INTERNATIONAL
PHARMACEUTICAL
PRIVACY CONSORTIUM

14 December 2015

Mr. Giovanni Buttarelli
European Data Protection Supervisor
Rue Wiertz, 60
1047 Brussels
Belgium

By email to: edps@edps.europa.eu

Subject: EMA External Guidance on Anonymisation of Clinical Reports for the Purpose of Publication in Accordance with EMA Policy 0070

Dear Mr. Buttarelli,

On behalf of the International Pharmaceutical Privacy Consortium (IPPC), I am pleased to provide you with our feedback concerning the European Medicine Agency's development of External Guidance on Anonymisation of Clinical Reports for the Purpose of Publication in Accordance with EMA Policy 0070. Information concerning the IPPC is contained within Appendix A.

As you know, EMA Policy 0070 requires applicants for marketing authorisations for medicinal products to prepare versions of the clinical study reports that have had personal data redacted. (See Policy 0070 at Annex 4.) These reports are to be made available to the public through an online publication process. Policy 0070 defines two sets of Terms of Use applicable to those wishing to access clinical study reports, with the applicable set depending on whether an individual wishes to access the data for general information purposes or if he/she intends to use it for academic and non-commercial research purposes.

We understand that the EMA is developing an External Guidance on Anonymisation of Clinical Reports for the Purpose of Publication in Accordance with EMA Policy 0070 and that consultation with the European Data Protection Supervisor on this guidance document is underway.[1] We welcome the publication of this guidance document as soon as possible but also wish to request that the EDPS, in consultation, as necessary, with EU Member State data protection authorities, confirm that the guidance can be relied upon without fear of violation of

[1] European Medicines Agency, Summary – Second stakeholder meeting on the implementation of EMA policy 0070 (on publication of clinical data for medicinal products for human use), available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/09/WC500194092.pdf.

any member state data protection laws. The processing of personal data by marketing authorisation applicants pursuant to the EMA's instructions as set out in Policy 0070 and related guidance will presumably need to comply with Member State data protection laws, and as a result, companies fear that they could be exposed to actions by local Member State data protection authorities if the guidance is not supported by Member State data protection authorities. **We ask, therefore, that the EDPS, in consultation/conjunction with member data DPAs, issue a statement recognising that compliance with the EMA's Policy 0070 represents a valid legal basis for the anonymisation of clinical study reports and that the EMA's guidance establishes one (or more) acceptable approach(es) for the anonymisation of clinical study reports.**

Nevertheless, many IPPC members have already established mechanisms for sharing clinical study reports and patient-level data with researchers. **So as not to interrupt the mechanisms that have already been established, we urge the EMA, EDPS, and Member State data protection authorities to allow companies flexibility in determining the most appropriate anonymisation methodology.** For example, some companies have adopted a methodology that relies primarily on redaction/alteration of a common set of direct and quasi-identifiers across different types of studies; other companies may choose to differentiate what quasi-identifiers need be removed/altered by study. Both approaches should be viewed as generally acceptable.

Finally, we note that the EMA's summary of the 7 September 2015 Stakeholder Meeting concerning the draft guidance document indicates that "Pharmaceutical industry associations argued that a straightforward and efficient process for anonymisation of documents was needed. In their view, EMA should describe a clear approach based on redaction of the original CSR rather than propose the use of a quantitative assessment of the risk of re-identification. Academia highlighted the challenge with non-analytical or qualitative approaches that can lead to . . . different outcomes depending on the extent of redaction." We believe the EMA mischaracterizes the essence of the debate, for it is not whether a qualitative versus quantitative approach should be adopted. Indeed, all approaches involve (i) the removal of direct identifiers and (ii) removal/alteration of quasi-identifiers, where the determination of which quasi-identifiers need to be removed/altered is based on the probability of each quasi-identifier being used for re-identification purposes. The essence of the issue which the EMA needs to address, however, relates to the determination of which quasi-identifiers need to be removed/altered and whether the list of quasi-identifiers that must be removed/altered can remain constant across all different types of studies; whether it needs to vary based on type of study, and if so, how "type of study" is to be defined; or whether the participants within a particular clinical study are deemed to comprise a closed data set and, thus, quantification must vary by study. This is best illustrated by an example: The age 94 may uniquely identify an individual within a particular clinical study or may identify a small enough group of individuals that the risk is considered unacceptably high (e.g., if there were four such individuals aged 94 within a particular clinical study – i.e., a closed data set –, the risk would be 1/4). However, within all clinical studies of a particular disease area, the risk may be much smaller (e.g., say there were 40 such individuals aged 94, then the risk would be 1/40). Within the entire

population of a particular geographic area, the risk would be smaller still. Thus, how risk is quantified is highly dependent on how the appropriate population is defined. **It is therefore important that, to the extent the EMA guidance endorses a particular "risk threshold" below which data can be considered acceptably anonymised, it clearly explain how such risk is to be measured.**

We thank you for the consideration of our comments and look forward to the publication of the final guidance. Please do not hesitate to contact us with any questions concerning our comments.

Sincerely,

Peter Blenkinsop
IPPC Secretariat and Legal Counsel

CC: Mr. Alesandro Spina
Data Protection Officer
European Medicines Agency

APPENDIX A: INTERNATIONAL PHARMACEUTICAL PRIVACY CONSORTIUM

MEMBERS	Members of the IPPC include: • AbbVie • Amgen • Astellas Pharma • AstraZeneca • Bristol-Myers Squibb • Celgene • Eli Lilly and Company • GlaxoSmithKline • Johnson & Johnson • Merck & Co., Inc. • Novartis • Novo Nordisk • Otsuka • Pfizer Inc. • Roche • Sanofi • Shire • Takeda Pharmaceuticals
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.