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European Parliament Adopts EHDS and Human Origin Substances Regulation, Welcomed by Commission

The Commission welcomes the adoption by the European Parliament of the **European Health Data Space (EHDS)** and new rules to increase the safety and quality of substances of human origin (SoHO). These are two cornerstones of a strong European Health Union which protects the health of citizens and improves the resilience of healthcare systems.

The European Health Data Space (EHDS)

This groundbreaking initiative, put forward by the Commission in May 2022, has two main aims:

- to place citizens at the centre of their healthcare, granting them full control over their dat
  a, with the goal of achieving better healthcare across the EU;
- to allow the use of health data for research and public health purposes, under strict conditions.

Thanks to the new rules, citizens will benefit from immediate and simple access to their digital health data when in the EU, regardless of their location. For instance, when a patient seeks healthcare abroad, healthcare professionals will be able, when necessary, to access key information from the patient's home Member State. This will improve evidence-based decision making, reduce repetition of tests and examinations and enhance patient care.

The EHDS also establishes a strong legal framework for the re-use of health data for research, innovation and public health purposes in full compliance with strict EU data security and access criteria, fundamental rights and cybersecurity rules. The data will help develop life-saving treatments and personalised medicines and improve European crisis preparedness.

Substances of human origin
The new regulation, proposed by the Commission in July 2022, provides a holistic approach for the regulation of substances of human origin. The new rules notably include better protection of recipients and donors of substances of human origin, as well as children born from medically assisted reproduction. The new framework foresees:

- Clear rules covering all substances of human origin except solid organs, such as faecal microbiota and human breast milk;
- Registration of all entities that carry out activities that could affect the safety and quality of SoHO;
- Reinforced expertise, building on existing technical bodies, notably the European Centre for Disease Prevention and Control (ECDC) and the European Directorate for the Quality of Medicines & HealthCare (Council of Europe), to keep technical guidelines up to date;
- More innovation, with a common procedure to assess and authorise SoHO preparations, proportionate to the risks these bring;
- Strengthened national oversight, and EU support for national authorities (such as training and IT);
- New measures supporting supply continuity that will help Member States to take action when the supply of critical SoHO is threatened;
- A SoHO Coordination Board (SCB) will be established, with and for Member States. It will support the implementation of the new regulation and provide legal clarity;
- Finally, the digital EU SoHO Platform will be created, to gather all required information, streamline reporting and increase visibility to citizens.

Source & Image Credit : European Commission

Published on : Wed, 24 Apr 2024