

Brussels, 4 December 2023

## Joint Letter: CPME, CED, EFN and PGEU Call to Action and Plenary Amendments for European Health Data Space

**To: Members of the European Parliament**

**CC: MEP Tomislav Sokol, MEP Annalisa Tardino, Shadow Rapporteurs**

**Subject: Exclusion of healthcare practices that qualify as micro and small enterprises from secondary data obligations, funding for healthcare professionals are crucial for a truly workable EHDS**

Dear Member of the European Parliament,

The Standing Committee of European Doctors, the Council of European Dentists, the European Federation of Nurses Associations and the Pharmaceutical Group of the European Union contact you with regards to the on-going process on the “Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space (EHDS) COM(2022) 197 final”. **We are reaching out to you ahead of the important plenary vote on this legislation, taking place on 13 December, and urge you to take our concerns into consideration.**

Healthcare professionals continue supporting the overall goal of the proposal for establishing the EHDS, and welcome the progress achieved by the European Parliament on this important text. Nevertheless, several concerns have emerged following the recent vote on the EHDS Draft Report by the ENVI and LIBE Committees.

In light of this, we call for your support and action in relation to:

- ***Bringing back wording on the exclusion of healthcare practices that qualify as micro and small enterprises<sup>1</sup> from the secondary data obligations:***

As representatives of healthcare professionals, one of the main stakeholder groups that will be directly impacted by this Regulation, we would like to express our regret regarding the exclusion of the wording on ensuring that healthcare practices that qualify as small enterprises are exempted from the secondary data obligations in the EHDS.

In light of this, we call for the re-introduction of wording on this important matter (AM 1219 or 1220), ensuring the reduction of administrative burdens for micro and small healthcare practices alike. In the current health workforce crisis, healthcare professionals must not be given additional tasks which take them away from patient care. Healthcare professionals’ precious time cannot be exhausted in preparing data for third parties including those which pursue private and commercial interest. In some instances, these additional burdens may even lead to closing of some practices and early retirement of healthcare professionals.

---

<sup>1</sup> European Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, section Annex, Article 2): ‘(...) a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million., (...) a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.’ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF#:~:text=The%20category%20of%20micro%2C%20small,not>

We therefore ask you to **please re-introduce this important wording through the following amendment:**

European Parliament Draft Report	Suggested amendment
<b>Article 41</b> <b>Duties of health data holders</b> Paragraph 1a: The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC.	<b>Article 41</b> <b>Duties of health data holders</b> Paragraph 1a: The requirement in the first subparagraph shall not apply to data holders that qualify as micro <b>and small</b> enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC.

- **Ensuring that concrete financial compensation for healthcare professionals in relation to their digitisation costs is earmarked and provided:**

We welcome the inclusion of more concrete wording in the Draft Report in relation to the importance of overall funding for the EHDS implementation, as well as regarding training of healthcare professionals but costs of digitalisation should not be passed on to them. Member States should foresee specific budget lines for direct financial support to healthcare professionals in order for them to adapt to the EHDS requirements.

We therefore ask you to **please address this through the following amendment:**

European Parliament Draft Report	Suggested amendment
Article 4, Access by health professionals to personal electronic health data  Paragraph 3a: Member States shall establish policies aimed at providing health professionals with the digital skills, competences, infrastructures and tools required to fulfil the obligations set out in paragraph 1 of this Article.	Article 4, Access by health professionals to personal electronic health data  Paragraph 3a: Member States shall establish policies aimed at providing health professionals with the digital skills, competences, infrastructures and tools <b>and the necessary financial compensation</b> required to fulfil the obligations set out in paragraph 1 of this Article.

In case of further questions, please do not hesitate to contact us. We remain committed partners in working towards a proportionate, workable and feasible European Health Data Space.

Yours sincerely,

*The **Standing Committee of European Doctors (CPME)** is a European not-for profit association representing 37 national medical associations across Europe, giving voice to over 1.7 million doctors.*

*The **Council of European Dentists (CED)** is a European not-for-profit association representing over 340,000 dentists across Europe through 33 national dental associations in 31 European countries.*

*The **European Federation of Nurses Associations (EFN)** is the independent voice of the nursing profession. EFN represents over 36 National Nurses Associations. Its work has an effect on the daily work of 3 million nurses throughout the European Union and 6 million in Europe.*

*The **Pharmaceutical Group of the European Union (PGEU)** is the association representing 400,000 community pharmacists in 32 European countries.*