Protection of data rights

Groups such as the European Consumer Organisation (BEUC)[23] and the EDPB/EDPS have raised concerns regarding the protection of personal data rights. Following the EDPB/EDPS recommendations EPSU amendments 4[24] and 8[25] deprive the Commission of the ability to unilaterally change the list of priority health data that must be made available for primary and secondary use, as this decision must be taken with greater levels of scrutiny and consultation.

20 Ibid, p.1

21 Ibid, p.5

22 Ibid, p.3

23 https://www.beuc.eu/sites/default/files/publications/BEUC-X-2022-104_Position_paper_on_the_proposed_European_Health_Data_Space.pdf

24 Amendments doc, p.3

25 Ibid, p.4

Furthermore, EPSU amendment 7[26] removes data generated from wellness or other digital health applications and data relating to wellness and behaviour from the EHDS system. This is because data collected from these devices is not of the same quality as data recorded by medical professionals and wellness and behaviour data can be so granular as to risk deanonymisation. As research organisations such as the European Organisation for Research and Treatment of Cancer have noted[27], the EHDS needs to have a clear ethical and methodological framework in order to protect citizens' fundamental rights. This is because there may be uses of data that are legal but not ethical. Therefore, EPSU amendments 11[28] and 12[29] provide for the EHDS Board to elaborate a common code of ethical conduct for the secondary uses of health data that all users must adhere to, just as ethical standards are elaborated for other forms of research.

Finally, the modification to amendment 84 simply strengthens the right to op-out elaborated by the rapporteurs by ensuring that data holders immediately restrict access to personal health data when requested.

26 Ibid, p.4

27 https://www.dropbox.com/s/yx3nipc7tdc0af9/F2664395-EORTC_EHDS_Position_statement_JUL2021.pdf?dl=0

28 Amendments doc, p.5

29 Ibid, p.6


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