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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 **(first reading)** - Adoption of the legislative act - Statements

Statement by Austria, France and Malta

Austria, France and Malta support the text submitted to the Council for adoption, which offers major advances for patients, healthcare professionals, industry and researchers. It represents a first step towards developing an ambitious European Health Data Space, and its implementation will need to be regularly evaluated.

In particular, Austria, France and Malta welcome the possibility for Member States to require health data for primary use to be located within the European Union (Article 86), as well as the introduction in Article 87 of the obligation for Health Data Access Bodies (HDABs) to host and process data for secondary use within the EU, to ensure greater protection for European citizens' health data.

Austria, France and Malta emphasise that the possibility of derogating from this principle, as provided for in Article 87(2), must not deny Member States the possibility of adhering to the principle laid down in paragraph 1.

The health data processed under the Regulation concern the most personal aspects of people's lives and therefore require greater protection, a prerequisite for building citizens' trust in the European Health Data Space and thus for enabling the Regulation to achieve its objective of improving people's health by boosting secondary uses of data, in particular for research purposes.

Moreover, given the very large volume of data processed by data access bodies (HDABs), it was essential to allow Member States to strengthen the protection and security measures surrounding their storage and processing.

Any other interpretation of Article 87 would fail to respect the two main objectives of the Regulation, namely, to ensure a high level of protection of the data concerned and to encourage the mass re-use of such data for secondary purposes.

Statement by Denmark

Denmark strongly supported the goals of the Commission's proposal. However due to the substantial changes made to the text during the trilogues we are not convinced that the regulation as presented today can deliver on the initial goals of the EHDS nor does it strike a reasonable balance between individual rights and common public interests. We also have concerns regarding the financial burden of the proposal and the possible consequences of the opt-out approach for our health systems.

Implementation of the EHDS will be complicated and involves substantial investments for the Member States. We are concerned about the economic burden EHDS places on the Member States and see a need to avoid imposing economic burdens on Member States without clear and apparent benefits for patients and health systems. It remains a priority going forward that associated delegated acts do not put further economic burden on Member States when implementing the EHDS.

Denmark regrets that it has not been possible to agree on an opt-out model with a stronger focus on ensuring Member States' ability to provide efficient and innovative health care services for patients in the future and foster research and innovation within the EU. In addition, there are concerns on how EHDS will affect the ability to safeguard and protect patients and healthcare workers.

Statement by Germany

Germany agrees to the Regulation, while referring to its statement on the Regulation on the European Health Data Space published on pages 13-15 of 16641/23 CRS CRP 42 in relation to the Council mandate of 6 December 2023. That statement still reflects Germany's understanding of the compatibility of the current German system for storing and making available electronic health data with the rules laid down in Chapter II of the Regulation. This is in the light of the rule that Member States are free to decide whether to enable emergency access if a patient objects to access to their electronic health record, and the fact that in Germany, the right to data portability between service providers is already implemented through the possibility of accessing a patient's electronic health data via the patient's electronic health record (*Patientenakte - ePA*).

Statement by Estonia

We support the general objectives of the European Health Data Space Regulation. It is a crucial step towards a more harmonised approach to facilitate secure access to health data for the benefit of patients, research and innovation and evidence-based public health policies.

We remain concerned that the obligation to Member States to provide the right to opt out from the secondary use of health data is not in line with the objectives of this Regulation and does not ensure the right balance between individual rights and common public interests. While citizens' rights and fundamental freedoms need to be protected at any time, there are important safeguards foreseen in EHDS Regulation that can be put in place to ensure that data processing is lawful, secure and in compliance with the GDPR. The introduction of a general opt-out would not contribute to greater data security but entails a risk of eroding the quality and completeness of datasets that are necessary for high quality scientific research and breakthrough innovations. This approach is at odds with the EU strategic political priorities in innovation, competitiveness, and strategic autonomy.

We believe that GDPR already sets high data protection standards in all Member States. Therefore, it is not justified to go beyond these standards in a regulation which aims to facilitate the secondary use of health data in public interests. We consider it important that Member States maintain the right to decide about introducing the opt-out right for secondary use of health data in their specific legal and cultural context. We interpret the provisions on the right to opt-out in the way that the right is limited to the implementation of the EHDS Regulation. Outside the scope of the EHDS Regulation, Member States, in accordance with GDPR (in particular articles 5, 6, 9, 23 and 89), maintain the right to regulate the processing of health data carried out in the objectives of general public interest by public authorities in the performance of their tasks, and for scientific research purposes.

We underline that opt-out provisions in this Regulation should not be considered as a precedent for any future EU legislative initiative setting up European data spaces in other sectors, considering sector specific needs, as well as different approaches to securing citizens' trust.

Statement by Greece

In principle, Greece supports the European Health Data Space (EHDS) initiative, although many provisions of the EHDS Regulation leave room for improvement.

Greece subscribes in particular to Member States' comments regarding the provision of the mandatory opt-out mechanism for the secondary use of data. We see some problematic points that would require further improvement (in particular Articles 7 and 8).

Against this backdrop, Greece looks forward to the Regulation being implemented in a manner that maximises the benefits for all Member States, including those which, like Greece, have invested considerably in interoperability and access to patients' electronic health records. Lastly, we note the high cost of implementation for the Member States, and expect the EU to assist in covering some of the costs.

Statement by Finland

Since the beginning of the negotiations, Finland has supported the objectives of the Regulation concerning better access to health data and sharing of this data. We remain convinced on their importance.

Finland understands that the final compromise text is the outcome of complex negotiations, at the end of which several changes were made to the text in order to reach an agreement. While Finland congratulates the Presidency for finding a compromise, we have serious concerns on the final text.

Finland is concerned that the final compromise text will not achieve the original objectives of the Regulation, especially concerning a competitive research environment, and may even lead to a situation where the EHDS system will not be used.

The compromise text as a whole causes considerable administrative burden and significant financial costs for the Member States, whereas the benefits remain very limited. This concerns both primary and secondary use. We risk preventing the use of already well-functioning and resourced processes and setting limitations on the use of data in the future.

Finland called for, in line with the general approach, a more flexible solution that leaves room for implementation. The financial impact of the Regulation is considerably high due to the various and extensive obligations imposed on the Member States, including those who have already invested a lot in their current system.

Finland raises in particular the difficulties in two central articles: the article on the opt-out for secondary use and the article on the right of single data holders to process data permits and data requests.

The article on the opt-out of the final compromise text is unnecessarily complicated in terms of implementation and interpretation of the opt-out option. This will lead to a burdensome and fragmented process, for example by creating uncertainty as to which actors may use the restrictions.

In the article on the right of single data holders to process data permits and data requests, the role of the health data access bodies in processing the data permits and data requests for data of trusted single data holders will impose unreasonable administrative burden and financial costs. It also makes it more difficult to adhere to the processing times specified in the Regulation. For Member States with existing and well-functioning process for processing data from single controllers, the compromise may reverse the progress in secondary use.