INTERNATIONAL PHARMACEUTICAL PRIVACY CONSORTIUM

23 May 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 Document on Data Protection Impact Assessments

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 guideline on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679. Information concerning the IPPC is contained within Appendix A and at www.pharmaprivacy.org.

I. LAYERED ASSESSMENTS

The IPPC takes note of the statement in Article 35(1) of the General Data Protection Regulation (GDPR) that "a single assessment may address a set of similar processing operations that present similar high risks" and wishes to set clear expectations for researchers, research participants, and others as to what this means in the clinical research context. Clinical studies in the EU are conducted pursuant to the Clinical Trials Directive (Directive (EC) 2001/20/EC) (soon to be replaced by the Clinical Trials Regulation (Regulation (EU) 536/2014)). Under these laws, clinical trials in the EU must be conducted in accordance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines on good clinical practice (GCP).[1] ICH GCP Guidelines have formalised a number of practices that have developed over many decades to protect research participants' privacy and data protection. These practices include:

[1] See, e.g., Recital 43 of Regulation 536/2014. See also ICH Guideline for Good Clinical Practice E6(R1) (10 June 1996), available at http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf.

- Key-coding (pseudonymisation) of data before it is reported to pharmaceutical company sponsors for analysis. The key-coding involves replacing research participant direct identifiers with a subject identification code.[2]
- Obtaining informed consent from research participants.[3]
- Oversight of the research by an Independent Ethics Committee whose responsibility is to protect the rights, safety, and well-being of research participants.[4]
- Protection of the confidentiality of records that could identify research participants.[5]
- Procedures to ensure the accuracy and completeness of records.[6]
- Protection of the security and integrity of study data and records.[7]

IPPC members anticipate each conducting a DPIA that addresses their overall clinical trial processes. Data protection issues unique to a specific clinical study or category of studies would then be addressed in a separate DPIA. We believe that a "layered" approach such as this to DPIAs will be most efficient to avoid duplication and focus attention on new or different data protection issues.

II. WHITELISTED DATA PROCESSING OPERATIONS

In the areas of clinical research and pharmacovigilance, a number of codes of conduct, guidelines, and authorizations have been approved by member state data protection authorities.[8] Where processing activities comply with the conditions specified by the supervisory authority, the value of conducting a DPIA may be outweighed by the burden, and it may be more productive to focus these resources on other data protection activities. Therefore, we support the concept of data protection authorities developing whitelists of processing activities for which no DPIA is required, pursuant to Article 35(5). This will have the further effect of incentivizing organizations to follow procedures approved by data protection authorities and included in the whitelist.

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[2] ICH GCP at § 1.58.
[3] ICH GCP at § 1.28, 2.9, and 4.8. See also Regulation 536/2014 at Recitals 29-31, point 21 of Art. 2(2), and Arts. 29-35.
[4] ICH GCP at §§ 1.27, 2.6, and 3.1-3.4. See also point 11 of Regulation 536/2014 at Recital 18, Art. 2(2), and Art. 4.
[5] ICH GCP at §§ 1.16, 1.21, 2.11. See also Annex I of Regulation 536/2014 at D.17(al) and at Art. 56.
[6] ICH GCP at §§ 4.9, 5.5, and 5.18. See also Regulation 536/2014 at Art. 48.
[7] ICH GCP at §§ 5.5.3. See also Annex I of Regulation 536/2014 at D.17(ak) and (am), and at Art. 56(2).
[8] For example, in France: Délibération n° 2016-262 du 21 juillet 2016 portant modification de la méthodologie de référence pour les traitements de données personnelles opérés dans le cadre des recherches biomédicales (MR-001) and Délibération n° 2016-263 du 21 juillet 2016 portant homologation d'une méthodologie de référence relative aux traitements de données à caractère personnel mis en œuvre dans le cadre des recherches dans le domaine de la santé ne nécessitant pas le recueil du consentement exprès ou écrit de la personne concernée (MR-003).

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

Sincerely,

Peter Blenkinsop
Secretariat and Legal Counsel

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.

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