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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

L'Autriche, la France et Malte soutiennent le texte soumis au Conseil pour adoption, qui porte de grandes avancées pour les patients, les professionnels de santé, les industriels et les chercheurs. Il constitue une première étape dans l'élaboration d'un espace européen des données de santé ambitieux et sa mise en œuvre devra faire l'objet d'une évaluation régulière.

L'Autriche, la France et Malte saluent en particulier la possibilité pour les Etats membres d'imposer la localisation des données de santé à usage primaire au sein de l'Union européenne (article 86), ainsi que l'introduction à l'article 87 de l'obligation pour les organismes chargés de l'accès aux données à usage secondaire (HDABs) d'héberger et de traiter les données à usage secondaire au sein de l'UE, au bénéfice de la protection accrue des données de santé des citoyens européens.

L'Autriche, la France et Malte soulignent que la possibilité de dérogation à ce principe, prévue au paragraphe 2 de l'article 87, ne saurait priver les Etats membres de la possibilité de s'en tenir au principe prévu au paragraphe 1er.

En effet, les données de santé traitées dans le cadre du règlement concernent les aspects les plus personnels de la vie des personnes et exigent à ce titre une protection accrue, condition *sine qua non* pour établir la confiance des citoyens dans l'espace européen des données de santé et permettre ainsi au règlement d'atteindre son objectif d'amélioration de la santé des personnes en renforçant les utilisations secondaires des données, notamment à des fins de recherche.

En outre, en raison du volume très important de données traitées par les organismes responsables de l'accès aux données (HDABs), il était indispensable de permettre aux Etats membres de renforcer les mesures de protection et de sécurité entourant leur stockage et leur traitement.

Toute autre interprétation de l'article 87 méconnaîtrait les deux objectifs principaux du règlement, à savoir assurer un haut niveau de protection des données concernées et encourager la réutilisation massive de ces données à des fins secondaires.

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

Deutschland stimmt der Verordnung unter Verweis auf die im Ratsdokument 16641/23 CRS CRP 42, S. 13-15 veröffentlichte „Erklärung der Bundesrepublik Deutschland zur Verordnung zur Schaffung eines europäischen Raums für Gesundheitsdaten" zum Ratsmandat vom 6. Dezember 2023 zu, die das weiterhin gültige deutsche Verständnis zur Vereinbarkeit des derzeitigen deutschen Systems der Speicherung und Verfügbarmachung von elektronischen Gesundheitsdaten mit den in Kapitel II der Verordnung vorgesehen Regelungen enthält. Dabei gilt die Maßgabe, dass den Mitgliedstaaten die Entscheidung freisteht, im Falle eines Widerspruchs des Patienten gegen Zugriffe auf seine elektronische Patientenakte Notfallzugriffe zu ermöglichen und dass in Deutschland das Recht auf Datenportabilität zwischen den Leistungserbringern bereits durch den Zugang zu den elektronischen Gesundheitsdaten eines Patienten über die elektronische Patientenakte umgesetzt wird.

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

Η Ελλάδα υποστηρίζει κατ' αρχήν την πρωτοβουλία για τη θέσπιση του Ευρωπαϊκού Χώρου Δεδομένων Υγείας (European Health Data Space – EHDS), μολονότι θεωρεί ότι πολλές από τις ρυθμίσεις του κειμένου του Κανονισμού για τον Ευρωπαϊκό Χώρο Δεδομένων Υγείας θα επιδέχονταν περαιτέρω βελτίωσης.

Η Ελλάδα συμμερίζεται, ειδικότερα, τις παρατηρήσεις των Κρατών Μελών σχετικά με την παροχή του υποχρεωτικού μηχανισμού opt-out για τη δευτερογενή χρήση των δεδομένων. Εντοπίζουμε, δε, ορισμένα προβληματικά σημεία που θα έχρηζαν περαιτέρω βελτίωσης (ιδίως άρθρα 7 & 8).

Στο πλαίσιο αυτό η Ελλάδα προσβλέπει στην εφαρμογή του Κανονισμού με τρόπο που θα μεγιστοποιεί τα οφέλη για όλα τα Κράτη Μέλη, συμπεριλαμβανομένων αυτών, όπως η Ελλάδα, που έχουν επενδύσει σημαντικά στη διαλειτουργικότητα και στην πρόσβαση στον ηλεκτρονικό φάκελο ασθενούς. Τέλος, επισημαίνεται το μεγάλο κόστος υλοποίησης για τα Κράτη Μέλη και προσδοκούμε στην συνδρομή εκ μέρους της ΕΕ για την κάλυψη μέρους του κόστους.

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.