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RE: Public consultation on EU Proposal for a Directive on Liability for Defective Products

27 April 2023

To Whom it May Concern,

The Irish Medtech Association is the business association within Ibec representing the medical technology sector. The Irish Medtech Association has more than 250 members, located throughout the island of Ireland. Our vision is for Ireland to be strongly positioned as a global leader in innovative patient centered medical technology solutions, helping to set the future global healthcare agenda, with a proven ecosystem that is a major contributor to the economy.

This will be achieved through the provision of safe and secure medical devices, in vitro diagnostic medical devices, and digital health solutions to more people in the EU. Thus, we fully support the European Commission's objective to ensure effective recourse mechanisms are in place in case a person has been harmed by a defective product.

We welcome the opportunity to provide feedback to the proposed revision of the EU Product Liability Directive (85/374/EEC) (PLD). We have carefully reviewed the Department's Public Consultation Document and have outlined our responses to the questions posed below.

We remain available to discuss the positions as outlined or provide additional detail if required.

Your Sincerely,

Eoghan Ó Faoláin,
Deputy Director,
Irish Medtech Association.

Question 1: What are your views on the scope of the proposed Directive? In your response, please provide specific details to support your position.

The Irish Medtech Association's vision is for Ireland to be strongly positioned as a global leader in innovative patient centered medical technology solutions, helping to set the future global healthcare agenda, with a proven ecosystem that is a major contributor to the economy. This will be achieved through the provision of safe and effective medical devices, in vitro diagnostic medical devices, and digital health solutions to more people in the EU.

Thus, we fully support the European Commission's objective to ensure effective recourse mechanisms are in place in case a person has been harmed by a defective product.

Whilst some of the proposed changes in this proposal were expected (e.g. the broadening of the definition of 'product' to encompass digital technologies), others are significantly more substantial, and have the potential to increase the risk profile indiscriminately for certain product categories - in particular medical technology. The changes as proposed will foreseeably increase product liability litigation, including as class actions. These changes will destabilise the careful balance the original PLD struck between fair and appropriate compensation for consumers where a product is defective, while facilitating timely consumer access to highly innovative medical technologies.

Question 2: What are your views on the definitions included in the proposed Directive, specifically the definition of a product?

In February 2020, the European Commission published a report which calls for a further clarification of the concept of "product" to better reflect the complexity of emerging technologies, such as digital products and software and products using artificial intelligence technology. The Irish Medtech Association believes the current definition of a "product" in the PLD is still relevant and appropriate even when applied to such innovative technologies. The Directive is technology-neutral and has been, amongst other things, applied to cars, vaccines, blood, as well as to a range of medical technologies such as breast implants, pacemakers and artificial hip replacements, proving that it can successfully regulate a wide array and types of products.

Furthermore, for medical technologies, Medical Devices Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR), make no distinction between tangible products and intangible products. There are two main categories in which software is deployed in the medical technology field: (i) embedded software which is part of a medical device (a product) and (ii) standalone software used for medical purposes. The Irish Medtech Association believes that embedded software should be treated as part of a product, allowing any claim to be brought against a medical device producer via the PLD. As part of the product design process, the producer decides what software to use in its products and is responsible for the overall safety of the device.

Standalone software under the MDR/IVDR is subject to significantly stricter regulation than software used in a non-medical setting. In practice, software can only cause damage of the sort contemplated by the Directive (as opposed to, for example, data loss) where it acts through a physical product. In such cases, the patient's claim would not be that the software constituted a defective product, but that the product in which it was installed, was defective as a result of the operation of its software.

Should the legislator consider specific refinements of the definition to make it more suitable for the digital age (e.g. movable products), the Irish Medtech Association advises against overly broad definitions which would lead to lack of clarity, and in turn risk undermining the effective application of the Directive.

In view of these considerations, we see no need to change the definition of 'product' in the PLD with respect to medical technologies. The Irish Medtech Association advises instead to rely on definitions of existing regulations applied via the use of guidance. This would promote a consistent and clear application of rules within the existing regulatory framework.

Question 3: In your opinion, are the conditions under which a natural person has a right to compensation adequate?

The draft proposal includes a fundamental alteration of the principles of the original 1985 PLD – a Directive which established a reasonable balance between protecting consumers who suffer damages, while safeguarding innovation and ensuring legal certainty.

This fundamental alteration contained in the proposal introduces several mechanisms (i.e. rebuttable presumptions and unilateral disclosure of evidence) to reduce the burden on claimants and increase the burden on defendants. This aims to address the perceived challenge that claimants carry the burden of proof in complex cases under the current PLD regime. In this context, the proposed text **specifically calls out innovative medical products** as an example for complex products. This drastically modifies the apportionment of risk between the affected parties, which is the basis for making strategic decisions in modern technological production.

Question 4: Are you satisfied that the list of instances specified in Article 6 is sufficient to capture when a product may be deemed defective?

We see three main issues with article 6:

1) The Medtech industry urges the legislators to drop Article 6(1)(g) as it is far too broad, and it conflates product liability with product safety rules.

The EU's product safety framework provides for a sophisticated regime to guarantee a high level of consumer protection. It is common for producers to be in continuous dialogue with regulators regarding product safety in the field of medical devices. With such extensive requirements in place, it can happen that a producer may find themselves in technical breach of an obligation (e.g. the late submission of a piece/pieces of necessary data). Regulators have the tools to ensure compliance, including tools to find that a breach of a technical obligation has occurred. However, the finding of such a breach in no way amounts to a regulatory determination that a product is unsafe for use or is "defective".

Under the Proposal, even a minor technical breach could be sufficient to allow a product to be presumed defective, even if the regulatory body made no such determination. This should not be taken into account in any assessment of defectiveness, but Article 6(1)(g) provides for this specific possibility. Such a possibility usurps the regulatory function already in operation in the Medtech sector and may lead to conflicting outcomes. In this scenario, even though a competent product safety authority has no issue with a product's risk profile, or with it continuing to be available on the market, the civil liability regime would presume the product to be defective, with all the consequences this entails.

Article 6(1)(g) should be removed from the Proposal. In addition, in the same context, Recital 33 also sets a very worrying precedent, is far too broad and it should be much more limited in scope.

2) The PLD is meant to be technology-agnostic. The Irish Medtech Association believes the references in Recitals 22 and 34 inappropriately prejudge the complexity of innovative medical devices. The portfolio of products in the medical technology industry is extremely diverse, ranging from high-tech products such as surgical robots, to high-impact products, such as implants, to every-day products such as glasses, plasters, COVID-19 tests, and pregnancy tests, to name a few. Thus, a blanket presumption of medical technology as a "complex product" does not reflect the reality of the sector.

   Specifically, the Recital 34 read in conjunction with Article 9 (4) creates a quasi-presumption that all innovative medical devices are complex/high-risk. This, in practice, will result in the reversal of burden of proof for an entire industry sector, which, we believe is unnecessary in light of the strong shift in EU product safety legislation which exists for this specific sector (i.e. MDR/IVDR). These recently updated regulations have significantly upped the rules on safety, transparency, and reporting, including; requiring information to be publicly available on post-market vigilance reporting on adverse safety; as well as so-called facilitation by competent authorities; as well as putting specific emphasis on corrective actions.

   Furthermore, Article 9(4) introduces the concerning notion that the burden of proof should be reversed if a claimant can show a mere "contribution" by the product to the alleged damage,

without even requiring any "materiality". In the field of healthcare, this will foreseeably expose manufacturers to a colossal liability burden, particularly for SMEs and start-ups that represent up to 95% of medical technology manufacturers in the EU.[1]

3) The facilitation of proof for injured parties will be significantly expanded under the proposal. The required causal connection between a product defect on the one hand and the damage on the other hand will in future be presumed in favour of the injured party if the damage was caused by "obvious malfunction of the product during normal use". Article 9.2 c) would appear to consider that any failure of, for example, an orthopaedic device (e.g. dislocation of a hip or knee joint) would presumably be an "obvious malfunction", leading to the reversal of the burden of proof. That, despite the fact that no such product is intended to be absolutely safe, have an unlimited life span and that some failures are inevitable. To date, courts have accepted this does not make those products defective within the meaning of the current PLD.

Question 5: What are your views regarding the range of economic operators that can be held liable for defective products?

The Medtech industry broadly support the intention to align definitions, but notes that for our sector there is not a full alignment, e.g. "fulfilment service provider". The approach taken in the sectoral legislation regulates distance sales (Article 6 MDR/IVDR) and specifies that devices offered to natural and legal persons in the European Union must comply with those regulations. The fulfilment service provider becomes responsible for the device when there is no representative in the EU (i.e. manufacturer, importer or authorised representative). For the sake of legal clarity, we would support alignment with those rules for other sectors.

Question 6: What are your views on the proposal in Article 8 that allows Member States to ensure that national courts, upon a request from an injured person, are empowered to order the defendant to disclose relevant evidence.

The proposal alters the existing risk apportionment and creates a significant imbalance in disclosure of evidence (Article 8), which provides that national courts are empowered to order defendants to disclose 'relevant evidence that is at its disposal' in some circumstances, while such evidence should be 'necessary and proportionate'[2] to support the claim. Claimants should be required to prove reasonable efforts to find the evidence elsewhere, as producers cannot be expected to become the data holder for claimants. Importantly, disclosure obligations should be reciprocal, for instance the final text should clearly state that claimants could be ordered to disclose medical records or other relevant evidence (e.g. social media activity) that are at their disposal. Claimants should also lose the right to rely on the presumption, under article 9, where they failed to disclose the required evidence. Furthermore, national courts should be able to decline such disclosure requests where it considers

them, for example, vexatious, unmeritorious or “fishing expeditions” (e.g. disclosure should only be ordered where this would assist the “fair administration of the claim”).

The draft PLD should also be considered in the wider context, as there is a risk of cross-border requests for disclosure in the context of Representative Actions (or similar). Such applications could be vexatious, particularly as certain Member States, like Ireland, have a more generous disclosure process, and these Member States could be targeted in instances where disclosure is not available in the jurisdiction where the claim originates.

We would also welcome clarification on the very broad (as it currently exists) scope of the evidence that needs to be disclosed by the defendant as per Article 8.

Question 7: Article 9 states that Member States shall ensure that a claimant is required to prove the defectiveness of a product. What are your views on the conditions listed in subsection (2) regarding instances where the presumption of defectiveness exists.

The Irish Medtech Association believes that despite the declared intention of the legislator to preserve the burden of proof and to **safeguard innovation**, the new “rebuttable presumptions” as created in Article 9(2) [3]**,** will in practice lead to a reversal of the burden of proof in many, if not all cases, as related to medical devices. **This will undoubtedly have a negative impact on innovation and a knock-on negative impact on the availability of innovative medical technologies for European patients.**

The second condition provides that: “the claimant establishes that the product does not comply with mandatory safety requirements laid down in Union law or national law that are intended to protect against the risk of the damage that has occurred […]”. This paragraph needs to be read in conjunction with Article 6(1)(f) providing that defectiveness should also consider “product safety requirements”.

It is imperative that the legislator not only uses the same concepts in both articles but furthermore clarifies what these requirements are. For example, it could be clarified that only a breach of mandatory legislative safety-related requirements that are intended to protect against the damage are relevant. It could also explain that the fact that a product, such as a medical device, is compliant with product safety requirements, i.e. IVDR and MDR, is itself a relevant factor (i.e. it’s not just non-compliance that is at issue). In other words, the proposal should use the same wording across the whole text and specify what is meant by "(mandatory) (product) safety requirements". Such a clarification would also support the EU’s safety regulation approach based on the precautionary principle.

Question 8: What are your views on the criteria required to meet the exemption of liability?

Article 10 raises a number of questions of interpretation specifically on the definition of "economic operator" that needs to be aligned with other legislation. Furthermore, for example, point d) would need to be re-worded, as otherwise the question remains - how can the defectiveness of a product be assumed where it is compliant with mandatory regulations? Authorities are regulators not legislators so they would for example issue product recalls, but in the Medtech sector, they would not issue "regulations".

Question 9: The proposal allows that in situations where two or more economic operators are liable for the same damage, they can be held jointly liable. What are your views on this proposal.

Please see comment above about the need to define "economic operator" in line with other legislation.

Question 10: What are your views on the time limits proposed in Article 14(1),(2) and (3)? If you are of the view that the time limits proposed are not sufficient, please provide details to support same.

Under the PLD, an injured person has 3 years within which to seek compensation. The period starts from the date on which the person becomes aware of the damage, the defect, and the identity of the producer. Separately, the producer can no longer be held liable 10 years after the date the product was put on the market. This is part of the balance that the Directive seeks to strike between the need to protect potential claimants' interests and providing legal certainty to industry.

Such expiry periods - already much longer than traditional warranties that are typically 2 years - are also in line with the notions of "lifetime" or "shelf-life" in industry specific regulations setting time limits for proactive obligations of manufacturers. They are also important for all stakeholders, as they provide certainty about the risk of claims for a product placed on the market and are essential for insurance purposes.

Therefore, the Irish Medtech Association believes that the current liability period is justifiable and considers any extension to this period to be disproportionate given its impact on insurability and thus economic viability of placing innovative medical technology on the market.

If you have any comments on this Chapter or on the proposal not covered in the questions above, including specific suggestions or amendments, please set them out below:

a) **An obvious malfunction was not a "defect" until today**

The facilitation of proof for injured parties will be significantly expanded under the proposal. The required causal connection between a product defect on the one hand and the damage on the other hand will in future be presumed in favour of the injured party if the damage was caused by "obvious

malfunction of the product during normal use". Article 9.2 c) would appear to consider that any failure of, for example, an orthopaedic device (e.g. dislocation of a hip or knee joint) would presumably be an "obvious malfunction", leading to the reversal of the burden of proof. That, despite the fact that no such product is intended to be absolutely safe, have an unlimited life span, and that some failures are inevitable. To date, courts have accepted this does not make those products defective within the meaning of the current PLD.

b) Psychological health

Article 4, 6 (a) broadens the definition of damage to also include "medically recognised harm to psychological health". The lack of further clarification creates the risk of "worried well" claims (i.e. anxiety about developing future disease) and more broadly does not consider that a certain level of anxiety is always present when patients have to undergo any medical treatment. It also lacks clarity about the scope of material loss related to psychological harm, e.g. cost of treatment, loss of income.

c) General comments

The Proposal should be considered in the context of other related legal requirements, not only safety related, but also "procedural", such as, for example the Representative Actions Directive. The Proposal increases the litigation risks, rather than encouraging and facilitating alternative dispute resolution mechanisms (even though the Commission has itself found that litigation to be less effective, less equitable and more expensive means to obtain compensation[4] than out of court mechanisms). In this respect, the Proposal represents a missed opportunity to promote more appropriate means of redress for injured parties.

The Proposal also risks causing confusion due to overlaps with the AILD and the lack of alignment with existing legislation (such as safety regulations), and it would make the legal framework for producers unnecessarily complex in the EU.

As written, the Proposal in practice represents an upheaval of 40 years of case law and jurisprudence, creates an environment of significant legal uncertainty for businesses in which to operate, and will adversely impact European patients access to innovative medical technologies.

[1] The European Medical Technology Industry in Figures 2022 https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf

[2] The interplay with the removal of the €500 threshold for product liability litigation is important as well, for the purpose of the proportionality requirement. Disclosure of evidence carries a cost for the defendant, which may be much more extensive than the worth of the actual claim, in particular if it is a "small claim".

[3] The article provides that "where (i) a defendant fails to comply with an obligation to disclose relevant evidence; (ii) the claimant establishes that the product does not comply with mandatory safety requirements; and (iii) the claimant establishes that the damage was caused by an obvious malfunction of the product during normal use or under ordinary circumstances, then the defectiveness of the product will be presumed (although defendants will have the right to rebut any such presumptions).

[4] European Commission, Alternative Dispute Resolution for Consumers, available at: https://ec.europa.eu/info/live-work-travel-eu/consumer-rights-and-complaints/resolve-your-consumer-complaint/alternative-dispute-resolution-consumers_en.