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From: Presidency
To: Permanent Representatives Committee/Council
Subject: Proposal for a Regulation on the European Health Data Space

Delegations will find attached a Presidency background note intended to serve as the basis for the exchange of views on the proposal for a Regulation on the European Health Data Space to take place on 14 June 2022 during the EPSCO Council meeting on health.

Proposal for a Regulation on the European Health Data Space

At a time when the COVID-19 pandemic is not yet over, the European Union is already having to face a new multisectoral crisis with considerable social and health impacts, namely the war in Ukraine. In this context, it is vital to prepare the future of the Health Union, combining action, prevention and ambition at European and international level.

Digital is set to become an essential pillar of this work. The COVID-19 pandemic has demonstrated the need to ensure rapid and secure access to health data in order to ensure the continuity and quality of care pathways. The health data that have been produced and shared have demonstrated their full potential for emergency decision-making, patient care and monitoring, research and innovation at national, European and international level, and the development of statistics and public policies.

The example of the COVID certificate has demonstrated the capacity of the EU and the Member States to mobilise and work together to organise an effective and rapid response to fundamental challenges such as the exceptional and justified restrictions on freedom of movement: technical choices, establishment of the regulatory framework, compliance with ethical values, etc. This has also demonstrated Europe's capacity to provide innovative solutions and to turn them into an unrivalled international standard. Interest in digital health in G7 and G20 fora is currently growing.

The Commission and the Member States agree that it is now essential to provide a legal framework for digital health initiatives, so as to give them a real European dimension and establish a secure, stable and interoperable framework for them. This is a necessary condition for building a robust Europe of Health through digitalisation. Such work has, for example, been long awaited in the fight against rare diseases, which spearheads the pooling of resources and knowledge for better patient care in the EU.

Through their enhanced cooperation in this new field, the Member States and the Commission have succeeded in ensuring compliance with shared ethical principles and increasing Europe's potential for providing healthcare services to its citizens.

The proposal for a Regulation on the European Health Data Space sets the framework for this European ambition

The draft Regulation on the European Health Data Space (EHDS) aims to unlock the full potential of health data for all individuals, patients, innovators and public decision-makers. It is part of the European Union's data strategy, which was presented in February 2020 by the European Commission and aims to create common European data spaces specific to key areas of activity, such as agriculture, energy and mobility. The EHDS is the first proposal for a common data space for a targeted area, and is one of the Commission's cross-cutting priorities in strengthening the Health Union.

The EHDS has a dual ambition. Given the heterogeneity of health systems in the EU, both in terms of funding and in terms of the organisation of care, and the lack of information sharing between Member States on patient care, patients currently cannot access a real continuum of care when they move within the European Union. The Regulation therefore aims first and foremost to allow EU citizens to access and share their health data in order to ensure the continuity of their care when they move within Europe (primary use of data). Health professionals can thus access care pathway documents in their original format, and translated into their language¹.

¹ This possibility was already provided for in the Directive on cross-border healthcare, but the scope of the text did not allow for the actual implementation of the mechanism.

The purpose of this Regulation is secondly to allow researchers, innovators and policymakers to access health data in a uniform manner at European level, within a secure framework and in compliance with all EU legislation (health, digital, protection of citizens, etc.). Access to this data is currently governed by the regulations of the Member States, and is conditional on a request being made to each national authority, in accordance with its own procedures. The development of a European ambition should make it possible to remove these obstacles to the secondary use of health data, allowing their re-use under secure and specific conditions.

This dual ambition is based in particular on the deployment of two common infrastructures, the MyHealth@EU facility for the care pathway and the HealthData@EU pilot project for the re-use of health data. Several instruments have also already been put in place by the European Commission since 2019 to pave the way for the future EHDS. This is the case with TEHDaS (Towards a European Health Data Space), a programme bringing together more than 26 EU Member States to set up a pilot for the European Health Data Space.

Building on a framework of ethical values to create the EHDS: European ethical principles for digital health

To ensure citizens' trust, digital health must be based on key pillars such as security, interoperability and ethics. The experience of many Member States shows that trust based on ethics is an indispensable prerequisite for citizens to support the development of digital health.

It was in this spirit that the Presidency proposed collectively formalising European ethical principles for digital health before the publication of the Commission's proposal for a Regulation. Adopted unanimously by the Member States, as well as Norway and Iceland within the framework of the eHealth Network, these principles centre on four dimensions directly inspired by the foundations of European culture: i) basing digital health on humanistic values, ii) enabling individuals to have access to and control over their health data, iii) ensuring that digital health is accessible to all, and iv) implementing environmentally responsible digital health. Each dimension has four principles, which are translated into concrete actions such as involving citizens in the development of the digital health strategy and tools and promoting digital sobriety.

To complement the working party negotiations on the proposal for a Regulation on the European Health Data Space, the Presidency would like to focus the exchange of views on the following questions:

- 1. The COVID-19 crisis has led to dramatic developments in digital health in most countries. In the light of the lessons you have drawn from the crisis, what benefits do you expect from the European Health Data Space?**
- 2. On what principles, work and recent progress can we base our joint efforts to develop a European space of trust for the sharing of health data for the benefit of all?**