DIGITALEUROPE

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DIGITALEUROPE contribution to EMA discussion paper on the Secondary Use of Data for Medicines and Public Health Purposes under the GDPR

Our comments and questions on the paper

DIGITALEUROPE represents a variety of industry actors actively involved in the development of medicines and related research.
The complementarity between data protection and innovation is an objective that a correct understanding of the GDPR principles, concepts and rules should always strive to achieve, including in medicine. We welcome to opportunity to help to determine the upcoming Q&A of the EMA on the GDPR and the Secondary Use of Data for Medicines and Public Health Purposes".
Clarifying the existing data processing regulatory framework is a key step to build a Common European Health Data Space.

General comments

- We urge the EMA to consider all sources for the secondary use of health data, besides clinical trials. Organisations derive data in scope also from clinical practice, such as from Electronic Health Records (EHRs), claims and registries (as per Figure 2 in the discussion paper). For example, researchers may wish to explore the data from patients admitted to hospitals across Europe with pneumonia symptoms in late 2019, to identify whether 2019-nCoV was present earlier than thought. This would require the secondary processing of patients' data, in a way that was not foreseen when they were first admitted to the hospital. The EMA should expand on these other data sources in its upcoming Q&A, including by providing practical and industry-specific examples.
- The application of scientific research in accordance with Article 9(2)(j) of the GDPR is especially important for the secondary use of health data. It is a clear example of how to better unlock the potential of health data in

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the EU and should be given more recognition in upcoming EMA consultation papers.

- It is very important not to mix secondary use of data and compatibility, as this paper seems to suggest. They are two different aspects of the GDPR. Organisations can use data for secondary purposes without them being compatible purposes, provided there is an appropriate legal basis.

Please find below more details on our recommendations. Our members stand ready to discuss and share our expertise and experiences.

Input and questions for the EMA on the nine key areas in the discussion paper

Secondary use of health data

There are regulatory divergences across the EU due to different applications of Article 89 of the GDPR across Member States. National governments can maintain or introduce further conditions, including limitations, on the processing of genetic or health data.

- What are for the EMA the specific activities that fall under the processing purpose of scientific research?
- Does the EMA intend to undertake initiatives to address the inconsistencies between the provisions of the GDPR and those of health-related local and national data protection regulations across the EU?

In addition, the paper highlights the GDPR states that processing of personal data for purposes other than those for which the personal data was initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. This is true to the extent that the processing applies to the compatible purpose and Recital 50. It is key to consider that processing for secondary purposes is also possible on the grounds of a different legal basis, if the purpose is not compatible with the original one. Developing Codes of Conduct would clarify some of the current challenges around access, processing, use and re-use of health data.[1]

[1] DIGITALEUROPE recommendations on health data-processing elaborate on this aspect more in detail

Establishing the legal basis for processing personal data

- DIGITALEUROPE points out how Data Protection Authorities (DPAs)'s guidance often seems to ignore that the same processing activities may fall under different legal bases simultaneously – particularly if an extremely narrow scope is assigned to each basis. The same health data from the patient may be technically necessary to deliver a service, thereby falling under the contract legal basis, but also be processed for the controller's own or mandated scientific research activities, thus being covered under the legal basis of legitimate interest.
  We are also generally concerned that consent is being emphasised as the primary legal basis for processing in several scenarios. It is neither the only nor the default legal ground. For medical research, consent can have downsides today primarily due to issues of legacy data.
- On the justifications for processing of sensitive (health) data provided in the paper, we strongly emphasise the importance to add those in Art. 9.2.(j), for which processing is necessary for archiving purposes in the public interest, scientific or historical research purposes.

Presumption of compatibility

As the paper points out, Recital 50 of the GDPR states that, where the processing is compatible, 'no legal basis separate from that which allowed the collection of the personal data is required.' Unfortunately, especially when consent is used for primary processing, there is still uncertainty on whether organisations need a legal basis for further processing. The industry needs more clarity on that.

- Can the EMA provide concrete examples of how Recital 50 is applied when the patient has given specific consent to one purpose?
- When is the compatibility of original and new purposes considered sufficient for the EMA, including when data is collected as part of routine clinical management?

On the establishment of the presumption of compatibility for research purposes, the paper refers to the EDPS recent explanation for which data should not be used to support measures or decisions regarding any particular individuals.

- How can organisations use data for clinical decision support systems that help doctors in making decisions about the health of specific individuals based on aggregated patient data?

Pseudonymisation

There are uncertainties regarding pseudonymisation and anonymisation as well as on the appropriate level of de-identification and anonymisation under given circumstances. Health policy-makers and regulators must mitigate these uncertainties as pseudonymisation and anonymisation are a fundamental safeguard enabling the secondary use of health data for scientific research purposes. We would support Member States adopting a consistent and internationally recognised approach to deidentification.

- What are the criteria by which the EMA consider information on the data subject as fully anonymised in research activities, as opposed to pseudonymised?
- What are the specific techniques that the EMA considers relevant for fully anonymising health data? What is the potential role of synthetic data?

Data Retention

The paper focuses on typical data retention approaches used for clinical trial data. It does not address sufficiently the issue of data retention of Electronic Health Records (EHRs), where there exists fragmentation in terms of requirements across Member States. Furthermore, whilst Member States have policies in place for the retention of data for primary purposes, we would welcome more clarity on retention periods where data is being used for secondary purposes.

- Does the EMA support the need for more harmonisation on the EHR data retention framework in the EU? What best practices would it suggest?
- Can the EMA elaborate on how existing data retention schemes should be applied for secondary uses of health data?

Transparency

Profit-seeking companies can indeed carry out scientific research and it is important to note that scientific research be defined broadly to not hinder medical innovation, as the GDPR provides. We would like answers on the following:

- Interpreting too strictly transparency at the time of collection of personal data risks to discourage future exploratory research. Critically, at the time data is collected all potential future uses of that data may not be known, and hence there is a need to balance transparency with the ability to conduct scientific research. For example, we could risk overwhelming

patients in a clinical setting by listing all potential future uses for their health data, when their main concern is receiving their primary treatment. This could lead to withdrawing of consent or confusion on the part of the patient. Does the EMA support transparency guidelines which better accommodate the potential use of personal data for future research activities whose specific goals are yet undefined at the time of data collection?

- Can the EMA offer specific examples of how organisations can provide transparency to individuals, particularly in the case of Real-World data projects? How does transparency function under conditions of retrospective data analysis where at the time of study many individuals may already be deceased?
- In addition to transparency through standard Informed Consent Forms (ICFs), can the EMA elaborate on guidelines for transparency on EHRs collection?

Rights of the "data subject"

The paper cites the ''right to erasure''. Data subjects can request an organisation who processes their personal data to erase such data without undue delay. However, under certain circumstances organisations are permitted to reject such requests, like when the personal data in question is within the 'public interest' and the removal of such data may threaten the integrity of the dataset.
As more data is being shared with multiple parties for more services, the difficulties of the right to erasure become evident. Emerging technologies further compounds such difficulties. For example, blockchain would make this right almost impossible as the technology relies on the input of data that is then transferred into a blockchain algorithm that is highly secured, incorruptible and cannot be tampered with. Therefore, the right to erasure renders blockchain technology itself mute. It is clear that the right to erasure is highly complex and can pose great difficulties for organisations if interpreted expansively. Therefore, we recommend that guidance be provided on the interpretation of the right to erasure with a focus on emerging technologies.

- Can the EMA elaborate on the interaction between the right to erasure and emerging technologies applicable to the field of medicine?

Registries

- The European Commission launched a call for proposals to support the development of rare disease (RD) registries for the European Reference

Networks (ERNs). What type of learnings can the EMA draw from the record-linkage efforts so far in this initiative?

- Building patient registries is fundamental to expand public health research information. Creating them requires a data linkage process that may increase the amount of data that can be combined for patient re-identification. Can the EMA provide examples on how to develop these fundamental registries while continuing to observe GDPR requirements?

International Transfers

DIGITALEUROPE believes international data flows and collaboration are both key assets of clinical research. A lesson learned from the COVID-19 pandemic is that international data transfers between researchers, labs and healthcare experts based on innovative technologies such as cloud computing, artificial intelligence and machine learning have improved real-time collaboration, the quality of data analytics and the speed of the research process for the sole benefits of protecting public health.

- Can the EMA provide further clarity that GDPR Article 49.1.d can serve as an applicable ground for international data transfers to disclose personal data to health authorities for health research and safety surveillance regarding pharmaceutical products?

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About DIGITALEUROPE

DIGITALEUROPE represents the digital technology industry in Europe. Our members include some of the world's largest IT, telecoms and consumer electronics companies and national associations from every part of Europe. DIGITALEUROPE wants European businesses and citizens to benefit fully from digital technologies and for Europe to grow, attract and sustain the world's best digital technology companies. DIGITALEUROPE ensures industry participation in the development and implementation of EU policies.

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