IPMPC
International Pharmaceutical &
Medical Device Privacy Consortium

19 November 2021

Domestic Data Protection team
DCMS
100 Parliament Street
London
SW1A 2BQ

By Email to: DataReformConsultation@dcms.gov.uk

Re: Consultation on UK Data Protection Regime

Dear Secretary Dowden,

The International Pharmaceutical & Medical Device Privacy Consortium ("IPMPC") welcomes the opportunity to provide comments on the Consultation on the UK Data Protection Regime published by the Department for Digital, Culture, Media & Sport. The IPMPC is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies and medical device manufacturers. The IPMPC strives to be a leading voice in the global pharmaceutical and medical device industries to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.[1]

The IPMPC strongly supports the objectives of the government to eliminate unnecessary barriers to responsible data use and innovation while maintaining high data protection standards. The biomedical industry has a long history of respecting patient privacy and data confidentiality in our R&D and commercial activities. Members of the IPMPC have built sophisticated privacy compliance programs, and we take our data protection responsibilities seriously. However, we are concerned that compliance with some data protection obligations are creating barriers to biomedical innovation without meaningfully enhancing individuals' privacy interests. We are encouraged by the government's focus on ensuring the continuation of real privacy protections while reconsidering practices and interpretations that are hindering scientific research.

[1] More information about IPMPC is available at www.ipmpc.org. This filing reflects the position of the IPMPC as an organization and should not be construed to reflect the positions of any individual member.

The IPMPC is also mindful that most of our members approach privacy compliance in a centralized manner. Where privacy requirements are harmonized across jurisdictions, IPMPC members are able to focus their efforts on taking practical compliance steps rather than on simply trying to understand local interpretations and variations. The existing UK GDPR largely mirrors the EU GDPR. There is a real risk that divergence between UK data protection law and the EU GDPR could complicate overall compliance, and so it is important to carefully weigh the risks and benefits of all changes. In light of this, we encourage the government to do two things in parallel: (1) issue guidance, wherever possible, making clear the government's interpretation of the existing text of the UK GDPR (and, by implication since it largely mirrors the UK GDPR, the EU GDPR), and (2) initiate legislative reforms to ensure that these interpretations are enshrined in UK statutory law.

A. Research Purposes

Consolidation of Research Provisions

The IPMPC agrees that further guidance and legislative reform is necessary on the application of data protection requirements to scientific research activities. We agree that research provisions are complex, dispersed, and layered within the existing legislation. We support efforts by DCMS to provide centralized guidance to researchers on the application of the law and to consolidate the applicable legislative provisions. (See Q1.2.1.)

Definition of Scientific Research

We believe lawmakers were clear in drafting a definition of "scientific research" in Recital 159 that encompasses technological development and demonstration, fundamental research, and applied research, and includes both publicly-funded and privately-funded research. We have been surprised by interpretations which have sought to narrow this definition,[2] and while we recognize that the recitals do not have the same legal status as the operative provisions in the event of conflict, we disagree with those who have attempted to dismiss the recitals as superfluous. Therefore, in the first instance, we believe that a forceful statement would be beneficial that (i) highlights that scientific research into treatments, diagnostics, and prevention of disease serves the public interest, and (ii) reiterates that "scientific research" is already defined in the recitals and that this definition must be adhered to by supervisory authorities. We are also supportive of legislative reform to move this definition to the operative articles to ensure that lawmakers' intentions are followed. (See Q1.2.2.)

Lawful Grounds for Processing

The IPMPC similarly believes that there are several grounds for personal data processing for research purposes under Article 6 that researchers can possibly rely upon. Guidance should make clear that researchers are free to point to these multiple, overlapping legal grounds. We encourage the government to issue guidance that explicitly states that (i) individuals and organizations have a legitimate interest in conducting scientific research, including research into the diagnosis, treatment, and prevention of health conditions and diseases; (ii) there is no incongruity in reliance on consent as the legal basis for processing of personal data in clinical trials but also stipulating that if consent is revoked, continued processing of data already collected can continue on the basis of the researcher's legitimate interests and compliance with legal requirements. (See Q1.2.4.)

Protection of the rights and interests of research subjects has long been a focus of the medical research community. The following safeguards and measures have developed over time to protect the rights and

[2] Please see our Comments dated 17 April 2020 to the European Data Protection Supervisor concerning his Preliminary Opinion on Data Protection and Scientific Research, available at https://www.ipmpc.org/resources.

interests of patients and other participants in health research. Many of these safeguards have been incorporated into official standards for the conduct of medical research (e.g., Guidelines for Good Clinical Practice adopted by the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH)). The IPMPC supports the creation of a new legal ground for research to simplify how the law is interpreted and applied to scientific research activities. To the extent a new legal basis is created, the IPMPC believe the following safeguards are appropriate in the context of health research (Q1.2.7.):

1. Transparency to the extent feasible with respect to future research intentions when data is collected directly from data subjects.
2. Pseudonymisation of data, to minimise processing of identified data while allowing for traceability for auditing purposes.
3. Limiting the collection and sharing of indirect identifiers to only those that are necessary for the research purposes.
4. Appropriate oversight of research activities involving the processing of personal data, including Ethics Committee review and approval when health research involves interactions with research participants (i.e., clinical trials) and internal oversight procedures before any further processing.
5. Confidentiality of all identifiable data through technical, physical, and administrative controls.
6. Training of all personnel on the applicable data protection safeguards that are required.
7. Performance of a data protection impact assessment (in accordance with GDPR Art. 35) to evaluate data protection risks and identify measures to mitigate those risks.

Re-use of Personal Data

With respect to further processing of personal data for scientific research purposes, the IPMPC does not see an inconsistency between Recital 33 and the requirement that consent be freely given, specific, fully informed, and unambiguous. Recital 33 was originally included in the EU GDPR to make clear that in situations in which personal data is collected for future research activities, it is sufficiently specific to describe future research in terms of categories instead of in terms of specific research projects. At the time that the legislation was being debated, this statement was viewed as helpful to make clear that even though the collection of personal data often occurs in the context of a specific research project (e.g., a clinical trial conducted pursuant to a specific research protocol), it is common and acceptable to ask the individual to consent to future categories of research (e.g., research concerning a particular disease, category of diseases, or even biomedical research generally). Instead of this common sense interpretation of the relationship between Recital 33 and Article 7, some bodies have chosen to see an inconsistency and to read Recital 7 as having no effect. Paradoxically, the requirement for "specific" consent has come to be applied in a stricter manner in the context of scientific research than in virtually any other setting, including even marketing. The IPMPC supports guidance and legislative reform by the UK government that clarifies that "specific" consent is obtained when a researcher obtains consent to use an individual's personal data for biomedical research purposes. (See Q1.2.8.)

Further, the IPMPC believes that researchers would benefit from clarity that further processing of health data for scientific research purposes in accordance with Article 89(1) is (i) compatible with the original purpose, (ii) lawful under Article 6(1), and (iii) permissible under Article 9(2)(j). (See Q1.2.9.) The interaction of Article 5(1)(b) with Article 6(1), Article (9)(2)(j), and Article 89(1) is complex. This complexity has created confusion in the health research community, and clarification of the interaction of these provisions through guidance and legislative reform would help to address this confusion.

Notice Requirements

The IPMPC agrees with the government that a great deal of confusion has been created by the difference in language in Article 13 concerning notice requirements when personal data is collected directly from an individual and Article 14, which applies when personal data is collected from a third party and includes an exemption for circumstances in which providing notice would require disproportionate efforts. When pharmaceutical and medical device companies sponsor clinical studies and collect data from research participants, they try to be as transparent as possible with respect to future research intentions. For proposed secondary research projects utilising previously-collected data, pharmaceutical and medical device companies have established internal processes to assess the scientific merit of such secondary uses and adequacy of data protection safeguards. This assessment involves examination of the original notice provided to data subjects and determination of whether the data subject has already received adequate information. Because the sponsor only has a copy of the key-coded data, the sponsor is not in a position to provide direct notification to former trial participants. Pharmaceutical and medical device companies are exploring ways to provide further information to former research participants, such as by providing this information to investigators and making information available on their websites.

The IPMPC supports clarifying that notice requirements do not apply under Article 13 when processing of personal data for research purposes, providing notice would involve disproportionate efforts, and the types of safeguards described above have been implemented. (See Q.1.2.10.) In the context of re-use of clinical trial data for further research purposes, it is important to note that this already reflects the state of the law. Article 11(1) is clear that "[i]f the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the 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." The government should make this clear in guidance and modify Article 13 to eliminate the risk of misunderstanding.

B. Data Minimization and Anonymization

The common practice of key-coding patient data before it is reported by clinical investigators to trial sponsors protects the identities of participants. The data collected by the investigator is reported back to the trial sponsor using 'case report forms' (or 'CRFs'), which summarize the information related to the study. The investigator assigns a code to each study participant and information is reported on the CRFs using the assigned codes. The decoding information that links the assigned codes to study participant identities is maintained confidentially by each investigator. There are only very limited circumstances in which the investigator is permitted to allow third parties (including the study sponsor) to have access to the decoding information. These limited circumstances include for purposes of auditing/monitoring of the study site by the sponsor to ensure that data has been accurately reported by the investigator. In these circumstances, the auditor/monitor is required to maintain the confidentiality of the information and is allowed access only at the study site (i.e., this information cannot be taken off-site).

Pseudonymisation is also used in the context of real world data (RWD) to protect the identities of patients while preserving traceability, where traceability is necessary. The data is key coded at its source before it is provided to health researchers.

It goes without saying that anonymisation is always the preferred course to minimise data protection risks. However, an impediment to reliance on anonymisation as a mechanism for conducting biomedical research is the lack of clear guidance from authorities approving of 'relative anonymisation' as a compliant

approach to anonymisation (as opposed to a requirement of 'absolute anonymisation'). The IPMPC interprets the European Court of Justice's judgment in *Patrick Breyer v Bundesrepublik Deutschland* (Case C-582/14) as indicating support for relative anonymisation as a compliant approach to anonymisation, and we encourage the government to make this explicit in both guidance and through legislative reform. (See Q1.6.3.)

Conclusion

The current COVID-19 pandemic highlights the importance of the development of harmonized, practical, and balanced guidance on the application of data protection requirements to health research. Personal data is critical to this research. In both the recitals and operative text, the UK GDPR – which mirrors the EU GDPR – recognizes the importance of privately funded biomedical research and provides for appropriate flexibility in the application of data protection requirements. The IPMPC supports guidance and legislative reform that clarifies the operation of data protection requirements to biomedical research and highlights this flexibility.

We thank you for the opportunity to provide these comments.

Sincerely,

Peter A. Blenkinsop
IPMPC Secretariat