By Email

To: European Commission, DG GROW
Attn.: [redacted] Digital Transformation of Industry, and Maurits-Jan Prinz, Member of the Cabinet of Commissioner Thierry Breton
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Follow up of the 8 July 2022 meeting – specific considerations on the interplay of Product Liability Directive (PLD) and "Collective Redress" Directive (RAD)

Dear [redacted], dear Mr Prinz,

Thank you again for meeting with MedTech Europe last week. In view of our brief discussion relating to the interplay of the Product Liability Directive 85/374/EEC (PLD) with the Representative Actions Directive (EU) 2020/1828 (RAD) and our sectoral legislations (Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR)), we take the liberty of sharing additional considerations on this interplay and providing some preliminary thoughts for discussion.

Our key concern relates to the fact that regulatory (ex ante) and liability (ex post) frameworks covering the medical technology sector have been in constant change affecting the medical technology industry, which has been investing heavily in ensuring readiness. The new MDR and IVDR, which were adopted in 2017, set up stricter rules regulating the safety and performance of medical technology. The Representative Actions Directive (RAD), approved in 2020, created new risks, in particular legal exposure (see below), specific to the medical technology. The foreseen broadening of the scope of the PLD to include "software" further adds to this by heightening the likelihood of an exponential increase in individual and collective litigation.

MedTech Europe fully understands the inclusion of PLD in the RAD scope. It is important that redress for damages suffered by patients by defective medical technologies is ensured in an effective way, individually or collectively. **It is the additional inclusion of the entire Chapter 2 of the MDR and IVDR into the Annex I of the RAD which creates specific and potentially detrimental issues for the medical technology industry as follows:**

- The MDR and IVDR were adopted in 2017 after a decade of discussions between the three EU institutions. The Regulations intend to create a **harmonised regulatory framework** for the market approval of medical technologies, market surveillance[1] and transparency. As major changes are required for all the actors involved (Notified Bodies, national competent authorities, and companies), the full entry into force of the Regulations has been postponed due to the complexity of the implementation. Of all these changes, strengthening the market surveillance system was a key aspect and remains the jurisdiction of **national market surveillance authorities**.

- Both the MDR and IVDR have been included in Annex I of the RAD. This **creates legal challenges and confusion**, notably with national authorities that are responsible for their implementation. In particular, it creates an **overlap between private and public enforcement decisions**, with the former being based on the RAD, and the latter on the IVDR and MDR. This could lead to a **fragmented enforcement of the Regulations across Europe** going against the objectives of the IVDR and MDR.

> **Exhibit:** Civil courts represent a higher authority than national Competent Authorities, meaning that civil decisions on MDR/IVDR matters, due to the addition of MDR/IVDR in the Annex of the RAD, may bind national Competent Authorities. This situation would restrict the national Competent Authorities' discretion to interpret sector-specific legislation, as well as limit their ability to make enforcement decisions and issue regulatory guidance. Competent Authorities have specialist scientific and technical expertise, as well as reporting and transparency provisions, which civil courts have not. With the inclusion of the MDR/IVDR in the Annex of the RAD, civil courts will have the power to challenge or to determine the course of medical devices regulation without specialist scientific and technical expertise nor the responsibility for overall medical device safety and supply chain integrity.

- This could be even more problematic when it comes to the **harmonisation brought by the CE marking**. CE marking of products is a manufacturer' responsibilities, in many cases subject to conformity assessment by Notified Bodies and national Competent Authorities are responsible for market surveillance. They can remove a CE marking; they can also take a national decision, e.g. to ban the sale of a product in their market – with the obligation to notify other Member States and the European Commission.

- In this regard, it is important to note that **the medical devices and in vitro diagnostic medical devices sectors are the only ones that have their CE mark-related regulatory framework added to the scope of the RAD**. Only one other "CE marked" sector is within the scope of the RAD (the Eco-design of energy related products sector), but **the scope is limited to only one article on information to consumers** and the specific annex that explains how this information must be conveyed. The equivalent in the entire Chapter II of MDR and IVDR would be Article 7 on claims made through information provided by the manufacturer, including but not limited to labelling, instructions for use and advertising. **Chapter**

[1] Article93(9) MDR: "The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States"

II covers the entire process of CE marking, obligations of economic operators and free movement of goods, with a much bigger focus on purely regulatory requirements.

> **Example:** A civil court in Member State A declares a medical device has been inappropriately CE marked, during a collective redress action (private enforcement). This decision, instead of being automatically binding in other Member States, as it would have been if brought under the MDR/IVDR, would only be treated as evidence of an infringement in Member State B. This decision could therefore be disregarded by Member State B or their national competent authorities or could be ignored by Courts in other Member States. This would disrupt the harmonisation of the CE Mark within the Union as the medical device would then be illegal in Member State A but not in others.

The above-mentioned situation **will be further affected by the revision of the PLD**, which aims at broadening its scope not only to tangible products but also to "software". Practically, this means that with the increased reliance and use of digital health solutions in the healthcare sector, we expected an exponential increase in individual and collective litigation (considering that in the last 3 years, there already has been a 120% increase[2]).

Despite this, **we also see the revision of the PLD as a possible opportunity to address our concerns, by clarifying the scope of the RAD for the medical technology industry to be exclusively PLD or only the relevant equivalent part to some other sectors e.g., Art. 7 of IVDR/MDR** [information to consumers]. **This would bring the scope in line with the approach followed for all the other industries and create legal certainty for both industry and competent authorities.**

We hope you will find these views helpful, and we remain at your disposal for any clarifications we might be able to provide. Thank you very much for your consideration.

Yours sincerely,

[redacted]

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[2] 2022 CMS European Class Action Report, p.5