LIBE Vote on the Data Protection Regulation: Impact on Health

The LIBE Committee vote on 21 October on the Data Protection Regulation is a crucial vote for the health sector as it is responsible for processing a significant amount of personal data.

We welcome the fact that health data has been identified as a special category in the European Commission's proposal in Articles 9 and in Article 81. However, a number of provisions in the Commission's original text and in proposed EP amendments will restrict the availability of health data, delay innovation, create legal uncertainty and increase compliance costs if they remain unchanged. We therefore urge MEPs to:

- **Clarify the way in which consent is to be treated in a health context**

We welcome the Commission's provision that in the context of health explicit consent is not required for the processing of data for health purposes according to the provisions of Article 81. However, we believe the text of Article 81 could be improved to explicitly state that where personal data concerning health is processed according to the terms and conditions of Article 81, explicit consent is not required.

Furthermore, we **oppose** the following amendments as they create legal uncertainty on the issue of consent in a health context or add unnecessary administrative burdens: **2972, 2974, 2975** and **2986.**

- **Balance the Rights to be Forgotten and to Erasure and Right to Rectification of data with the need to ensure effective healthcare provision (Articles 16 & 17)**

Implementing the right to be forgotten and to erasure and the right to rectification in the healthcare context requires careful consideration of the consequences:

- Deleting data from electronic health records may run counter to individual treatments and patient safety: for example, healthcare providers will not have access to life-saving information on the patient when establishing a diagnosis.
- Statistical analyses might be weakened, particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatrics.
- In the same way with regards rectification, it is important in a healthcare context that medical hypothesis and speculation can be retained within an individual's health record as this may prove crucial to the appropriate delivery of healthcare to the data subject at a later date.

We are concerned that whilst Article 17(3)(b) provides an exemption '*for reasons of public interest in the area of public health'*, it is not clear whether this exemption applies to healthcare provision. We ***support*** the inclusion of amendment **1431** as it would clarify that the exemption includes healthcare purposes. A similar exemption for healthcare purposes should be included in Article 16.

- **Clarify the scope of the regulation to allow a workable and effective data protection regime (Article 2)**

Anonymised and pseudonymised or key–coded data are used to conduct medical research, monitor the efficiency of treatments, monitor disease trends, support public health policies, etc. We ***support*** the inclusion of amendments **683, 687** or **696** to Article 2 (Material Scope) as this clarifies that data that has been rendered anonymous is outside the scope of this Regulation.

- **Avoid excessive administrative burden on the health sector**

A key objective of the reform is to make data controllers accountable for their processing of personal data, while avoiding excessive administrative burden. However a few provisions risk creating legal uncertainty and bureaucratic complexity:

- Article 28 requires each data controller and processor to maintain documentation of 'all processing operations'. Healthcare providers already retain detailed documentation of their processing activities, but do not maintain individual records for every individual patient or episode of care. It would be an impossible extra administrative burden to document all data processing operations in the healthcare context. We ***support*** amendment **1839** as it removes the requirement for documenting 'all' processing operations and clarifies that data controllers should define the *purpose* of their data processing.

- Article 33 requires that the processing of data concerning health is subject to a data protection impact assessment requirement. We ***support*** amendments **2018, 2022** and **2023** which clarify that a single privacy impact assessment can be used for multiple processing operations that present similar risks. We also ***support*** amendments **2051 to 2057** as they remove the requirement that data controllers must seek the views of data subjects or their representatives on the intended processing as this would create an additional burden and delay to processing of health data.

- **Facilitate life saving medical research and innovation:**

We broadly support Article 83 of the Commission's proposal and the associated provisions for scientific research. However, the Regulation sets out that data can only be processed where this is compatible with the purposes for which they were initially collected. Health research often relies on data collected previously, for example as part of an individual's health record. We therefore ***welcome*** amendments **3062, 3065** and **3069** as they clarify that further processing of data for scientific research purposes is a 'not incompatible' purpose, in line with the current Data Protection Directive.