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INTERNATIONAL
PHARMACEUTICAL
PRIVACY CONSORTIUM

15 February 2017

Isabelle Falque-Pierrotin
Chairwoman, Article 29 Working Party
Office N° MO-59 02/013
European Commission
B-1049 Brussels
Belgium

By email to: just-article29wp-sec@ec.europa.eu and presidenceg29@cnil.fr

Subject: Comments on GDPR Guidance Documents

Dear Ms. Falque-Pierrotin,

I am writing on behalf of the International Pharmaceutical Privacy Consortium (IPPC) to provide feedback on the Article 29 Working Party's recently published guidelines concerning implementation of the General Data Protection Regulation (GDPR). The IPPC believes that a common interpretation of the requirements of the GDPR in the context of medical research will benefit research participants, researchers, research ethics review committees, and data protection authorities. Information concerning the IPPC is contained within Appendix A and at www.pharmaprivacy.org.

Guidelines on the Right to Data Portability (WP 242)

The IPPC takes note of the Working Party's statement that "the primary aim of data portability is to facilitate switching from one service provider to another, thus enhancing competition between services (by making it easier for individuals to switch between different providers."[1] Nevertheless, the data portability right could significantly impact clinical investigations to evaluate the safety and efficacy of new and existing drug products if it were interpreted to mean that clinical trial participants have the right to obtain study results before those results have been published and submitted to medicines authorities. We believe that the text of the GDPR and the Working Party's guidance document makes clear that the data portability right is not so expansive.

[1] WP 242, at § I.

When a prospective research participant enrols in a clinical study, he or she is informed that access to research records will be restricted for the period during which the individual wishes to remain actively enrolled in the study. This is necessary to ensure the research study's integrity and is required by international good clinical practice (GCP) guidelines and health authorities around the world. However, an individual can choose to withdraw from further participation in a study at any time and obtain access to records that relate to him or her. We do not believe that the right of data portability impacts this long-standing practice.

Clinical studies typically involve both manual and automated processing of personal data. Some information is expressly provided by research participants to researchers and much additional information results from the clinical investigator's objective observations of the research participants. Our understanding of the Working Party's guidance is that the right of data portability would apply to this raw data. Nevertheless, we also understand that "inferred data and derived data . . . do not fall within the scope of the right to data portability" and that, for example, "an assessment regarding the health" of an individual constitutes inferred data.[2] We read this to mean that a researcher's conclusions as to the effects of a study drug on a participant's health fall outside the scope of the data portability right, as would all analysis of the aggregate research data. We further understand that Article 20(4) excludes data covered by intellectual property rights (in particular, *sui generis* database rights) and trade secrets, like a researcher's conclusions and analysis of aggregate research data, from the right of data portability. Indeed, an undue expansion of the right of data portability to inferred data and derived data could violate the data controller's intellectual property rights and result in the disclosure of trade secrets.[3]

Guidelines for Identifying a Controller or Processor's Lead Supervisory Authority (WP 244)

Clinical investigations to evaluate the safety and efficacy of drugs are often conducted on a global basis and may involve multiple sites across the EU, as well as sites outside the EU. While organizational structures vary, in some cases a non-EU affiliate that is a member of a group of undertakings is the primary sponsor of a study, while an EU affiliate acts as the primary decision-maker with respect to the processing of personal data collected at EU sites. Where two legal entities share in the determination of the purposes and means for the processing of personal data, we understand this to be an instance of joint controllership.

In the above situation, where the EU establishment has the authority to implement decisions about the processing of personal data and to take liability for the processing, we understand the Article 29 Working Party's guidance to mean that this EU entity can be

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[2] WP 242 at III.

[3] Moreover, we do not believe that avoidance of lock-in effects and high switching costs justifies an expansion of the data portability right. These are matters more appropriately addressed by anti-trust laws, which appropriately consider factors such as the existence of a dominant market power, an exclusionary practice, and whether there are efficiencies that offset the harms of the exclusionary practice.

identified as the main establishment and a lead authority designated in accordance with the location of that main establishment.

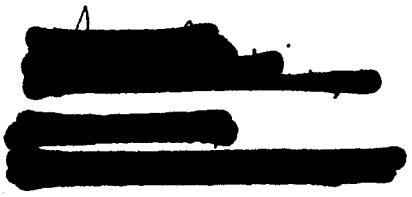
Further, if a sponsor of a clinical trial conducted in the EU does not have any establishment in the EU for this purpose but is subject to the GDPR by virtue of Article 3(2), we ask the Working Party to designate the DPA of the jurisdiction where the sponsor's representative is established according to Article 27(3) as the lead supervisory authority.

Guidelines on Data Protection Officers (WP 243)

The IPPC supports the flexibility provided in the Working Party's guideline for structuring the Data Protection Officer (DPO) position. In some organizations, a DPO team may be more effective at fulfilling the tasks required under the GDPR than a single individual. We agree that in such cases, a clear allocation of tasks and designation of a lead contact point is important. In other organizations, a single individual, such as an existing Chief Privacy Officer, may be in the best position to serve as the DPO. The DPO's level of expertise and accessibility is not necessarily dependent only on his/her own skills but rather on the combination of his/her own skills and those of his/her local "network", e.g., local privacy liaisons who may have local legal expertise and language(s) abilities. We agree that the focus should be on ensuring effective internal oversight of all processing of personal data, as opposed to formalistic or unrealistic structures.

We thank you for consideration of our comments. Please do not hesitate to contact us with any questions.

Sincerely,



APPENDIX A: INTERNATIONAL PHARMACEUTICAL PRIVACY CONSORTIUM

VISION	The vision of the International Pharmaceutical Privacy Consortium is to be the leading voice in the global bio-pharmaceutical industry to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.
MISSION	As an organization of pharmaceutical companies, the IPPC advances the protection of individual privacy, anticipates and responds to new challenges affecting the protection of health information, augments member companies' data protection capabilities through the development and sharing of industry best practices, educates internal and external stakeholders on data protection in the pharmaceutical industry and the importance of data to pharmaceutical innovation, and provides a forum to ensure that the global pharmaceutical industry speaks with one, coherent voice on data privacy issues.