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LIFE SCIENCES REGULATORY INSIGHT

Product liability in life sciences

Key Features of the Revised PLD

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Welcome

The EU's revised Product Liability Directive (Revised PLD) represents a significant shift in the EU's product liability landscape. With its expanded scope, modernised definitions, and evidential reforms, the Revised PLD is particularly relevant to the Life Sciences sector.

In this article, we explore the key features and implications for manufacturers, developers, and stakeholders in the sector.

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The European Commission's reform agenda

Historically, the concepts of product safety and liability used to be confined to 'bricks and mortar' products. Now, the term 'products' encompasses much wider concepts, including:

- Software
- AI systems
- Mobile apps
- Hardware products with integrated software, and
- IoT-connected products.

To address these developments, the various product safety and liability legislative frameworks have recently undergone significant reform at the European Union level. As part of this reform, the EU has adopted a range of complementary product safety and liability measures designed to meet the challenges of the digital age and deployment of artificial intelligence (AI).

A cornerstone of this package of measures is the EU's Artificial Intelligence Act 2024[1] (AI Act). It entered into force on 1 August 2024. The AI Act seeks to foster trustworthy AI through compliance with regulatory requirements and managing the relationship between providers and regulators. The Revised Product Liability Directive[2] is another central component of this reform agenda and works alongside the AI Act. It has adapted the strict liability regime applicable to producer liability for defective products[3]. The changes aim to address liability issues arising from digital technologies and AI, circular economy business models, and global value chains.

Originally intended to operate in tandem with the now-shelved proposal for an EU Artificial Intelligence Liability Directive (AILD), the Revised PLD now assumes a more prominent role. In addition to the AI Act and the Revised PLD, other complementary legislative measures include a revision of horizontal product safety rules (the General Product Safety Regulation[4] or GPSR) and sectoral product safety legislation.

For the Life Sciences sector, there has also been significant recent sectoral product safety legislative reforms including the EU Medical Device Regulation[5] (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation[6] (IVDR). Similarly, expected reform is underway for medicines with the European Commission's proposal for a new Directive[7] and a new Regulation[8] to revise and replace the EU's current general pharmaceutical legislation (the EU Pharmaceutical Package).

These significant reforms underscore the EU's holistic approach to safety and liability, recognising that they are two sides of the same coin. While legislation like the AI Act and the GPSR aim to prevent harm through risk management and regulatory compliance, the Revised PLD ensures that where these measures fail, effective remedies and redress are available to consumers. In this way, the Revised PLD plays a critical role in reinforcing consumer trust and legal certainty in the use of digital technologies across the internal market.

[1] Regulation (EU) 2024/1689
[2] (EU) 2024/2853
[3] Product Liability Directive 85/374/EEC
[4] (EU) 2023/988
[5] Regulation (EU) 2017/745
[6] Regulation (EU) 2017/746
[7] https://oeil.secure.europarl.europa.eu/oeil/en/procedure-file?reference=2023/0132(COD)
[8] https://oeil.secure.europarl.europa.eu/oeil/en/procedure-file?reference=2023/0131(COD)

One of the key functions of the Revised PLD is to close existing gaps in liability. It does this by extending strict liability to cover software and digital products. It also clarifies the definition of "defect" in the context of software and AI. In addition, it enhances access to evidence and easing the burden of proof for claimants in certain circumstances. These changes aim to ensure that injured parties can obtain redress in situations where software and AI systems cause harm, even where fault is difficult to establish.

For those operating in the Life Sciences sector, particularly manufacturers and providers of innovative technologies, this reform marks a critical shift. Given how this reform may significantly affect their liability exposure, manufacturers and developers in the Life Sciences sector should familiarise themselves with key features of the Revised PLD.

Product Liability Directive

The Product Liability Directive[9] (PLD) established an EU-wide system of strict liability for product liability claims. This means that there is no requirement for a claimant to prove that a defendant producer was negligent or at fault.

The PLD provides that a producer is liable for damage caused wholly or partly by a defect in their product. A product is considered 'defective' if it fails to provide the safety that a person is entitled to expect. This assessment is an objective one. It is carried out with regard to what the public is generally entitled to expect, and with reference to a range of circumstances, including:

- The presentation of the product
- Its reasonably expected uses, and
- The time it was put into circulation.

The concept of 'putting a product into circulation' isn't explicitly defined in the PLD. However, case law from the Courts of Justice of the EU clarifies that a product is put into circulation when the product leaves the production process and enters a marketing process in the form it is offered to consumers. This includes products like medical devices that are not explicitly placed 'on the market' prior to their first use.

Under the PLD, the burden of proof is on the claimant to prove the damage, the defect, and the causal relationship between the two. In Ireland, claimants commonly bring a product liability claim in tandem with a claim in negligence and/or in contract.

Several statutory defences are available to producers under the PLD and, if successfully invoked, a defendant can avoid liability for a defective product. These defences include:

- That the defect did not exist at the time the product was put into circulation, or that the defect came into being afterwards
- The 'state of the art' defence – i.e., that the defect was not discoverable due to the state of scientific and technical knowledge at the time the product was put into circulation.

It is also important to be aware that there is a limitation period of three years to bring a claim under the PLD. This is subject to a longstop provision where a claimant's right of action will be extinguished 10 years after the product's date of circulation, if they haven't brought a claim in that time.

Revised Product Liability Directive

The PLD was adopted in 1985. In the 40 years since, we have seen a dramatic change in the types of Life Sciences products on the market due to developments in technologies like AI and machine learning. There has also been an increase in products imported directly from outside the EU, and the emergence of new actors in the supply chain, like online marketplaces. As a result, the European Commission proposed a reform of the PLD to address these challenges.

The Revised PLD was adopted by the European Parliament in March 2024. It was then formally adopted by the European Council in October 2024. The Revised PLD entered into force on 8 December 2024 and applies to products placed on the market 24 months after this date. There will be a lengthy transitional period during which product liability claims may be brought under either the PLD or the Revised PLD, depending on which regime is applicable. Member States have until December 2026 to transpose the Revised PLD into their national legislation.

The Revised PLD is designed to ensure that the EU's strict product liability regime remains fit for purpose. This is particularly important in an era of increasingly complex and software-driven technologies, including AI systems.

[9] 85/374/EEC

The Life Sciences sector is particularly affected, as the use of AI and software in products like digital health tools and medical devices may now lead to greater liability risks for manufacturers and developers under the Revised PLD.

This liability exposure for harm caused by a defective product may continue to arise in the traditional sense, or where the defect stems from complex or autonomous behaviour of AI-driven systems. As a result, relevant stakeholders in the Life Sciences sector should familiarise themselves with the noteworthy reforms and features under the Revised PLD, including:

- **Product:** Under the PLD, the general consensus was that liability applied only to software embedded in tangible products, meaning standalone or digital-only software typically fell outside the scope of the regime. This uncertainty has been categorically addressed by the Revised PLD, which expands the definition of a 'product' to expressly include software. This revised definition includes both standalone software and digital manufacturing files. It makes clear that software is a product, irrespective of the mode of its supply or usage and whether it is stored on a device or accessed through a communication network, cloud technologies or supplied through a software-as-a-service model.

While the term 'software' is not defined in the Revised PLD, the recitals make clear that it applies to software of all kinds, including operating systems, firmware, computer programmes, applications, and AI systems.

The Revised PLD includes several limited exceptions. One exception concerns pure information, such as software source code. Another applies to free and open-source software that is not developed or used as part of a commercial activity.

This wider definition of what is considered a 'product' will expand the scope of liability for software products beyond those incorporated into a tangible product, as required under the PLD. As a result, it will have far-reaching consequences for software developers in the Life Sciences industry. This means that medical apps, AI-based diagnostic tools, and software-dependent medical devices could all give rise to claims under the Revised PLD.

- **Defectiveness:** New factors have been added into the Revised PLD for determining whether a product is defective. These include a device's cybersecurity vulnerabilities, self-learning functionality, and interconnectedness. For example, this could apply to a smart insulin pump that communicates wirelessly with a continuous glucose monitor and a smartphone app.

- **Defendants:** The Revised PLD expands the pool of 'economic operators' that can be held liable for a defective product. In addition to manufacturers, importers, and in some cases, distributors of a product or a component of a product, the Revised PLD also includes:

  - The providers of related services [10]
  - Authorised representatives
  - Fulfilment service providers
  - Third parties making substantial modifications to products already placed on the market, and
  - Online platforms in certain circumstances. This occurs when they play more than a mere intermediary role in the sale of products between traders and consumers.

The Revised PLD's expanded definition of an 'economic operator' is designed to ensure that there is always an EU-based representative liable for damage caused by a defective product. This could be the designated authorised representative, importer, or fulfilment service provider.

The inclusion of related service providers is particularly relevant to the Life Sciences sector. This is because many medical devices now use and rely on cloud-based platforms, AI-driven analytics, and app integrations to deliver remote patient monitoring in real time. The Revised PLD includes as an example of a related service '*a health monitoring service that relies on a physical product's sensors to track the user's physical activity or health metrics'*. As a result, related service providers that may previously have considered themselves outside the scope of strict product liability laws, now have a potential liability exposure if their service contributes to a product's defect and ultimately, to any harm caused to consumers.

Damage: The definition of 'damage' has been extended under the Revised PLD. It now brings in scope medically recognised damage including psychological health and damage from the destruction or corruption of data not used for professional purposes. Now, a product may be considered defective even in the absence of a physical injury, for example where using a defective product causes the claimant severe stress or anxiety.

- **Scope of liability:** One of the previous statutory defences allows the original manufacturer to avoid liability for defects that emerge after the product is put into circulation. Under the Revised PLD, the scope of liability may be extended to the time after a product was put into circulation where it is still under the manufacturer's control.

[10] A digital service that is integrated into or inter-connected with a product without which a product would be incapable of performing some or all of its functions.

For example, where a product has been substantially modified through software updates. This is particularly significant for connected devices, where the hardware manufacturer retains the ability to supply software updates or upgrades to the hardware by itself or via a third party. As a result of these new provisions, manufacturers of medical device products with digital elements may be liable for damage arising from changes to those digital elements that occur after the physical product is placed on the market.

- **Discovery:** The Revised PLD introduces a discovery model for statutory product liability claims. Under this model, a claimant who has presented facts and evidence sufficient to support a plausible claim can seek an order from a defendant to disclose relevant evidence at its disposal. While this is a significant development for civil law EU countries, it would have minimal effect in Ireland as we already have discovery in civil proceedings. In addition, the Revised PLD expressly acknowledges that it does not affect national rules on pre-trial disclosure of evidence. The Revised PLD provides that where a defendant fails to disclose relevant evidence in response to a request, the product in question will be presumed to be defective.

- **Rebuttable presumptions:** The Revised PLD contains rebuttable presumptions on defectiveness and causation designed to ease the burden of proof for claimants. For example, in cases where a product is technically or scientifically complex, it may be excessively difficult for a claimant to prove the defect or the causal link between the damage and the defect. In these cases, a court may presume the defectiveness of the product or the causal link, if the claimant has met certain conditions.

  The Recitals to the Revised PLD offer guidance on how national courts should assess technical or scientific complexity on a case-by-case basis, taking into account a range of factors. These include the complex nature of the product itself, with innovative medical devices expressly cited as an example of such a complex product. Reference is also made to other factors including the complex nature of the underlying technology, such as machine learning, and the complex nature of the information and data to be analysed by the claimant.

  The Recitals also highlight the potential complexity of establishing causation. For example, proving a link between a pharmaceutical or food product and the onset of a health condition or demonstrating a connection that requires an understanding of the inner workings of an AI system.

  The Recitals to the Revised PLD also offer guidance about how an assessment of excessive difficulties should be carried out by national courts on a case-by-case basis. While a claimant should provide arguments to demonstrate excessive difficulties, proof of these difficulties should not be required. The Recitals to the Revised PLD give an example of a claim concerning an AI system and note that a claimant should not be required to explain an AI's system's specific characteristics or how those characteristics make it harder to establish a causal link.

- **Limitation provisions:** The Revised PLD contains two modifications to the pre-existing ten-year 'longstop provision' or 'expiry period'[11]:

  - First, an extension to 25 years in certain cases involving latent personal injuries, unless the injured person has, in the meantime, initiated proceedings against a potentially liable economic operator.
  - Second, where a product has been substantially modified, the calculation of time runs from the date that the substantially modified product has been placed on the market or put into service.

- **Collective redress:** Businesses may not only be liable for harm caused to individual consumers by defective products. They may also be subject to a collective redress action if a product defect impacts the collective interests of a group of consumers/litigants under the Collective Redress Directive[12](CRD).

[11] A claimant's right of action is extinguished upon the expiry of a specified time limit from the date the product was placed on the market or put into service, unless legal proceedings have been initiated against an economic operator within that period.

[12] 2020/1828

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Artificial Intelligence Liability Directive

As discussed previously, alongside the revisions to the PLD, the EU also proposed the Artificial Intelligence Liability Directive (AILD) to revise and harmonise Member States' non-contractual, fault-based rules concerning claims for injuries caused by AI systems. In Ireland, this would have impacted on claims in negligence under tort law.

While the PLD provides for a harmonised application of strict liability rules across the EU, the more 'traditional' fault-based rules tend to vary widely across Member States. The AILD sought to address the concern that Member States would apply their national fault-based rules inconsistently to cases about AI systems and models.

The European Commission announced the withdrawal of the AILD from its 2025 Work Programme [13] on 11 February 2025. The reason provided for its withdrawal was that the Commission saw 'no foreseeable agreement' on the proposal.

The Commission stated that it would assess whether another proposal should be tabled, or another type of approach should be chosen. This may provide an opportunity for stakeholders to express their opinions on what, if any, new proposal or approach should be adopted to specifically address damage caused by AI systems.

Conclusion

The extended scope of the Revised PLD reflects the evolution of product liability within the EU and the realities of modern, technologically advanced products. In the absence of the AILD, the AI Act and the Revised PLD will act as a bilateral model for regulating safety and liability. This will lead to greater harmonisation in how AI systems are regulated under EU product safety and liability law.

For the Life Sciences sector, where AI is increasingly integrated into medical devices, diagnostics, and digital health tools, the expanded scope is particularly impactful.

The potential liability exposure of manufacturers and producers is increased by a range of notable features under the Revised PLD including:

- The inclusion of standalone software and AI systems within the definition of a product
- The broader range of economic operators who may be held liable for damage caused by a defective product, and
- The introduction of rebuttable presumptions of defectiveness and causation.

As Member States move to transpose the Revised PLD into their national legislation by the December 2026 deadline, companies in the Life Sciences sector should assess these reforms. In addition, they should consider how these reforms may affect their product development, risk management, and litigation strategies moving forward.

[13] https://commission.europa.eu/strategy-and-policy/strategy documents/commission-work-programme commission-work programme-2025_en

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