CoR INTERREGIONAL GROUP ON HEALTH & WELL-BEING

"Discussing the proposal on establishing a European Health Data Space"

Thursday, 16 March 2023 13:30 – 14:30

Online meeting

Minutes

13:30 Welcome and introduction by the Chair, Birgitta Sacrédeus

The Chair of the Interregional Group, **Birgitta Sacrédeus**, welcomed all the participants and explained that the meeting was organised to talk about the implementation of the EHDS as one of the main opportunities at EU level, and exchange opinions between the European institutions and stakeholders on tracing a path towards a European Health and Data Space. The event was structured around two speeches from Anna Prokůpková, Advisor on Health and Environment Policy at the European Parliament (GREENS/EFA), and Sirle Mere, Member of the Secretariat-General of the European Committee of the Regions, NAT— Commission for Natural Resources.

13:35 "Towards the European Health and Data Space: insights from the European Parliament" by Anna Prokůpková

Anna Prokůpková started her speech by welcoming the Commission's proposal. She informs the audience that the deadline for the amendments at the Parliament will be Thursday, 23rd of March, and the negotiations should start in April. Then, she presents the main points and concerns from the GREENS. First of all, in their opinion, there is not enough emphasis on digital health literacy for both patients and healthcare professionals, as well as not enough focus on how to support vulnerable populations (the proposal needs more safeguards on this). In her opinion, there is the need to consider a careful impact assessment and review after five years of the entry into force of this text is needed, but also to carry out a conformity assessment or, at least, to have ex-ante checks on economic operators when it comes to Electronic Health Record (EHR) systems. Concerning interoperability, they also want to see more safeguards on this point, as well as more clarifications on some terms and concepts linking to GDPR, genetic data, etc. The engagement of stakeholders has been a crucial point for the party: they made amendments on all levels. Despite this, engaged stakeholders should only be the ones free from financial interest related to the proposal. There also is the need to strengthen the system of penalties and the possibility for users to launch a complaint procedure.

Concerning primary use, in her opinion, some clarifications on data are needed, and she agrees with CoR position on the fact that Member States should have the further possibility to regulate what data consumers can add to avoid the oversharing of information, which should not be used for secondary purposes. The GREENS agree with the possibility of having exceptions on keeping records of who accessed personal data when it could threaten healthcare professionals, but more details on this regard are still needed. Again on secondary use, as GREENS, they are in favour of opt-in systems: this is not one-size fits-all sharing of data, it needs to be stratified as the reality it represents.

Ms Prokůpková affirms that the GREENS do not agree with how the original proposal foresees delegated acts on things that should be clearly stated in the Regulation itself. For this reason, they would eliminate these delegated acts or co-legislations.

The GREENS welcome the provision of the Commission, according to which the results of the EHDS should follow the open science principle, as well as Council's intention to eliminate telemedicine from the proposal.

13:45 "CoR Opinion on the European Health Data Space: an overview" by Sirle Mere

Sirle Mere presented the European Committee of the Regions' Opinion on the proposal. According to the CoR, the initiative will create new opportunities for primary and secondary use of data, especially considering cross-border healthcare and innovation of medicine. Despite this, it can be improved: the major problem is the lack of recognition for regional and local implementation of the initiative. A multi-level governance approach is key for the EHDS to reach sustainability, interoperability and security of health data. The CoR calls on the Commission to clarify the role, the composition and the powers of the EHDS Board, and affirms the will to be represented in it. The clarification of several definitions is also needed.

Since digitalisation increases cybersecurity risks, everyone must apply the highest protection data security standards: citizens must be sure that their data will be collected, processed, stored with careful and protected security systems. Concerning digital literacy, the level of literacy is still too heterogeneous between and within Member States. Increased control over health data should not be neglecting vulnerable groups (in particular elderly and disables, both between patients and professionals).

Ms Mere highlights the concern that the EHDS implementation relies on knowledge and skills, on which regions are experiencing a lack of experience. In this sense, providing sufficient human resources and infrastructure to store and access data, also at regional and local levels, would be vital.

Quality of data is a cornerstone of the proposal: data need to be reliable, consistent, fit for the purpose and measurable. In its policy recommendations, the CoR suggests how to ensure that.

Regarding costs assessment, the CoR sustains that costs estimates in the proposal are modest and naive, they do not identify all the direct and indirect costs that are going to fall on regional and local authorities: they need more clear and more supportive funding. The Commission is called to make clear how to sustain the need for additional infrastructure or data storage in Member States. Lastly, the CoR agrees with the GREENS on the fact that too many details have been left to be regulated and implemented by delegated acts in the later stage of the implementation and, at this point, it is not clear what the implementation of the regulation will mean in practice.

13:55 Open debate with stakeholders

From the debate, we had the opportunity to listen to the perspectives of public health organisations, regional and local health authorities' representatives, social and health insurers from across the EU, organisations of patients' representatives.

The European Public Health Alliance (EPHA) raised a question about intellectual property rights, since some MEPs believe the legislation is going to roll back on that. Despite this, EHDS is a tool for sharing data and should be carried out by fitting already existing legislation. There are some IP packages to review but we should not make rules for it.

EUREGHA puts the need for more consideration for regional and local authorities under the spotlight. In a practical level, in fact, it is not the EU creating digital health literacy, for example, but regions. The role of these actors should be better acknowledged in the text, since two-thirds of Member States have decentralized healthcare systems. Concerning funding allocation, it is going to be a tricky point: budget is already pre-allocated from the proposal and from different programmes, and the Commission considers the funding is already enough.

From the European Social Insurance Platform (ESIP), the intervention concerns the public return of investment when public data are used for research in the context of secondary use. It is a major concern that it is not included in the final text, and it could cause society to pay twice (when they share the data and when they have to pay for the final product to reach patients). It can be difficult for double standards to include legal provisions on this, but the best way to do it could be through the fees chapter, although politically and practically is difficult because there is no real alignment between different visions. About clinical data from 3rd countries, there is no clarity for the moment, but it has been stressed that the procedure must be careful, since outside the EU there is no GDPR implementation.

From the European Cancer Organisation (ECO) emerges the importance of including stakeholders' representatives in the Board, as well as the requirement to the Commission to conduct a study on GDPR impact on cancer research. They also explain their position on opt-out as the most pragmatic approach for the respect of individual rights and doubts about how to raise digital health literacy among the population.

14:30 End of the meeting