EUREGHA POSITION STATEMENT ON EHDS

EUREGHA - The European Regional and Local Health Authorities network strongly supports the European Commission's initiative to establish a EUROPEAN Health Data Space, aimed at tapping into the potential short and long-term advantages of health data. EUREGHA believes that embarking in such a Europe-wide effort in this field would be ultimately beneficial for the effective use and exchange of data within and across Europe, as well as achieving tangible improvements of outcomes for patients, improve research and innovation in healthcare, and boost health systems efficiency and sustainability. As the COVID-19 pandemic reminded us, European health collaboration towards a European Health Union and the necessity of digital transformation of healthcare systems as one of its pillars are critical nodes to address current and future health challenges.

Looking specifically at regional and local health authorities, we can clearly highlight both their significant role in the EHDS implementation, and the impact that the initiative can have on their activities. Regional and Local Health Authorities are already driving digital and health data transformation in many countries. By investing and engaging in innovative health data solutions and projects, collaborating with other regions across borders, and playing a central role in engaging with their community to address healthcare professionals and health facilities' needs, they understand and address needs such as digital health literacy and availability of digital means across the population. Equally, a well-established, resourced EHDS can greatly support regional and local health authorities in organising their services better, also in view of pandemic preparedness and crisis response, increasing knowledge on how to engage their communities and providing more tailored care to their population, while setting up better collaboration with healthcare professionals and their whole ecosystem.

While EUREGHA supports the EHDS proposal, with this brief paper we wish to highlight a number of significant issues that should be taken into serious account by EU institutions and Member States during the next stages of the EHDS building process. They include: **the importance of recognising the role of regional and local health authorities in the EHDS implementation and community engagement; boosting interoperability and legislative harmonisation; data access, control and quality; cost assessment and resources allocation**.

Furthermore, as a general input, EUREGHA encourages further definitions and clarification of key terms used in the current proposal. There is a real risk of adding complexity, obstacles, and delays throughout the EHDS implementation phase if too many issues are left unresolved and depend on subsequent actions, such as delegated and implementing acts.

It is also noteworthy to mention EUREGHA supports most of the provisions included in the European Committee of the Regions (CoR) opinion on the EHDS, approved on 8 February 2023. EUREGHA will further work with the CoR, in particular through its role as secretariat of the CoR Interregional Group

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on Health and Wellbeing, to further promote a stronger positioning of Regions and Local Authorities on this crucial initiative.

This EUREGHA Position Statement is not per se reflective of each individual EUREGHA network's region position and take.

The statement is followed by specific amendments.

TRUE MULTI-LEVEL GOVERNANCE RECOGNISING THE ROLE OF REGIONAL AND LOCAL HEALTH AUTHORITIES

EUREGHA firmly advocates for a more explicit recognition of the role of regional and local authorities in the Regulation.

Indeed, in the context of the EHDS' implementation, regional and local authorities play a key role, which usually reflects the organisational structure of the country concerned. In the European Union, **19 out of 27 Member States have a decentralised health system**, which means that regions are the actors with the most practical role in the organisation and delivery of health and social care services, as well as the main link with citizens and then local communities, thus a key driver of trust in the population. However, in the proposed text and in the current institutional discussion, there is no direct recognition nor clear mention of the role of Regional and Local Health Authorities. This raises concerns about the consideration given to them in the implementation of the EHDS, with potential impact on the recognition in the allocation of resources, the acknowledgement and consideration of already existing initiatives run at regional and local level, and the importance granted to listening to their voices regarding the future development of the initiative.

On this last point, and since multi-level governance is fundamental to ensure the success of the Initiative, the Regulation should ensure that **the EHDS Board, to be enhanced in general with stronger stakeholder representation, will also actively engage with regions and local authorities' representatives, through both the European Committee of the Regions and networks such as EUREGHA**.

INTEROPERABILITY AND HARMONISATION ARE KEY FOR THE SUCCESS OF THE EHDS

The EHDS success will heavily rely on successfully tackling **technical interoperability issues, defining clear common standards, improving harmonisation of existing (GDPR) and with other key EU legislative frameworks (AI Act, Data Act, Data Governance Act)**.

Additionally, differences in capabilities and resources must be carefully evaluated both within and between Member States, as they hinder interoperability and limit equal access to digital health

services. Border regions should be given special attention: the EHDS may have a large positive impact on **cross-border healthcare** by expanding on programs like MyHealth@EU to facilitate people movements and improving data sharing for secondary use, particularly for policy making and health system organization.

Build interoperability on existing structures and initiatives

EUREGHA believes that EHDS complementarity with existing national data infrastructure, services, tools and platforms will be crucial. These should be linked to the EHDS implementation, since they are already embedded in the health system organization, trusted by the public and to ensure proper use of existing investments and resources. It is equally necessary to ensure that the design and implementation of the EHDS will take into consideration already existing best practices and projects at regional and local level. In 2023, **EUREGHA will work with its network members to prepare a booklet of existing best practices in the field of health data**, which can be used as an important point of reference for the EHDS implementation going forward.

In this respect, regional and local authorities must be assisted and supported to guarantee adequate economic - including through dedicated EU funding – and human resources to maintain, and where feasible, possible and desired, scale up their practices and share them with other regions across Europe for mutual learning.

Clear data standards adoption and legislative harmonisation

A crucial step in the EHDS implementation is the **definition and adoption of clear data standards, enabling exchange of data based on common criteria, facilitating data exchange within and across borders, and supporting the creation of high-quality datasets**. Data standards can also have a positive impact on tackling language barriers, facilitating translation processes.

Legislative harmonisation - avoiding ambiguous legislative texts potentially leading to unequal interpretation across Europe - is equally key but, currently, it is not yet achieved. This constitutes an important obstacle for health data use within and across countries, which should be addressed by the EHDS. A concrete example is the well-known diverse implementation and interpretation of the GDPR across Europe, also linked to different approaches and maturity levels on health data. This constitutes an obstacle as we are building a European-wide initiative that promises to break barriers in data sharing while ensuring data protection. Too diverging approaches can hamper health data progress and cooperation, and slow down its use for research, innovation and policymaking. Without harmonisation, it is difficult to achieve 'legal interoperability' within and between Member States.

Finally, harmonisation will have to be considered not only concerning the application of the GDPR, but also in light of new regulatory frameworks such as the Data Governance Act, Data Act, or the AI

Act. This is important to avoid building an EHDS potentially clashing with provisions applicable to health data and coming from other essential pieces of EU legislation, thus creating risk for confusion and unnecessary complexity.

THE EHDS BETWEEN DATA PROTECTION, ACCESS, AND CONTROL

EUREGHA recognises the importance of the EU's leading role in strengthening data security and protection. Given the extremely delicate nature of health data, the EHDS should thus be built on privacy and security by design, an essential step to ensure trust.

Crucial elements of discussion are **individuals' access and control of their data, and consent options and procedures**. It is important to find a correct equilibrium between protecting citizens' privacy on one hand, as well as giving them the adequate tools that will allow them to participate in their care and providing quality healthcare on the other hand, thus enabling the attainment of the ambitious EHDS objectives. Finding and deploying appropriate solutions to achieve this, such as opt-out mechanism applied where advisable, should be prioritised. In particular, when it comes to secondary use of data, individuals should be also given the right to select which type of secondary use, and thus which stakeholders would have access to their full or partial data, they would accept, instead of a simple generalised consent impacting all possible secondary uses.

The EHDS should be designed to ensure that regional and local health authorities will have the possibility to properly use sufficient and high-quality data to improve health systems and policies, also in view of preparedness and response to potential future crises.

Data quality and data types

Ensuring data quality will be paramount for the success of the EHDS. It will be important to ensure adequate attention **concerning efficient data quality checks to limit the negative impact of potentially faulty or incorrectly amended data usage**. Once again, ensuring data quality will be crucial also given the growing importance of Artificial Intelligence (AI) applications in healthcare.

As reported in the Regulation, the EHDS will promote better exchange and access to different types of electronic health data, including electronic health records, genomics data, patient registries, and some types of data are identified as a priority to be integrated into the EHDS in a staged process with a transition period. In addition, it would be important to add further clarity on the kinds of data that authorities will be able to use and combine and also how the medical record will be converted to structured data ensuring data quality.

As concerns data, it is equally important to highlight that in some Member states social and health data are recorded together, while in others there is a clear distinction between the two of them and in terms of the authorities that oversee their execution. Highlighting the fact that **the exclusion of social services from the European Health Data Space could negatively affect the continuum of**

care, it should be clarified whether and how this data will be covered in the Regulation implementation.

COST ASSESSMENT AND ADEQUATE RESOURCES ALLOCATION

Regional and local health authorities will often play a central role in the implementation of the EHDS. The digital transformation of health and care is, however, costly and the EHDS implementation must be sufficiently supported with adequate resources.

At the same time, regions, within and across countries, do not all have the same level of socio-economic development nor the same starting point in terms of health data and. Thus, to correctly assess the resource needs and consequently allocate them correctly across Europe, it will be necessary to **carefully assess the existing digital and health data preparedness**. Such assessment would be a great help in minimising differences in the quality and access to healthcare, and it should be done both at the beginning of the EHDS implementation and on an ongoing basis to assess situation changes.

Furthermore, EUREGHA believes that the costs estimate included in the original EHDS proposal does not consider that **regional and local administrations will have to bear not only direct expenses, such as high-level infrastructure and facilities digitalisation but also the indirect ones**, contributing to the creation of the ecosystem within which the EDHS will operate. For example, the EHDS's success will also heavily rely on strong investments in the skilling and upskilling of the health workforce, which requires important long-term investments, and even hiring potential new professionals specialised in health data management, analysis and use. Another example of potential direct expenses for the EHDS implementation can be represented by the translation of electronic health records. In case this should fall, even partially, on regional and local health authorities, the costs generated by these efforts must be taken into consideration.

For these reasons, EUREGHA strongly believes that h**igher funding and resources from the European Union, as well as synergies with already existing funds and projects – both European and at the national level -, are essentially needed** to ensure proper implementation of the EHDS and to ensure the best regional and local implementation to increase equal access to the potential benefit of the EHDS for all Europeans.

REGIONS DRIVING PEOPLE AND COMMUNITY INVOLVEMENT FOR A SUCCESSFUL EHDS IMPLEMENTATION

The role of regional and local health authorities in driving the success of the EHDS will not only be limited to 'technical implementation', but equally to the 'social implementation' of the EHDS. Indeed, engagement with individuals through regions and local authorities is of vital importance to better understand, for example, the needs and concerns of individuals and the health workforce,

levels of skills, digital health literacy and access to digital health. Regions and local authorities can be considered a true bridge between their population and the EU, in particular for initiatives of great direct impact such as the EHDS.

Improve individuals' digital health literacy and health workforce's skills

On one hand, the proposal allows patients to be more in control of their data, and on the other hand it inevitably risks increasing their responsibility. Due to the existing level of digital health literacy or even general digital access, people might find this troubling, and this needs to be addressed properly: the **Regulation should ensure that vulnerable groups or groups with less digital preparedness are not neglected**. To ensure proper implementation of the EHDS, it is necessary to look toward a common European vision on digital health literacy, including through a harmonised strategic direction to be then implemented, with adequate resources, at the national, regional and local levels.

A similar approach should be adopted for the health workforce. Upskilling and reskilling the health workforce, identifying and training new professional figures is thus crucial. In doing so, however, it is necessary to consider the important existing challenges faced by the workforce, such as workforce shortages and the need to preserve the workforce's mental health. Regions and local health authorities are already playing an important role in the skills field, both individually and through cooperation across borders, including through initiatives such as Interreg projects. EUREGHA is also active on this issue via its participation in the project BeWell - Blueprint alliance for a future health workforce strategy on digital and green skills. Among the key objectives of BeWell, there is the definition of a Skills Strategy, which can drive and harmonise future actions in the field, and the management of the European Commission Pact for Skills Large-Scale Skills Partnership for Health.

Building trust through transparency and demonstrating the EHDS benefits

Building trust will be key to the success of the EHDS. To achieve this goal, **the EHDS should provide individuals with tools to consult their own health data and participate in their care**. This includes opening up the discussion on finding a correct equilibrium that will guarantee the privacy of citizens while also ensuring an effective implementation of the EHDS and exploitation of the benefits it could bring. In granting control, including regarding the possibility to retrieve information on how their data is being used and accessed, it will be also necessary to consider potential related risks, and thus protections, for healthcare professionals.

Furthermore, to better encourage and inform individuals about sharing and use of their data, in particular for secondary purposes, it will be important to **invest in showcasing the great impact that the use of their data can have on research, innovation and policy-making**. Such transparent

demonstration of 'return on investment for data sharing', can lead to increased levels of trust and engagement. Regional and local health authorities can play an important role in this increased level of engagement with individuals by providing information and explaining the benefits of health data, especially if supported with adequate resources to engage in specific initiatives and projects.

COLLABORATION WITH NEIGHBOURING THIRD COUNTRIES AND REGIONS

EUREGHA highlights the importance for regional and local health authorities outside of the EU to engage with the EHDS. It is for instance essential to ensure that research and data exchange between neighbouring regions will not be negatively affected by the implementation of the EHDS. It is thus important to keep in mind the need to avoid interruption of already existing collaborations with EU neighbouring regions through a clear and precise process facilitating partnership while guaranteeing adherence to the EU rules.