IPMPC
International Pharmaceutical & Medical Device Privacy Consortium

14 March 2025

IPMPC Response to the European Data Protection Board's Public Consultation on Guidelines 01/2025 on Pseudonymisation

The International Pharmaceutical and Medical Device Privacy Consortium (IPMPC) appreciates the opportunity to comment on the European Data Protection Board (EDPB) Guidelines 01/2025 on Pseudonymisation. The IPMPC supports the EDPB's efforts to promote clarity and consistent application of data protection requirements across the EU.

The IPMPC is a global privacy and digital policy organization focused on the concerns of the pharmaceutical and medical device industries. With over 40 member companies and hundreds of member participants from around the world, the IPMPC strives to advance members' compliance with privacy, security, AI, and other digital governance obligations, with the ultimate aim of supporting innovation in health diagnostics, treatments, and disease prevention, and enabling the delivery of life-saving and quality-enhancing health care to patients.[1] For nearly 25 years, the IPMPC has actively engaged with policy makers and data protection authorities across Europe to facilitate regulators' understanding of why and how data is processed in the pharmaceutical and medical device industries and to promote policies that align regulatory goals with members' data needs.

The medical technology and pharmaceutical industries share a long history of and commitment to advancing medical science. By turning scientific research into solutions for patients, healthcare professionals, and health systems, the medtech and pharmaceutical industries have contributed to better outcomes for patients and greater efficiency in healthcare.

The European Court of Justice (CJEU) is currently examining whether pseudonymised information must automatically be treated as 'personal data' as to all recipients of such information or whether an assessment is required as to whether a recipient has 'reasonable means' to identify concerned individuals (see EDPS v SRB (Case C-413/23).). In its application to intervene in that case, the EDPB argued that the issues raised overlap and intersect inseparably with the Board's guidance role relating to the adoption of guidelines on the concept of 'personal data' and that of 'pseudonymisation' under the GDPR.[2] In light of this, the IPMPC

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[1] More information about IPMPC is available at www.ipmpc.org. Faegre Drinker Biddle & Reath LLP serves as Secretariat and Legal Counsel to the IPMPC.

[2] Order of the President of the Court, data 29 November 2023 concerning the EDPB application to intervene in Case C-413/23 P, available at https://curia.europa.eu/juris/document/document.jsf?text=&docid=285442&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=24605453.

encourages the EDPB to hold off adopting further versions of the Guidelines 01/2025 on Pseudonymisation until the CJEU has issued its judgment in the case. The CJEU's judgment in the case will provide important legal clarity. To avoid creating confusion or inconsistency, it would be prudent to take the CJEU's judgment into account before conducting further work on the Guidelines.

The IPMPC has had the opportunity to review and fully supports the contributions by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and MedTech Europe to the EDPB's consultation. While a full recitation here of the observations and recommendations in those submissions is unnecessary, we would like to re-emphasize these points:

- The Guidelines should take into account the regulatory frameworks that already exist in pharmaceutical and medical device research that protect the identities of research participants, and care must be taken to avoid creating any conflicts with those frameworks.

- The Guidelines should neither exclude nor impose particular pseudonymisation techniques. While practical guidance is helpful on how pseudonymisation can be achieved, imposing rigid, one-size-fits-all requirements will discourage the adoption of pseudonymisation.

- The Guidelines should recognize that the choice of pseudonymisation techniques must necessarily involve a context-dependent assessment of the cost/burden versus added value of the measures being considered.

We appreciate the opportunity to provide comments on the Guidelines. Please do not hesitate to reach out to us should any of our comments require further clarification.