INTERNATIONAL PHARMACEUTICAL PRIVACY CONSORTIUM

mdpc medical device privacy consortium

23 January 2018

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 on Consent and Transparency

Dear Ms. Falque-Pierrotin,

The International Pharmaceutical Privacy Consortium (IPPC) and Medical Device Privacy Consortium (MDPC) welcome this opportunity to comment on the draft guidances relating to consent (WP259) and transparency (WP260) under the General Data Protection Regulation (GDPR) that have been developed by the Article 29 Working Party (the "Working Party" or "WP29") and released on 12 December 2017.[1]

The IPPC is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies. The MDPC is comprised of data protection professionals from a number of medical device companies. The IPPC and MDPC agreed to merge in 2017, and a list of the combined membership can be found in Appendix A.

The IPPC/MDPC supports the Working Party's efforts to clarify GDPR requirements. As the 25 May 2018 deadline approaches, practical guidance as to the new standards is welcome and much needed. At the same time, IPPC/MDPC is concerned that certain parts of the guidance documents, as they are currently written, rather than creating practical insight on how to comply with GDPR requirements, instead could create confusion, thereby impeding medical research and the delivery of health care.

The IPPC/MDPC notes that several interpretive points proposed by the WP29 represent substantial departures from current practices. In particular, the Working Party's interpretation that separate consents must be obtained for each purpose of processing[2] and that processing must rely on only one, unchangeable legal basis[3] are different from—and significantly more onerous than—the text of the GDPR itself. Moreover, we believe that some of the Working Party's interpretations of rules

[1] http://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=611232

[2] See Section 3.1.3 of the draft guidance.

[3] See Section 6 of the draft guidance.

relating to processing for scientific purposes[4] are more burdensome than what was intended by the legislator. For the reasons set forth below, the IPPC/MDPC urges WP29 to reconsider these interpretations.

I. WP259 – CONSENT

Before diving into specific comments on the draft guidance, a more general discussion of how the guidance could impact medical research and health care delivery may be useful. Section A, below, is therefore intended to frame our more specific comments in Section B. IPPC/MDPC has also prepared the attached paper on *Biomedical Research Under the GDPR*, which reflects our interpretation of how the GDPR applies to medical research.

a. Background

i. *Medical research*

The practice of obtaining informed consent to participate in medical research involving human experimentation can be traced back to the Nuremberg Code of 1947.[5] Since then, this practice has become a bedrock principle of modern medical ethics, incorporated into the World Medical Association's Declaration of Helsinki, and adopted by governments throughout the world.[6] It is, therefore, surprising, if not unfortunate, that the Working Party spends very little time in the draft guidance discussing the application of its rules on consent to the processing of personal data in medical research.

Seeking to avoid a situation where 70 years of practice and learnings could potentially be upended, or worse, a conflict of laws could be unintentionally created, the legislator chose to be quite specific in the GDPR as to the relationship of consent for the processing of personal data under the GDPR to consent to participate in clinical trials. Recital 161 provides that "For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council should apply." The legislative intent to grant deference to standards and rules for medical research could not be clearer.

WP259, unfortunately, creates unnecessary uncertainty as to the application of GDPR consent requirements to the processing of personal data in medical research. It does so in several ways: First, it suggests data protection authorities will question what processing of personal data is actually

[4] See Section 7.2 of the draft guidance.

[5] "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment."

[6] See, e.g., International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (E6), which has been adopted by medicines authorities in the European Union, United States, and Japan. See also Article 7 of the United Nations International Covenant on Civil and Political Rights (ICCPR).

"necessary" to fulfill an agreement between a data subject and a controller. (The guidance states: "There needs to be a direct and objective link between the processing of the data and the purpose of the execution of the contract.") The guidance suggests that all parties to an agreement share a common purpose that can be objectively identified by a third party, like a data protection authority, such that it is possible to determine whether the processing of personal data is *actually* necessary to that shared purpose. As a descriptive claim, this is rarely true, and as a normative one, we think it is misguided. Second, the guidance suggests that where multiple legal bases could apply to the processing of personal data, it is misleading to frame the processing as a free choice by the data subject, and, therefore, a legal basis other than consent should be relied upon by the controller from the start. A controller is, according to the Working Party, prohibited from switching legal bases. This view ignores that once consent to participation in a clinical trial has been provided, certain processing of personal data may be necessary in reliance on that consent even after the consent is withdrawn. The public interest in ensuring high standards of medicinal products and medical devices necessitates the continued processing, even after withdrawal of consent, of personal data already collected.[7]- This public interest is not simply co-incident to reliance on consent to participate in a trial but arises *because of* such reliance. Third, and related to this last point, WP29 suggests that data subjects have an absolute right to withdraw consent and to request the erasure of their data, notwithstanding legal and ethical obligations to continue processing personal data that arise as a result of prior reliance on the data subject's consent to participation.

ii. *Health care delivery*

The quality of health care that is available today is due to the efforts of scientists over many decades to build upon prior medical discoveries and expand scientific understanding. A patient *today* is the beneficiary of *yesterday's* scientific research and innovation. The principle of reciprocity reflects the idea that individuals who have benefited from past medical advances should be willing to contribute to future advances themselves.

As new medical technologies are brought to market, this idea has been incorporated more explicitly into some terms and conditions of use. Simply put, the nature of the exchange in these situations is that if you, as patient, wish to benefit from use of the product, then you must agree to allow data concerning your use of the product to be used in a proportionate manner to improve the product or advance medical understanding of the disease/condition.

WP259 appears to characterize consent in these circumstances as inappropriate and misleading. Essentially, the Working Party's argument appears to boil down to 'consent cannot be considered freely-given if it is the result of an exchange.' We disagree.

b. Specific comments

Our specific comments on WP259 are broken down into four areas: (a) the requirement of granularity; (b) the prohibition on "switching" the legal basis for processing; (c) the prohibition on bundling of consent to data processing with other matters; and (d) the Working Party's specific guidance on consent in the context of scientific research.

[7] This public interest is recognized in various EU laws. See, e.g., *infra* note 9.

i. Granularity

WP259 states that "If the controller has conflated several purposes for processing and has not attempted to seek separate consent for each purpose, there is a lack of freedom." As a result, the consent is not to be considered valid. The implication is that data protection authorities will assess whether each purpose of processing described in a consent form could be broken down into smaller units – i.e., more specific purposes – and, if so, that the consent form must be presented in such a fashion with each purpose presented as a separate opt-in option.

This approach suffers from the problem of infinite divisibility without actually providing any objective criteria for determining 'how specific is specific enough.' Instead, the question that should be asked is whether the data subject has been given sufficient information such that he or she can reasonably distinguish what types of activities are within the scope of the consent and what types of activities fall outside of scope. If the data subject is able to make such a distinction, then the consent is "informed" (as to the purpose of processing), and any requirement to provide further information fails to respect the free choice of the individual.

Moreover, the relevant question under the GDPR in assessing whether consent is valid is whether the consent has been freely given, not whether the data subject has been given total freedom to pick and choose those parts of the consent that he/she likes in some à la carte fashion. The Working Party seems to have been influenced in its thinking by concern as to contracts of adhesion with a consumer, but if that is, in fact, the main concern, then consumer protection law already provides standards for determining validity and interpreting ambiguous clauses in these circumstances. Namely, the standard for validity is one of conscionability and fairness, and questions of interpretation are resolved against the drafting party. Those same standards can be applied in the data protection context to ensure that consent is specific and freely given.

The IPPC/MDPC believes that the Working Party's conclusions regarding granularity may not reflect a realistic vision of the way patients give consent and consume health care services. In particular, there is a very real risk of information overload. For example, in the clinical trial context, informed consents are already required by law to convey considerable amounts of information to data subjects. The IPPC/MDPC is concerned that requiring pharmaceutical and medical device companies to provide even more extensive information in the form of ever more granular options risks backfiring by making informed consent forms even longer and inundating data subjects with information. While various approaches can be adopted in an attempt to aid data subjects' comprehension, there is no panacea to the problem of notice fatigue.

Since the Working Party cites Recital 32 of the GDPR is support of its conclusions regarding granularity, it is worthwhile to take a closer look at that language. The Recital provides as follows, in relevant part: "Consent should cover all processing activities carried out for the same purpose or purposes. When the processing has multiple purposes, consent should be given for all of them." The Working Party appears to read the second sentence as saying that '*separate* consent must be given for *each* purpose.' In our view, that reading changes the meaning. In fact, what the recital is saying is that consent for different purposes of processing can be combined into one "request" as long as each of the purposes is clearly described in the consent form.

This interpretation makes sense from a pragmatic standpoint as well; in many cases it is not feasible to track each data element of collected data as it relates to a particular purpose. Many systems are not built to differentiate purposes with the degree of specificity required to customize processing for any combination of conditions and purposes selected by participants in a program. For example, clinical trial data systems may not allow for the data to be analyzed pursuant to a complex matrix of individual preferences. This interpretation also avoids the risk associated with requiring separate consents for each purpose of processing that users may be inundated with interactive demands, thereby making consent forms more confusing and frustrating than they would otherwise be.

Separate from the Working Party's discussion of the need for granularity in describing processing purposes, the draft guidance also indicates that consents must be specific as to third party recipient controllers of the data ("if the data is to be transferred to or processed by other controllers who wish to rely on the original consent, these organisations should all be named"). This is particularly problematic in the context of scientific research, where it may not be possible to identify all recipients by name at the time of data collection. The clear aim of Recital 33 of the GDPR is to provide flexibility to researchers in these circumstances, and the guidance should reflect this.[8]

ii. Switching of legal bases

The IPPC/MDPC disagrees with the Working Party's conclusion that processing operations must be limited to one single legal basis per purpose of processing, and no switching of legal bases is later allowed. First, this interpretation simply does not reflect the reality of how the IPPC/MDPC's members process personal data. In many—if not most—instances, processing in fact occurs *both* with the valid consent of patients or research subjects (e.g., Art. 9(2)(a)) *and* on independently justifiable grounds as well, like a statutory requirement (e.g., Art. 9(2)(g) or (i)), to protect the health of the data subject (e.g., Art. 9(2)(c) or (h)), or to conduct further scientific research (Art. 9(2)(j)). Second, it is incorrect to conclude, as the Working Party does, that in these cases, data subjects have not been provided with a genuine choice.

In clinical trials, for example, individuals are given the choice of participation in the trial, which is in turn conditioned on their agreement to the processing of their personal data for certain defined research purposes. If individuals choose not to participate in the trial, then no further personal data is collected. However, once individuals have gone through the informed consent process and enrolled in a clinical study, it is considered unethical and a violation of health regulatory requirements to remove already collected study data.[9] To do so would impact the integrity of the study results as unfavorable data could be easily manipulated.

---

[8] Recital 33 of the GDPR states: "It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."

[9] Recital 76 of the Clinical Trials Regulation ((EU) 536/2014) states: "With a view to respecting [data protection] rights, while safeguarding the robustness and reliability of data from clinical trials used for scientific purposes and the safety of subjects participating in clinical trials, it is appropriate to provide that, without prejudice to Directive 95/46/EC, the withdrawal of informed consent should not affect the results of activities already carried out, such as the storage and use of data obtained on the basis of informed consent before withdrawal." Article 47 of the Clinical Trials Regulation requires compliance with ICH GCP

As the above example shows, once consent has been granted, reliance on that consent may necessitate continued processing of personal data even after consent to data processing is withdrawn. It is important in the consent form to describe what will happen if consent to data processing is withdrawn, including whether any continued processing will be necessary pursuant to a different legal basis. However, to prohibit such switching of legal bases, or to describe the original consent as misleading or unfair, as the Working Party does, runs counter to the legislation.

Throughout the text of the GDPR, there are implicit or explicit recognitions of overlap among some of the categories in Art. 9 and 6, and provisions that explicitly allow for continued processing of personal data where the original legal basis becomes inapplicable. For example, with respect to the right of erasure, Article 17(1) provides that the right of erasure applies, inter alia, where the data subject withdraws consent to the processing and "there is no other legal ground for the processing." This and similar provisions make clear that the GDPR was always intended to recognize the existence of multiple legal bases at the same time.

iii. Bundling of consent to data processing with other matters

The Working Party cites Art. 7(4) and Recital 43 for its position that provision of a product or service, or eligibility to take part in some activity, cannot be made a condition of consent to data processing unless that data processing is absolutely necessary to the product, service, or activity. However, the actual language used in the GDPR is not as absolute as the Working Party suggests. Article 7(4) calls for "utmost account" to be given to whether performance of a contract is conditional on consent, and Recital 43 creates a presumption that the consent has not been freely given. The Working Party takes this language one step further, however, and concludes that it means that it is only in "exceptional cases" where consent to data processing can be required as a condition of performance of a contract.[10]

We believe that the Working Party's interpretation goes beyond what the legislator intended and recommend that WP29 revert to the language in the GDPR itself. Whether an individual has a genuine free choice to provide consent or not in a particular situation is dependent upon whether the product/service/activity in question is reasonably necessary to life, health, safety, work, or well-being. This in turn requires a case-by-case analysis, and that is why the legislator chose to establish a rebuttable presumption.

iv. WP29 specific commentary on consent in the context of scientific research

The IPPC/MDPC has concerns with the Working Party's suggestion that where consent to future scientific research purposes has been obtained, as those purposes are more concretely defined, the GDPR requires entities performing scientific research to provide continuous updates to data subjects.

---

guidelines, which, in turn, require in Section 5.5.3 that the sponsor ensure that "there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail)".

[10] The Working Party's interpretation is not consistent with judicial precedent concerning the validity of consent in other contexts. In other contexts (e.g., civil law consents), consent can be invalidated where there is duress or coercion, not simply where one party has received some consideration in exchange for providing consent.

Such a requirement could be extraordinarily onerous on a logistical level[11] and is unsupported by the plain text of the GDPR, which mentions nothing about continuing disclosures to research subjects. Instead, the GDPR rightly recognizes that scientific research presents unique challenges and offers life-changing benefits that justify a more flexible consent framework.[12] The IPPC/MDPC urges WP29 to adopt an interpretation that gives effect to the GDPR's intent to facilitate scientific research through more flexible requirements, including in its interpretation of consent requirements.

We also have concerns with the WP29's statement that, while recognizing that an absolute right to withdraw consent could undermine types of scientific research, concludes that "the GDPR is clear that consent can be withdrawn and controllers must act upon this – there is no exemption to this requirement for scientific research. If a controller receives a withdrawal request, it should delete or anonymise the personal data straight away if it wishes to continue to use the data for the purposes of the research." Notwithstanding the fact that this statement would create a conflict with clinical trial requirements,[13] it is also contrary to the express language of Article 17(1)(b) that states that where a data subject withdraws consent, erasure is required only "where there is no other legal ground for the processing." This language makes clear that if another legal basis exists (e.g., the scientific research exemption in Art. 9(2)(j)[14]), continued processing is permitted. The WP29's statement is also inconsistent with Art. 17(3)(d) and Art. 21(6), which place clear restriction's on a data subject's right to erasure and to object to processing in the context of scientific research pursuant to Article 89.

II. WP260 – TRANSPARENCY

The IPPC/MDPC agrees with WP29 that clear and plain language disclosures are important to ensure that individuals are able to understand how information about them is collected and used. However, we are concerned that the proposed interpretation discouraging conditional language like "may," "might," "often," and "possible" will be untenable given that many processing operations are, in fact, contingent on the user's choices and other events that are not ascertainable at the time of the consent.

---

[11] For example, participant identities in medical research are typically coded, and the study sponsor only has direct access to the coded data. The sponsor is unable to re-identify the patient to ask for new consents. Only the principal investigator is allowed by law to perform such re-identification.

[12] See supra note 8 concerning Recital 33. In addition, Recital 161 states: "For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council should apply." Recital 29 of the Clinical Trials Regulation, in turn, states: "It is appropriate that universities and other research institutions, under certain circumstances that are in accordance with the applicable law on data protection, be able to collect data from clinical trials to be used for future scientific research, for example for medical, natural or social sciences research purposes. In order to collect data for such purposes it is necessary that the subject gives consent to use his or her data outside the protocol of the clinical trial and has the right to withdraw that consent at any time. It is also necessary that research projects based on such data be made subject to research on human data, for example on ethical aspects, before being conducted."

[13] See discussion at *supra* note 9.

[14] The draft guidance suggests in footnote 65 that the scientific research exemption would not enable continued processing because "controllers will still need a lawful basis under Article 6 GDPR for retention of the data." It is unclear if this statement is intended to mean that (i) the Working Party does not see the legal bases enumerated in Art. 9(2) as applying to non-special categories of personal data even if the criteria in one or more of those exemptions are otherwise met; or (ii) the Working Party views the requirements of Articles 6 and 9 as cumulative, and so meeting an exemption in Article 9 is not viewed as automatically fulfilling the requirements of Article 6. In either event, however, the compelling legitimate interests of the controller would meet the requirements of Arts. 6, 17(1), and 21(1) where they override the data subject's interests.

For instance, a medical device manufacturer may need to obtain consent for the use of products that collect a range of health monitoring data, with little knowledge at the outset of which types of analyses the data subject's physician will need to perform using the device or what data elements may be relevant to the analysis. In some cases, it is not always clear at the time of the consent exactly how particular data elements can provide predictive or diagnostic insights about a patient's health, but it is to the data subject's benefit to be able to provide consent to the processing of those elements anyway. An interpretation that prohibits the use of flexible language would undercut the medical device manufacturer's ability to accurately describe the anticipated processing.

III. CONCLUSION

IPPC/MDPC members have been actively engaged in preparing for the GDPR implementation deadline for nearly two years. However, these new draft guidances would require significant changes to processes that would take large companies longer than the remaining time before the GDPR effective date to implement even if they were to start today.

The IPPC/MDPC thanks the Working Party for the opportunity to comment on these guidance documents. It is our hope that this feedback aids WP29 in its effort to produce a clarifying, useful, and reasonable final guidance.

Please do not hesitate to reach out to us with any questions about these comments.

Sincerely,

Peter A. Blenkinsop
IPPC/MDPC Secretariat

Appendix A: Members of the IPPC/MDPC

3M
Baxter
Abbott Laboratories
AbbVie
Allergan
Amgen
Astellas Pharma, Inc.
BD
Boston Scientific
Bristol-Myers Squibb
Celgene
Eli Lilly and Company
GlaxoSmithKline
Johnson & Johnson
Merck & Co., Inc.
Novo Nordisk
Otsuka Pharmaceutical Co.
Pfizer Inc.
Philips Healthcare
Roche
Sanofi
Shire
Siemens Healthcare
Takeda Pharmaceuticals