

## **The Medical Scientific Societies warn about the brake on Biomedical Research and the progress of medical science posed by the current draft of the Regulation on the European Health Data Space**

Healthcare systems hold data that have been provided by citizens to obtain health care. These data, with the necessary guarantees of confidentiality, security, and respect for people's rights, can be used to continue advancing the understanding of diseases and thus contribute to improving the health of future patients and subsequent generations, in what we call the secondary use of health data for scientific research purposes. The correct use of the data is one of the most valuable tools for the progress and the benefit of the citizens in health.

The new regulation on the European Health Data Space (EHDS) aims to ensure a legal framework consisting of trusted EU and Member State governance mechanisms and a secure processing environment that will allow researchers, innovators, policy-makers and regulators at EU and Member State level to access relevant electronic health data to promote better diagnosis, treatment and well-being of natural persons, and lead to better and well-informed policies. It is noteworthy that the regulation stipulates that each secondary use of data must be expressly approved by a competent body at the national level (Health Data Access body).

However, recently, the European Parliament and the Council of the EU have proposed amendments that change somewhat the system of responsibilities, to put the focus more on the consent of patients rather than on the proper functioning of the system that oversees that access is provided with guarantees of respect for the rights of the subjects. We believe that the current proposals, especially those referring to the need for explicit consent for the use of certain data<sup>1</sup>, fail to improve safeguards

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<sup>1</sup> *Amendment 312, Article 33 – paragraph 5 a (new)*

***Electronic health data referred to under paragraph 1, points (e)\*, (fa)\*\* and (m)\*\*\*, shall only be made available for secondary use after obtaining the consent of the natural person. Such an opt-in mechanism shall be easily understandable and accessible and provided in a user-friendly format whereby data subjects are made aware of the sensitive nature of the data.***

***\* (e) human genetic, genomic and proteomic data;***

***\*\* (fa) data from wellness applications;***

***\*\*\*(m) electronic health data from biobanks and dedicated databases***

on the use of health data for research purposes. On the contrary, they place an undue burden of documents and consents on patients who are often in a vulnerable situation and a burden on doctors already overwhelmed by bureaucratic tasks that limit the real medical and human time they dedicate to their patients. Proposals for the explicit consent of each subject for the use of their data (so-called *opt-in*) imply an unjustified use of resources and increase in costs, as well as a substantial bias and loss of quality of data to be used for research purposes. This will ultimately lead to a slowdown in obtaining relevant improvements in disease prevention, diagnosis and treatment of patients and also in the role of the EU in global biomedical research.

Therefore, the medical scientific societies, concerned with adequately protecting the advancement of science for the benefit of society, without undermining the protection of individual rights of persons, propose:

- Carefully review the rationale for incorporating individual consent mechanisms, that were not foreseen in the Commission's initial proposal, for the use of data for research purposes. Requesting individual consent for future use, which will be necessarily vaguely defined, is not the best solution to protect the rights of individuals and instead poses an obstacle to research. In order to preserve data protection rights, we propose to work more on the system of guarantees (i.e. pseudonymization, anonymization,..) than on procedures based on consent. If the regulation finally retains the option of consent for secondary scientific use, at least this should be done using the *opt-out* approach (presumed consent with the option to withdraw it) and never using the *opt-in* approach (express consent).
- Eliminate special treatment for human genetic, genomic and proteomic data, data from biobanks and dedicated databases and data from wellness applications for research purposes and eliminate the requirement of express consent for their secondary use. An array of genetic and proteomic data are already part of patient's medical records (e.g. tumour markers, disease-related mutations,...) and their separation from the rest of laboratory data is a burden that would make research unfeasible or, in any case, an unjustified burden that would seriously harm the advance of research in cancer, rare diseases and

many other diseases. Genomic and proteomic data, even in the case of whole exome or genome data, are health data that can be handled securely in a pseudonymized form. They should be subject to the same guarantees that the regulation already provides for all personal health data. The same applies to data from specific registers or databases or obtained through wellness applications.

- Facilitate cross-border research collaboration. International health research activities include data within and outside of EU borders and EHDS must take this into account to make sure that the EU is not left out of global research.
- Promote as soon as possible information and education activities to the public about the importance of health data sharing for research purposes and the safeguards that are put in place to protect their rights. There must be public confidence in the system that will ensure the correct use of health data and eliminate any ill-founded fear about the secondary use of data for research purposes. To this end, information and transparency on approved uses are key, as well as the involvement of stakeholders, including citizens and scientific societies, in the governance of the system that will oversee access to health data for medical research purposes.