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EFPIA Response to Article 29 Committee Guideline on Data Portability

EFPIA thanks the Article 29 Committee for initiating further consultation on the guidance developed as part of its 2016 Action Plan. We encourage the Committee to give further consideration to the expansion of stakeholder consultation as a routine part of its procedures.

The following are EFPIA comments the guideline on data portability. Overall, they highlight the need for further discussion to clarify the specific application of the data portability right in the context of research and healthcare delivery.

The context that we are describing is one concerning sensitive personal data, retained in directly-identifiable form for purpose of treatment and regulatory purposes, often indefinitely, but processed in pseudonymised form by pharmaceutical companies and others for purposes of research. The research contributes to knowledge but also provides the basis for regulatory decision-making. The ability to create combined data sets from different sources is extremely important for research, as is the ability to replicate results using the original data sets.

1. The concept of data being ported from one controller to another is relatively unexplored, in a healthcare/research context. The most obvious case is if a patient chooses to change their treating physician, though there are also increasing examples of patients wishing to hold personal health data resources. EFPIA notes that the Guideline clarifies that portability can mean transfer to another controller or retention by the individual.

2. The porting of data should not compromise the integrity of the original data set. In this sense, a "sharing" concept rather than a "transfer" better conveys how the goal of portability can be achieved in the context of research. We welcome the view that "Data portability does not automatically trigger the erasure of the data from the data controller's systems and does not affect the original retention period applying to the data which have been transmitted, according to the right to data portability."

3. Data-sharing can facilitate innovation. We note that the guideline states that "Data portability can promote the controlled sharing of personal data between organisations and thus enrich services and customer experiences . Data portability may facilitate user mediated transmission and reuse of personal data concerning them among the independent services they are interested in". We welcome the recognition of the importance of user-mediated transfer and would welcome further discussion regarding the interaction with data portability rights.

4. The Guideline states that *"Inferred data and derived data are created by the data controller on the basis of the data "provided by the data subject".*

These personal data do not fall within the scope of the right to data portability. For example, a credit score or the outcome of an assessment regarding the health of a user is a typical example of inferred data. Even though such data may be part of a profile kept by a data controller and are inferred or derived from the analysis of data provided by the data subject (through his actions for example), these data will typically not be considered as "provided by the data subject" and thus will not be within scope of this new right." On this basis, EFPIA understands that the results generated during clinical research would fall outside the scope of the obligation and would welcome this being confirmed in the final guideline.

5. The guideline confirms that pseudonymous data is within scope of the data portability obligation and provides some guidance on the responsibilities of controller and data subject where the data des not permit direct identification. EFPIA notes that Article 11 of GDPR states that "[...] *a controller shall not be obliged to maintain acquire or process additional information in order to identify the data subject for the sole purpose of complying with this Regulation*". Pharmaceutical companies are not normally in a position to identify individuals whose data they hold for research purposes. EFPIA suggests that the Guidance should make clear that where data is pseudonymised and the key enabling re-identification is held outside the company, it would practically prevent a company from complying with a portability request. EFPIA suggests that it would be more appropriate to respond to requests by directing the requestors to the original data sources (typically independent clinical researchers) where these are held in identifiable form, as this would ease the identification process.

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