MedTech Europe's Response to the EDPB Public Consultation on Guidelines 02/2024 on Article 48 GDPR

Introduction

MedTech Europe welcomes the opportunity to contribute to the EDPB's public consultation on Guidelines 02/2024 on Article 48 GDPR. These guidelines play a crucial role in providing clarity and legal certainty regarding the conditions under which personal data may be transferred or disclosed to third-country authorities.

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our mission is to make innovative medical technology available to more people, while helping healthcare systems move towards a sustainable path. MedTech Europe encourages policies that help the medical technology industry meet Europe's growing healthcare needs and expectations. It also promotes medical technology's value for Europe focusing on innovation and stakeholder relations, using economic research and data, communications, industry events and training sessions.

Given that the medical technology industry operates in a highly regulated global environment, clear and practical guidance is essential to ensure compliance while enabling innovation and patient access to medical technologies.

Key Observation and Recommendation

Clarification on the Scope of "Pharmaceutical Products"

Point 13 states that:

> *"Article 48 does not limit the purposes for which data may be requested by the third country authority. Thus, requests from third country authorities issued in different contexts and for different purposes would fall within the scope of the provision e.g. requests from law enforcement or national security authorities, financial regulators or public authorities responsible for approving pharmaceutical products."*

We assume that the reference to "pharmaceutical products" in this context is intended to encompass medical devices and *in vitro* diagnostics, given their regulatory framework and the nature of personal data processing involved. However, to enhance clarity and ensure comprehensive coverage, we recommend explicitly including medical technologies in the wording. A revised formulation could read:

> *"(…) or public authorities responsible for approving pharmaceutical products and medical technologies."* [1]

Closing Statement

MedTech Europe believes that this clarification would enhance the guidelines by ensuring they are clear and applicable across all relevant sectors. We appreciate the EDPB's work in providing guidance on this complex issue and encourage continued engagement with industry stakeholders to ensure that the final version fosters both legal certainty and regulatory compliance.

We remain committed to constructive dialogue and look forward to further collaboration with the EDPB on this important matter.

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[1] *A medical technology is any device, instrument, apparatus, software, or system intended for medical purposes, including diagnosis, prevention, monitoring, treatment, or alleviation of diseases or conditions. This definition includes also digital solutions, such as health apps and artificial intelligence algorithms, services like remote monitoring, and in vitro diagnostics (IVDs).*