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"Digital Health 2020 - EU on the Move"

An event organised by the German Presidency of the Council of the European Union

Speech by European Data Protection Supervisor

Wojciech Wiewiórowski

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1. Introduction

There is no doubt that the matters being discussed today, in particular **digital Health and** the current and future application of **Big Data and AI-based technologies in the healthcare sector are of fundamental importance to the EU**. For our health, but also for the future development of our industry and science.

This year **due to the COVID-19 emergency**, a considerable amount of scientific research was made to fight against the SARS-CoV-2 in order to produce findings as fast as possible. At the same time, **the importance of "digital health"** - all-encompassing meanings of this notion - **has also become more and more visible**.

In this regard, please allow me to underline the **need to improve the accessibility, effectiveness and sustainability of eHealth systems within the EU**; and to make informed, evidence-based policy decisions. A strategic public health policy will benefit EU citizens and increase the quality of healthcare and scientific research, while minimising costs.

The **European Data Protection Supervisor** is responsible for monitoring EU institutions' compliance with data protection laws and advising the legislator on any new rules or policies, which may have an impact on data protection and privacy rights. **First and foremost**, we are not protecting data, **we are protecting human beings** described by this data and we should enable data to work for humankind and not harm people that can be identified by this data.

The **EDPS is a full member of the European Data Protection Board (EDPB)**, consisting of data protection authorities from the European Union Member States (I should say European Economic Area), to ensure the consistent application of the GDPR in the European Union.

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In order to facilitate interoperability, the eHealth network, assisted by the European Commission ("Commission"), developed an IT tool, the so-called **eHealth Digital Service Infrastructure ('eHDSI'**), to exchange health data under the Connecting Europe Facility programme, also developed by the Commission.

According to the **Data Strategy**, the Commission intends to create a **European Health Data Space** that would develop and interconnect the eHealth initiatives I have just mentioned. This data space would **enhance research and innovation** and facilitate policy-making decisions and regulatory activities of EU Member States in the area of public health.

The **EDPS strongly supports such initiatives and its key role to improve the quality and access to healthcare**; all the **while** reiterating the importance of **adopting all of the necessary data protection safeguards** alongside the creation and development of the EHDS.

In this regard, I would like to announce that **next Monday 16 November**, we are going to publish a **Preliminary Opinion on the forthcoming European Health Data Space**. The purpose of this Preliminary Opinion is to contribute to the Commission's work on the future EHDS, by identifying essential elements that should be considered when developing the EHDS from a data protection perspective, in particular.

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2. Scientific research for primary and secondary use

In the context of this important discussion and fundamental initiatives towards cross-border sharing and access to health data for primary and secondary use, it is essential to underline that **personal data is the raw input of scientific research and it is therefore critical to ensure its quality and reliability.**

Genetic, biometric and health data are very sensitive types of data but they are to be used for the good of humankind.

This is also very much applicable in times of COVID-19. In this regard, the **EDPB has issued specific guidelines on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak**, focusing on specific elements for the processing of health data in the context of the pandemic, such as the legal basis for processing, data protection principles, information to data subjects and international transfers.

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The **EDPS Preliminary Opinion on scientific research and data protection** has been prepared in this context in order to provide some (initial) clarifications as to how the GDPR approaches scientific research. **Scientific research occupies a privileged position in the GDPR**. Indeed the GDPR adopts a rather liberal approach with respect to the processing of personal data specifically in relation to scientific research. This stems from the rationale that the GDPR actually aims to encourage innovation and clearly acknowledges that **research is a public good destined to increase society's stock of knowledge,** which is a key priority for the EU.

There is indeed a lighter regime for research that is justified by the importance of science for society. The GDPR provides for the possibility to derogate to the so-called purpose limitation principle. This means that researchers can use this data beyond the purposes for which it was first collected.

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However, that flexibility shall remain in line with the EU Charter of Fundamental Right; scientific research and innovation cannot legitimise an excessively liberal interpretation of these derogations. Indeed, **all these exemptions or derogations shall be interpreted in compliance with the higher standard established in Article 8 of the EU Charter of Fundamental Rights** on the right to data protection in order to respect the "essence" of this fundamental right. This is why the GDPR's liberal approach is not without considering and evaluating the expectations of the scientific community.

At the same time, the EDPS is aware that the GDPR has not achieved the desirable level of harmonisation with respect to scientific research activities. Indeed, EU Member States can add conditions and limitations with regard to the processing of genetic, biometric or health data (Article 9.4 GDPR), creating a risk of fragmentation. This issue must be addressed so as to not impair the flows of personal data.

We are also aware that many divergences and questions often arise in the context of identifying the roles and responsibilities of researchers within the meaning of data protection law.

More importantly, we would like to reiterate that **the GDPR offers new opportunities for the standardisation of data protection practices in the field of scientific research.**

It provides for **new incentives to elaborate Codes of Conduct** (Art. 40 & 41 GDPR), Binding Corporate Rules (for global enterprises involved in research activities) and certification mechanisms (Art. 42 & 43 GDPR). Codes of Conduct can be developed **by research organisations and healthcare professionals themselves** to complement the application of the GDPR in a specific context, by bringing an added value to the interpretation of the GDPR. Scientific research and life sciences research are the areas in which the adoption of Codes of conduct **may bring an added value with respect to consent practices, reuse of personal data, and specific appropriate safeguards to be implemented in the conducting of research.**

Some Codes of conduct are already in preparation, especially in the pharmaceutical sector and in the biobank sector. However, we would like to point out that "pharmaceutical" codes of conduct for data protection have not been adopted despite multiple attempts made in the last 25 years. This problem is not due to data protection authorities' lack of acceptance, but rather in finding consensus between stakeholders in the sector.

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The European Data Protection Board, which took up its duties in May 2018, is playing a decisive role in this, by ensuring that sound guidance is delivered on a wide number of subjects. The

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guidelines on consent and transparency, as well as the Opinion on the interplay between the **Clinical Trial Regulation and the GDPR are**, for example, **of direct relevance for the scientific research community.** The relevant Expert SubGroup is also currently working on dedicated Guidelines for scientific research, addressing some of the most pressing questions such as the presumption of compatibility, primary and secondary use of health data, data protection principles' application and information to data subjects. The work is currently ongoing and hopefully the discussions within the EDPB will be able to provide more guidance and harmonisation between EU Member States' provisions in the context of scientific research.

3. Artificial Intelligence in the healthcare domain

Artificial Intelligence (AI) in **the healthcare domain** offers a number of advantages and can be deployed for a wide range of purposes, such as the improvement of day-to-day patient care, clinical decision making support, or facilitating translational medicine. AI is already being used for different purposes, including machine learning, natural language processing, or even physical robots. One of the most recent innovations in this field is a new diagnosis application that is able to detect asymptomatic COVID-19 infections by differentiating between cough sounds of healthy people and infected people with a 70% accuracy.

The Commission has anticipated the growing importance of AI. Indeed, in its Communication on enabling the digital transformation of health and care in the Digital Single Market, the Commission sets out to develop a strong approach to artificial intelligence. With this ambitious plan, the Commission intends to become a global leader in innovation. Therefore, the Commission's White Paper on Artificial Intelligence maps out a two-fold agenda, to promote the development of AI, as well as addressing the risks associated with the use of this new technology.

There is **no doubt that we can highly benefit from AI, but it is not a technological silver bullet**. As a new and innovative technology, it has serious inherent risks; therefore, its use needs to be carefully assessed.

In the Opinion about the Commission's White Paper on AI, the EDPS supports the idea that **large-scale deployment of AI should only be allowed, when the technology has reached a certain maturity level**. To decide, whether this is the case or not, the EDPS suggests a **qualified analysis of credible identified sources for each potential application area**.

The success of any upcoming EU Data Space, and particularly in the context of health data, will depend on a strong legal basis, on the establishment of a **strong data governance**

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mechanism and on full compliance with the GDPR providing sufficient guarantees for a **lawful, responsible, ethical management anchored in EU values, including the respect for fundamental rights**. **Any future data space should serve as an example of transparency, effective accountability and proper balance between the interests of the individual data subjects and the shared interest of society as a whole.**

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