

Response to the European Data Protection Board Consultation on the Guidelines 05/2021 on the interplay between Article 3 and the provisions on international transfers as per Chapter V of the GDPR

28 January 2022

Introduction

MedTech Europe welcomes the opportunity to provide comments to the European Data Protection Board (“EDPB”) Guidelines 05/2021 on the interplay between Article 3 and the provisions on international transfers as per Chapter V of the General Data Protection Regulation (GDPR) (hereafter referred to as the “Guidelines”).

Medical technologies (“medtech”) cover products, services or solutions used to save and improve people’s lives. The range of medtech products goes from disposables, diagnostics, capital equipment and surgical innovations, which can be used in a care setting, to implant technology, biomaterials and connected health IT such as eHealth, mHealth, human genome decoding, disease prediction, biobanks, biomarkers and many more. These products and solutions, more often than not, **rely on the collection, analysis, and sharing of health data, to better understand diseases and treat them as part of an efficient and effective healthcare system.**

The continued ability to transfer smoothly patient-related data in and outside of the European Economic Area (“EEA”), is critical to the research and development of new medical technologies, monitoring the safety and effectiveness of existing products on the market, and providing support services for medical technologies currently in use.

Hereby, we aim to seek clarity on some parts of the Guidelines and provide reflections for increasing the impact and the usability of the Guidelines.

Some open questions and reflections

1 - Location of the exporter

MedTech Europe asks to confirm that a transfer of personal data may be carried out by an **exporter who may be located either** in the EU **or** outside of the EU.

The first criterion under **paragraph 7** of the Guidelines suggests that the controller or processor must be subject to the GDPR for the given processing, irrespective of where it is located. Paragraph 10 also states:

"It is worth underlining that controllers and processors, which are not established in the EU, may be subject to the GDPR pursuant to Article 3(2) for a given processing and, thus, will have to comply with Chapter V when transferring personal data to a third country or to an international organisation."

In such a case, where the **controller or processor is not established in the EU but is nonetheless subject to the GDPR** by way of Article 3(2) applying to it, and where such controller or processor shares or makes the data available to another controller or processor in a third country outside the EU, then **this constitutes a transfer** that is subject to Chapter V of the GDPR.

However, **paragraph 4** seems to suggest that the exporter must be located *in the EU*. See in particular the following sentence: "*The following sections aim at clarifying this interplay between Article 3 and the provisions of the GDPR on international transfers in Chapter V in order to assist controllers and processors in the EU...*".

MedTech Europe asks **the EDPB to clarify whether a transfer of personal data may be carried out by an exporter who is located either in the EU or outside of the EU.**

2 - Existence of two different (separate) parties

The second criterion under paragraph 7 of the Guidelines only applies to disclosures of personal data between two different (separate) parties (each of them a controller, joint controller or processor). In that respect, the Guidelines recall that entities which form part of the same corporate group may qualify as separate controllers or processors and thus that the disclosures of personal data between such entities may constitute transfers of personal data. The Guidelines provide the example of an EU subsidiary sharing personal data with its non-EU parent company. However, **the Guidelines do not address the situation of an EU branch office sharing data with its non-EU parent or vice-versa, an EU parent company sharing data with its non-EU branch.**

Given that a branch is a **direct extension of the parent company**, **MedTech Europe asks the EDPB to clarify whether there could be a transfer in that situation.**

3 - Direct disclosure by a data subject in the EU

3.1. Disclosure on the data subject's own initiative

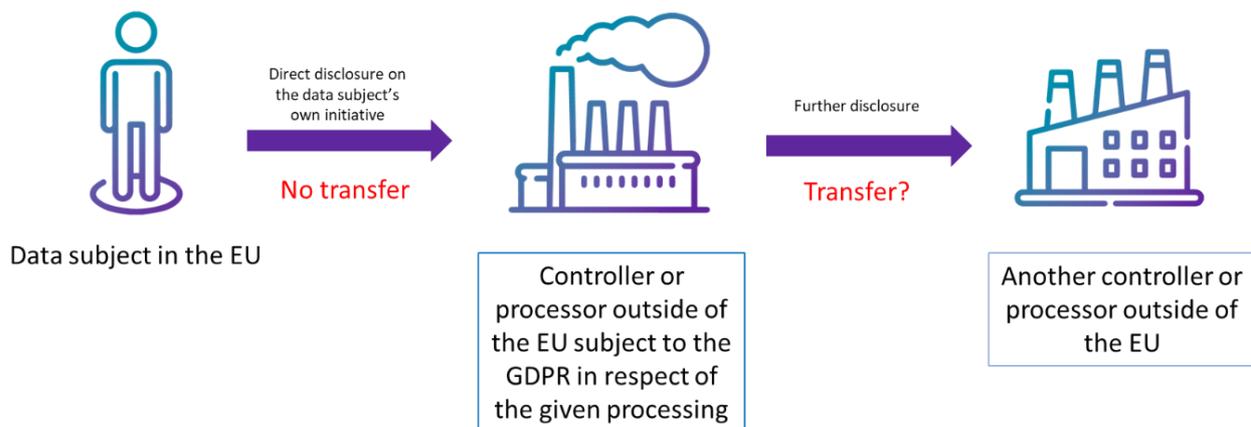
The Guidelines suggest that there is no data transfer subject to Chapter V of the GDPR when personal data are disclosed by the data subject to a recipient outside of the EU (acting as a controller, joint controller or processor) provided that the two following cumulative criteria are met: (1) the data are disclosed directly by the data subject to that recipient; and (2) the disclosure occurs on the **data subject's own initiative**. Example 1 of the Guidelines suggest that the above criteria would apply to the personal data **actively and knowingly**

provided by the data subject to the non-EU recipient (such as name, delivery information, etc.). **It is unclear whether the disclosure by the data subject of observed data (by virtue of the use of the service) would constitute a transfer.** We would welcome it if the EDPB could elaborate on the above criteria and further specify the types of personal data or disclosure scenarios to which those criteria apply and recommend providing some **additional examples**.

MedTech Europe recommends the EDPB to further **clarify whether the disclosure by the data subject of observed data (by virtue of the use of the service) would constitute a transfer.**

3.2. Onward disclosure

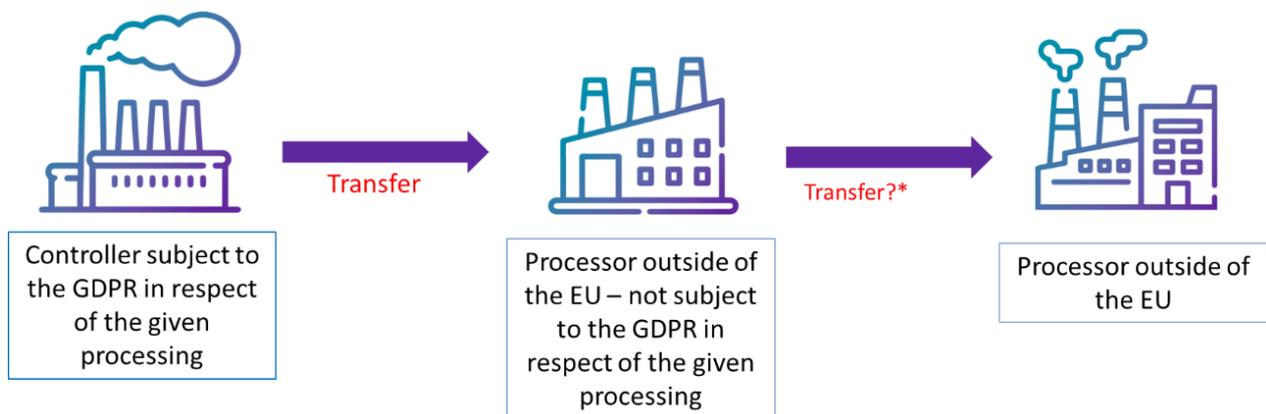
Where the data are disclosed **directly by data subjects** in the EU on their own initiative to a controller or processor located outside the EU subject to the GDPR in respect of that processing (in such case, this does **not** constitute a transfer), and where **that controller or processor shares or makes the data available to another controller or processor also located outside the EU, please confirm whether the latter situation constitutes a transfer** in accordance with the Guidelines and whether Chapter V of the GDPR applies in the latter sharing of data.



MedTech Europe recommends the EDPB to further **clarify the situation of onward disclosures and whether the situation in which controller or processor shares or makes the data available to another controller or processor also located outside the EU would constitute a transfer, following disclosure on the data subject's own initiative** (see visual above).

4 - Onward transfers and location of the importer

By limiting the definition of a transfer of personal data to the disclosure of the data between a controller or processor subject to the GDPR for the given processing to a non-EU controller/processor (the importer), the Guidelines exclude onward transfers from that definition, in cases where the importer is not subject to the GDPR in respect of that processing and further discloses the data to another recipient (in the same or another third country). The intent of Chapter V of the GDPR however is to apply to onward transfers. **Please clarify how the definition of a transfer would apply in the context of onward transfers**, as described above. Should an onward transfer not fall within the definition of a transfer, as provided for in the Guidelines, **we assume that the importer would only have to consider the rules applicable to onward transfers under the initial data transfer mechanism (if any)**. Clarification on this point would also be welcome.



**If, for example, the initial transfer were to be based on SCCs, the SCCs include explicit rules on onward “transfers”, but the further disclosure in the above example would not meet the first criterion provided for in the Guidelines and qualify as a transfer.*

Example: Company A, a Spanish controller subject to the GDPR, uses a Mexican processor - which is not subject to the GDPR - for the processing of personal data relating to its clients. The sharing of personal data between Company A and the Mexican processor constitutes ‘a transfer’, as per the EDPB Guidelines 5/2021. If the Mexican processor uses a Mexican vendor for maintenance of the database of Company A (IT Company C), it is unclear whether this further processing of the data by the IT company C would constitute a transfer as it would not meet the first criterion of what constitutes a transfer as per the Guidelines 5/2021. However, if the initial transfer between Company A and the Mexican processor was based on Standard Contractual Clauses, the further processing of the data between the Mexican vendor and IT Company C would be covered under that agreement.

MedTech Europe recommends the EDPB to further **clarify the situation of onward discloses and whether the situation in which controller or processor shares or makes the data available to a processor also**

located outside the EU would constitute a transfer, following a disclosure of a controller subject to the GDPR (see example and visual on page 4l).

5 - Processor sending non-EU data back to its controller in a third country

We understand that Example 3 of the Guidelines covers the situation in which a **non-EU controller collects personal data of employees or customers located in its country of establishment** (i.e., in a third country) and **sends such data to an EU processor**, who – after further processing – sends back the data to the country of origin.

While we recognise that – in theory – there could be a transfer in this scenario from a processor located in the EU, we **urge the EDPB to explicitly acknowledge the specific nature of that transfer and the limited privacy risks posed by such transfer** since it is a transfer of personal data back to the third country of origin. As recognised by the Guidelines, the provisions of Chapter V aim at ensuring the **continued protection of personal data processed on EU territory** (or personal data of individuals located in the EU). They do not aim at granting protection to personal data of non-EU residents collected outside of the EU by a purported controller (or processor) not subject to the GDPR for that processing. Given the limited risks of a transfer back to the country of origin, **the EU processor should be able to rely on a derogation for that transfer**, such as Article 49(b) or (c) GDPR, as agreed by some EU supervisory authorities in the past¹.

Summarising, MedTech Europe **asks the EDPB to explicitly acknowledge the specific nature and the limited privacy risks posed by a transfer involving an EU processor who received and sent data back to its controller in a third country.**

6 - Consideration of the extraterritorial reach of Article 3(1) of the GDPR & consistency with Guidelines 3/2018 on the territorial scope of the GDPR

The scope of the Guidelines is about the interplay of Article 3 with Chapter V of the GDPR. Nonetheless, the Guidelines focus mainly on the interplay between Article 3(2) and Chapter V of the GDPR. We would recommend including some additional guidance on **the interplay between Article 3(1) and Chapter V of the GDPR** as well as **providing a few examples** that focus specifically on the relationship with Article 3(1)).

If we take Example 1 of the Guidelines and slightly change the facts so that the company established in Singapore has an EU presence (e.g., an office in Berlin to lead and implement commercial prospection and marketing campaigns towards EU markets), we were wondering if in that case, the disclosure of personal data by a data subject through the e-commerce website would still not constitute a transfer of personal data. If we assume that the processing activities are carried out by the company in Singapore and the European office would carry out some of the processing activities, similar to Example 2 of the Guidelines 3/2018 on the

¹ See, in particular, CNIL's Deliberation No. 2011-023 of 20 January 2011 under the previous EU data protection framework.

territorial scope of the GDPR, does that mean there would be a transfer of personal data between the European office and the non-EU company operating the e-commerce website?

We recommend clarifying under which conditions a local establishment of a controller or processor established outside of the EU could be considered an exporter.

7 - Pressing need for legal certainty

The Guidelines encourage the development of a transfer tool, such as a new set of standard contractual clauses (“SCCs”) but only “*in cases where the importer is subject to the GDPR for the given processing in accordance with Article 3(2)*”. We would like to recall **the importance of this new set of Standard Contractual Clauses to take into account all situations where the importer would be subject to the GDPR for the given processing**, either under Article 3(1) or Article 3(2) of the GDPR. In the meantime, **there is an urgent need for legal certainty to address new transfers** of personal data to importers subject to the GDPR in respect of the given processing. Currently, organisations are left in a situation where the SCCs adopted under the previous Data Protection Directive 95/46 have been repealed without any **practical replacement solution** to protect the data transferred to such importers. The European Commission has announced a Q&A on SCCs but clear guidance would be required on the steps to be taken or interim solutions to be relied upon, pending the adoption of that Q&A or the new set of SCCs.

Meanwhile, the EDPB Secretariat has informally mentioned that companies should wait for the new SCCs to be released² and refrain from adopting the new set of SCCs for the types of transfers that do not qualify for the current sets of SCCs. However, **it is not clear when this will happen and what precisely companies should do in the meantime**, creating a situation in which some companies already started to implement the new SCCs but which may need to be replaced once the European Commission publishes its Q&A or the new set of SCCs.

MedTech Europe asks the **EDPB to officially clarify what companies should do until the European Commission has published its decision**. In addition, we recommend the EDPB **continue playing a constructive part in securing transfers of personal data by providing such guidance**.

Conclusion

Concluding, we would appreciate if the above considerations will be taken into account by EDPB, whether it is to update these Guidelines or for the development of additional ones, perhaps more focused on clinical/healthcare research, and we would welcome a further discussion on the specificities of the medtech industry.

² See IAPP LinkedIn Live conversation summary, available [here](#).

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our purpose is to make innovative medical technology available to more people, while helping healthcare systems move towards a more sustainable path. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, please visit www.medtecheurope.org

If you have any further questions, please reach out to:

Caterina Marcon
Privacy Counsel, MedTech Europe
c.marcon@medtecheurope.org