Juristische Zeitschrift für Pharma, Biotech und Medtech
Revue juridique des technologies pharmaceutiques, bio- et médicotechniques
Law journal for pharma, biotech, and medtech

Life Science Recht

www.LSR.recht.ch

4/2024

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Stämpfli Verlag

The New EU Product Liability Directive

A Warning to the Life Sciences sector

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Keywords: product liability, risk, injury, litigation, manufacturer liability

Abstract: The life sciences industry in the European Union faces increasing legal risk. As the regulatory compliance burden constantly increases, so too does the risk of product liability litigation. This dual risk of public and private enforcement should not be underestimated. This is especially true because the new EU Product Liability Directive deliberately seeks to make it easier for individuals to win when they sue organisations. However, risk can be minimised when commercial strategy includes a realistic analysis of legal risk. This article gives an overview of product liability litigation in general and highlights key changes relevant to life sciences in the new EU Product Liability Directive, which is set to enter into force in late 2024.

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* The author represents here his personal opinion.

I. Introduction

The threat of product liability litigation against life sciences companies is increasing.

The European Union Product Liability Directive was passed in 1985. It has recently been revised in a way that makes it easier for an individual to sue a life sciences company alleging that a product caused either physical or psychological injury.

The life sciences industry is, whether fairly or not, a target for product liability claims. Products intended to improve human health might in some cases not have the intended result, or might be suspected of causing an adverse event simply because the product was part of the medical history of a patient. The international nature of the industry creates additional risk, because regulatory and litigation issues on the same product can arise in many jurisdictions simultaneously, and litigation in one jurisdiction can also influence another.[1]

Product liability risk needs to be considered at many stages of the operations of a life sciences company: from product development, to drafting product information, to quality in the manufacturing process, to pharmacovigilance. Also, due diligence for corporate transactions will uncover current or impending product liability issues and could jeopardise a potential merger or acquisition.

Product liability litigation can be extremely costly, both financially and reputationally.[2] Organisations will often have insurance to mitigate the risk of product liability claims.[3] However, even then, reputational risk and loss of management time responding to

1 For example, product liability litigation is very common in the United States and court findings or fact research by well-funded plaintiff firms there can inspire or influence litigation in other jurisdictions. Equally, the demand-side equation to the United States litigation industry means legal developments in Europe are monitored by plaintiff lawyers in the United States.

2 For example see the experience of Bayer following its acquisition of Monsanto and subsequent litigation concerning the safety of the weed-killer product Roundup – 'Can Bayer recover from its chronic pain', The Economist, 7 March 2024 https://www.economist.com/business/2024/03/07/can-bayer-recover-from-its-chronic-pain.

3 The European Commission estimate about 80% of producers in the EU have insurance cover for product liability claims, though that figure is lower for small enterprises (about 70%) – see page 215 of 'European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Impact assessment study on the revision of the Product Liability Directive (PLD) 85/374/EEC' – No. 887/PP/GRO/IMA/20/1133/11700 – Final report, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2873/138110.

claims are an unwelcome burden. Litigation may also prompt regulatory action, or vice versa.

Product liability risk will affect every organisation differently. In some circumstances, it can hinder innovation; but conversely, in other situations, it can drive innovation and improve patient safety.[4] These divergences show us why life sciences organisations should analyse legal risk based on their specific circumstances, including: the jurisdictions in which they operate[5]; the nature and use of their products; their supply chain and product life cycle; and their ability to withstand litigation if any does emerge.[6]

It is true that litigation risk is lower in Europe than in the United States, where product liability litigation against manufacturers is common and awards of damages can be in the hundreds of millions of dollars or more.[7] However, that is comparing Europe to an extreme, and the level of legal risk in Europe is increasing as more pro-consumer laws are passed.

This article will explore the policy background behind the original 1985 Product Liability Directive (PLD) and the new PLD, before highlighting some of the key changes in the new PLD which demonstrate why legal risk is increasing for life sciences companies, and then will set out some ideas on how to mitigate the risks that arise from those changes.

II. A little history and the first Product Liability Directive (1985)

For law students in common law jurisdictions, one of the most famous cases they encounter is a product liability case: *Donohoe v Stevenson*.[8] The case was decided by the House of Lords in England in 1932. It is memorable for its facts (a consumer found a decomposed snail in the bottle of ginger beer they were drinking). For lawyers, it is significant because it established the law of negligence in common law jurisdictions. After the decision in *Donohoe v Stevenson,* consumers could sue manufacturers for injuries caused by products, even if there was no contract between them. That legacy is embodied in the PLD today, as individuals do not need to have a contract with a producer (or other entity in the supply chain) to be able to make a legal claim.

Also in the 1930s, the regulation of medicinal products began to increase in the United States, as the Federal Food, Drug, and Cosmetic Act was passed in 1938. The Act was motivated by the death of around 100 people in 1937 due to a poisonous antibiotic, elixir sulfanilamide.[9] The Act gave the power to the regulator (the FDA) to order the withdrawal of unsafe drugs, as even with a known dangerous substance like elixir sulfanilamide it did not at the time have the legal power to seize the product on safety grounds and had to rely on the product having been mis-sold as an 'elixir' when it was a 'solution'.[10]

Another tragedy occurred in the early 1960s, as the thalidomide sedative drug caused severe deformities in newborn children if taken at a certain stage of pregnancy, with an estimated 10,000 people affected worldwide.[11] In 1972, 36 children died in France when a talcum powder product was mixed accidentally with a poison, leading French politician Jacques Sourdille to criticise that the free circulation of products in Europe *"should not be confused with the free circulation of poisons"*.[12]

Ultimately these tragedies and the growth of consumer protection as a concept and policy goal[13] inspired increasing product regulation and also the first statutory liability system for products in the European Union, the Product Liability Directive (PLD).

The PLD was initially proposed in 1976 and finally became law in 1985 (85/374/EEC).[14] The European Union (EU) was becoming concerned not just with

4 Galasso, Alberto, and Hong Luo. 2022. "When Does Product Liability Risk Chill Innovation? Evidence from Medical Implants." American Economic Journal: Economic Policy, 14 (2): 366–401.

5 This is especially important in the life sciences sector given certain countries have little product liability litigation as state or industry funded compensation schemes are available for patients with injuries proven to have been caused by a medicinal product, while about half of EU Member States have compensation schemes for vaccine injuries, though that is not always a barrier to litigation as seen currently with litigation claims in England relating to Covid-19 vaccines despite a state vaccine compensation scheme there.

6 The life sciences industry has operators of varying sizes, with larger companies typically dominating the pharmaceutical sector due to high barriers to entry (EFPIA suggest it takes on average $2.558 billion and 12–13 years for a pharmaceutical company to bring a product to the market. See EFPIA, The Pharmaceutical Industry in Figures, available at: https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf). Meanwhile, MedTech Europe estimate that 90% of the European medical technology industry is SMEs (see MedTech Europe Facts & Figures 2024, available at: https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europes-facts-figures-2024.pdf).

7 See for example the Johnson & Johnson talcum powder litigation which may cost more than $9 billion. 'Johnson & Johnson adds $1.1 billion to proposed talc settlement', Reuters, 5 September 2024, available at: https://www.reuters.com/business/healthcare-pharmaceuticals/johnson-johnson-wins-over-long time-holdout-talc-settlement-wsj-reports-2024-09-04/.

8 [1932] AC 562.

9 'The Accidental Poison That Founded the Modern FDA', The Atlantic, 16 January 2018, available at: https://www.theatlantic.com/technology/archive/2018/01/the-accidental-poison-that-founded-the-modern-fda/550574/.

10 'Sulfanilamide Disaster', the FDA Consumer Magazine, June 1981 issue, available at: https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf.

11 See website of the manufacturer Grünenthal: https://www.thalidomide-tragedy.com/the-history-of-the-thalidomide-tragedy (accessed 6 September 2024).

12 'The European Parliament and the Origins of Consumer Policy' study as part of the Eureopean Parliament History Series, March 2024 https://www.europarl.europa.eu/RegData/etudes/STUD/2024/757647/EPRS_STU(2024)757647_EN.pdf (page 13, accessed 6 September 2024).

13 Ibid, page 25.

14 The text of the original PLD is available at: https://eur-lex.europa.eu/eli/dir/1985/374/oj.

promoting economic growth but also the rights, health and safety of citizens and consumers.

This long, 9-year period from the initial proposal in 1976 to the PLD entering force in 1985 gives some insight into the level of political tension on the policy choices in this area. There was criticism of the directive from across the political spectrum in the European Parliament: on the left, because in their view the protection of consumers remained insufficient; on the right, because the directive would allegedly damage innovation and the entrepreneurial spirit.[15]

The PLD sought to balance those perceived tensions, and that debate has continued with the recent revision to the PLD (discussed below).

This political debate is not just a matter of historical interest but is central to understanding the legal rules that have developed in the area. At its core, the policy behind the law is that the company that manufactures a product which injures a person ought to pay compensation, subject to some exceptions to ensure a degree of balance between consumer and producer.

This is seen as a fair allocation of risk in a consumer society, in part because the producer can insure against the risks of claims. The second recital of the original PLD captures this thought: *"liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production."*

Several decades before that, in 1944 the policy was articulated by Justice Traynor in the United States in a case where a bottle of Coca-Cola exploded *(Escola v. Coca-Cola Bottling Co. (1944) 24 Cal. 2d 453, 462, 150 P.2d 436)*:

> *"Even if there is no negligence* [by the manufacturer], *however, public policy demands that responsibility be fixed wherever it will most effectively reduce the hazards to life and health inherent in defective products that reach the market. It is evident that the manufacturer can anticipate some hazards and guard against the recurrence of others, as the public cannot. Those who suffer injury from defective products are unprepared to meet its consequences. The cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business."*

The strict (no fault) liability in the original PLD was based on a test that manufacturers would be liable if their product caused an injury and failed to deliver the safety a person was entitled to expect from the product.[16]

The safety a person is entitled to expect is based on numerous factors, including any warnings in the product literature. If a particular side effect is warned about and a patient then develops that side effect, the patient would struggle to convince a court that they were entitled to expect the product would not cause that side effect.

The original PLD also contained the safeguard for manufacturers of the 'development risk defence'.[17] If a side effect develops which was not foreseen, a manufacturer may be able to rely on the defence if the level of scientific knowledge at the time the product was sold meant the existence of the side effect could not be discovered.

There have been a relatively low number of court judgments on the PLD across Member States.[18] However, the absence of court decisions is not a useful barometer for assessing the overall importance of the PLD. Product liability cases are often complex and therefore are expensive and difficult to bring to a trial. If the case is strongly in favour of either claimant or defendant, it is very unlikely the case would be determined by a judge.

The European Commission impact assessment study on the revision of the PLD[19] explained that one of the two problems the new PLD has sought to address is that *"injured parties face difficulties in claiming compensation for damages caused by defective products"*. The perception is therefore that the old PLD is not pro-consumer, or at least not sufficiently so. That perception may be about to change.

III. The new Product Liability Directive (2024)

After almost 40 years, the PLD has been updated by EU lawmakers.[20] Political agreement on the new PLD has been reached, and the text is subject only to final proof-reading. The final text is set to be signed in or around October 2024. There will be a two-year transition period during which Member States must pass national laws to give effect to the directive. At the end of the two-year period, the new law will apply to products sold from that day onwards. Therefore, a product sold in 2025 will remain subject to the old PLD, even if litigation in connection with that product is brought in, say, 2027.

The headline reason for updating the PLD is described by the European Commission as *"adapting liability rules to the digital age, circular economy and global value chains"*.[21] The new PLD does account for

15 Ibid, note 13.
16 Article 6.
17 Article 7(e).
18 European Commission: Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Impact assessment study on the revision of the Product Liability Directive (PLD) 85/374/EEC – No. 887/PP/GRO/IMA/20/1133/11700 – Final report, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2873/138110.
19 Ibid.
20 For the text of the New PLD as adopted see: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0132_EN.html.
21 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12979-Civil-liability-adapting-liability-rules-to-the-digital-age-and-artificial-intelligence_en.

those three modern issues, but lawmakers have taken the opportunity to improve the rights of consumers in other ways too.

It is important to say that the new PLD does retain the development risk defence[22] and the core test of defectiveness is still based, at least in part, on entitled expectations of safety rather than an absolute standard of safety[23].

The new law is the outcome of the typical legislative process in the EU, including contributions from various industry groups. From the life sciences sector, the industry body EFPIA warned in its 2022 submission on the draft directive that: *"In order to protect themselves against unnecessary speculative litigation risks, producers will likely have to spend more on insurance premiums and legal fees, as well as devoting time to defensive market strategies, instead of innovating. This will ultimately be reflected in consumer prices and the availability of products on the market, and may even require producers to pull out of certain markets altogether."*[24]

There is some merit to that submission, because the Commission's impact assessment estimates that the new PLD will cause a 5% increase in the number of claims for personal injury due to defective products.[25] A 5% increase might not appear hugely significant when viewed in isolation. However, the changes will also mean that the likelihood of success in each claim will be greater for the injured party,[26] and the burden of defending the claims greater for the producer. The new PLD does that by: broadening the definition of 'product'; increasing the type of harm that can be compensated, which will include psychological injury; lowering the standard of proof; increasing the type and amount of documents that parties to litigation will need to disclose; increasing the risk of follow-on litigation based on regulatory interventions; and broadening the factors that will be considered when assessing defectiveness.

These changes have significant implications for the life sciences sector, as the policy trend of improving consumer rights continues.

A. Broadening definition of 'product' and responsible entities

Article 4 confirms that the meaning of 'product' includes software. The definition of software includes applications of AI, regardless of whether they are placed on the market as stand-alone products or are subsequently incorporated as components into other products, including as updates or upgrades.

Producers of components can be liable under the new PLD[27] and components includes "related services". Recital 17 provides the example of a related service as: *"a health monitoring service that relies on a physical product's sensors to track the user's physical activity or health metrics"*.

If a product or component manufacturer is established outside the EU, then the importer of the product or component into the EU, or the authorised representative in the EU of the manufacturer, can also be held liable.

Therefore the new PLD contains a broad definition of 'product' and it does not apply only to traditional manufacturers but also to, for example, software companies, operators in the digital health and medtech spaces, and various entities along the supply chain.

B. Psychological damage

Article 6 confirms that 'injury' includes psychological damage.

This is an important feature of the new PLD and has the potential to broaden national laws in jurisdictions where psychological damage as a standalone injury was not previously compensated. For example, in Ireland, for a person to be compensated for psychological injury, the injury typically needs to arise either alongside a physical injury (for example depression after a broken leg) or as a PTSD-type reaction to witnessing a shocking event.

Recital 21 explains this change. It refers to a psychological injury as being *"medically certified damage to psychological health that affects the victim's general state of health and could require therapy or medical treatment, taking into account, inter alia, the International Classification of Diseases by the World Health Organization"*.

ICD-11 is the WHO's latest medical international classification of diseases. Chapter 6 concerns mental disorders and includes for example: depressive disorders, which are characterised by a depressive mood which significantly affects an individual's ability to function; general anxiety disorder; social anxiety disorder; obsessive-compulsive disorder; and disorders due to substance use and addictive behaviours which are defined as *"mental and behavioural disorders that develop as a result of the use of predominantly psychoactive substances, including medications …"*.[28]

22 Article 11(e); note also that the existing Member States who derogated from this defence may under Article 18 opt to continue that derogation (i.e. the defence would not be available for operators). However, only Finland and Luxembourg did avail of the derogation under the original PLD.

23 Article 7. "in part" because an additional element has been introduced that a product is defective if it does not provide the safety that is required under EU or national law (discussed at E. below).

24 EFPIA position paper, 11 December 2022: https://www.efpia.eu/media/677330/efpia-pld-position-paper.pdf.

25 Ibid, note 19, page 303.

26 Ibid, note 19: In a review of almost 800 product liability judgments in the EU, the Commission impact study estimates that claimants succeeded in 60% of claims.

27 Article 8(1)(b).

28 ICD-11 can be browsed on the WHO website at: https://icd.who.int/browse/2024-01/mms/en.

This is an important change. Currently, product development or warnings in product literature might not always include consideration of the psychological impact of a product, especially where it is a secondary effect (i.e. where the product is not intended to influence mental health but ultimately does have that impact). Even the strengthened clinical evaluation and safety requirements set out in Annex I of the EU Medical Devices Regulation (MDR) state only in a general way that devices *"shall be safe and effective and shall not compromise the clinical condition or the safety of patients"*.[29] The MDR itself does not contain any references to psychological or mental health (though see below on certain Common Specifications under the MDR which apply to consumer products).

A focus on mental health impacts is an important trend in product safety in many industries; see for example product liability law-suits alleging mental health impacts against social media[30] and video game[31] companies.

Specific to the life sciences industry, allegations of a failure to warn patients about potential psychological dependence on opioids has featured in class action product liability litigation against a drug manufacturer.[32] Drug dependence and withdrawal symptoms causing negative mental health outcomes can also occur with drugs not typically associated with abuse.[33]

Psychological risks from medical devices should also be considered, particularly with emerging technologies such as neurotechnology where there may not be a significant body of evidence on the impact of the device on a person. Reflecting that risk with newer technologies, the Common Specifications to Annex XVI of the MDR[34] set out at Annex VII how manufacturers of non-invasive consumer equipment intended for brain stimulation must analyse, eliminate or reduce as far as possible any psychological risks.[35] It is important to clarify that this provision applies to products which do not have an intended medical purpose (i.e. consumer products) but which are similar to medical devices in terms of functioning and risk profile. However, the line between what is or is not a medical purpose is not always clear, as recital 19 of the MDR says that *"software intended for life-style and well-being purposes is not a medical device"* but does not then define "well-being".[36] Regardless of the exact regulatory definitions, to reduce litigation risk for psychological harm producers of medical technology and devices should assess the potential mental health impacts of their products or services.

C. Easing the standard of proof

One of the most significant ways the new PLD makes it easier for consumers to obtain compensation is by easing the standard of proof.

The level of proof a claimant must achieve to win their case is particularly important in product liability cases concerning life sciences products, because the scientific evidence might not be clear-cut and a legal test must be applied to decide who wins the case. EU lawmakers perceived the standard of proof across Member States as being too onerous. Recital 48 of the new PLD explains that in complex cases: *"…requiring the usual standard of proof as required under national law, which often calls for a high degree of probability, would undermine the effectiveness of the right to compensation"*.

Article 10 of the new PLD will therefore allow for presumptions of a product's defectiveness or causation between defect and injury in certain cases. These changes are an effort by the EU to codify existing case-law of the Courts of Justice of the European Union (CJEU).

The causation presumption is based on the decision of the CJEU in 2015 in *Boston Scientific Medizintechnik GmbH v. AOK Achsen-Anhait*[37] where individual pacemakers could be presumed as defective without proof that they were, provided that they were part of the same group or production series that did have an actual defect.

The presumption for cases with "excessive difficulties" is based on the 2017 decision of the CJEU in *N.W, L.W, C.W v Sanofi Pasteur*.[38] In that case the CJEU held that the PLD does not prevent national courts from reaching a conclusion even if medical research neither establishes nor rules out the existence of a

29 Annex I, Chapter I, Regulation (EU) 2017/745.

30 See for example, 'Social media is a defective product, lawsuit contends', Politico, 26 January 2023, at https://www.politico.com/news/2023/01/26/social-media-lawsuit-mental-illness-00079515. For a United States legal analysis on product liability and social media see Bergman, Matthew 'Assaulting the Citadel of Section 230 Immunity: Products Liability, Social Media, and the Youth Mental Health Crisis', Lewis & Clark Law Review, Vol 26.4, available at: https://law.lclark.edu/live/files/34281-264-4-bergman.

31 'The first video game addiction lawsuit got knocked out. Will others follow?' Reuters, 21 June 2024. Available at: https://www.reuters.com/legal/litigation/column-first-video-game-addiction-lawsuit-got-knocked-out-will-others-follow-2024-06-21/.

32 Haffajee, Rebecca L, Mello, Michelle M, 'Drug Companies' Liability for the Opioid Epidemic' 2017 New England Journal of Medicine, 2301-2305 377 24 https://www.nejm.org/doi/full/10.1056/NEJMp1710756.

33 Lerner, Alicja, Klein, Michael, 'Dependence, withdrawal and rebound of CNS drugs: an update and regulatory considerations for new drugs development', Brain Communications, Volume 1, Issue 1, 2019, fcz025, https://doi.org/10.1093/braincomms/fcz025.

34 The Common Specifications applies to products without an intended medical purpose and are defined in the MDR as a "set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system" and are available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02022R2346-20230622.

35 Section 3.3(a) of Annex VII.

36 Steindl, Elisabeth, 'Consumer neuro devices within EU product safety law: Are we prepared for big tech ante portas?' Computer Law & Security Review, Volume 52, 2024, 105945, ISSN 0267-3649, https://doi.org/10.1016/j.clsr.2024.105945. https://www.sciencedirect.com/science/article/pii/S0267364924000128.

37 Cases C-503/13 and C-504/13.

38 Case C-621/15.

link between, in that case, a vaccine and the occurrence of the victim's disease, so long as there was serious, specific and consistent evidence to allow the national court to conclude that there was a defect in the vaccine and that there was a causal link between that defect and the disease suffered.

In summary, under Article 10:

- a defect will be presumed if a defendant fails to disclose evidence[39] or breaches product safety law[40] (see below);
- causation will be presumed where alleged damage is "typically consistent" with the alleged defect[41] (i. e. based on the *Boston Scientific* decision);
- and a defect or causation will be presumed if the claimant faces "excessive difficulties", for example due to technical or scientific complexity, but the claimant must still show that it is "likely" that there was a defect, or causation between defect and injury[42] (i. e. based on the *Sanofi* decision).

Recital 48 shows that the lawmakers had life sciences in mind for Article 10. In explaining what could be construed as "excessive difficulties", the recital says: *"Technical or scientific complexity should be determined by national courts on a case-by-case basis, taking into account various factors. Those factors should include the complex nature of the product, such as an innovative medical device; the complex nature of the technology used, such as machine learning; the complex nature of the information and data to be analysed by the claimant; and the complex nature of the causal link, such as a link between a pharmaceutical or food product and the onset of a health condition or a link that, in order to be proven, would require the claimant to explain the inner workings of an AI system."* (emphasis added)

However, there remains an important safeguard for producers because the claimant must still show that it is "likely" that there was a defect, or causation between defect and injury. During the drafting phase, there was discussion as to whether a claimant would need to show the defect or causation was 'possible', 'likely' or 'probable'. Ultimately the new PLD uses 'likely'. The impact of this provision will vary between Member States. The European Commission's intention was to provide a middle ground: in Member States where a high degree of probability is currently required, the standard of proof will be lowered; while in other Member States ironically the standard of proof may be raised. In Ireland, where in civil litigation the standard of proof is the 'balance of probabilities' test (i. e. a likelihood of 50.1%), the use of 'likely' may not change judicial practice as at least in the English language 'likely' and 'probable' are synonymous and 'likely' has no specific legal meaning in Ireland.

The presumptions have attracted significant attention and have been referred to as reversing the burden of proof. However, that is not the correct description for the "excessive difficulties" presumption, as the burden will remain on the claimant to show a 'likelihood' to their allegations. The impact of this provision may therefore be more subtle, like a signal to judges that in general they should not be too strict in their assessment of evidence in product liability cases.

The presumption of defect if a defendant fails to disclose evidence or breaches product safety law are of more concern, albeit that, as presumptions, it is also important to remember that they can rebutted by the producer.[43]

D. Disclosure

The introduction of document disclosure obligations for operators is a further pro-consumer innovation in the new PLD. This is significant, because civil law jurisdictions in the EU, in contrast to common law, often have limited disclosure obligations in civil procedure.

In summary, under Article 9, if a claimant shows they have a plausible claim, then a national court must order disclosure by the operator to the claimant of relevant evidence necessary and proportionate to support the claim. The provision is based on a similar provision at Article 5 in the Antitrust Damages Directive (2014/104/EU) and its interpretation will likely be based on existing case-law under that directive.

Recital 42 explains the reason for this new provision: *"Injured persons, are, however, often at a significant disadvantage compared to manufacturers in terms of access to, and understanding of, information on how a product was produced and how it operates. That asymmetry of information can undermine the fair apportionment of risk, in particular in cases involving technical or scientific complexity. It is therefore necessary to facilitate claimants' access to evidence to be used in legal proceedings."*

Requests for disclosure are likely to be common in product liability cases concerning the life sciences sector, because how a life sciences product operates is typically not understood by the average consumer and life sciences cases are technically and scientifically complex.

A further interesting development is set out at Article 9(6) and explained in recital 42: *"Such evidence [which needs to be disclosed] includes documents that have to be created ex novo by the defendant by compiling or classifying the available evidence."* This provision is based on a decision of the CJEU on the Antitrust Damages Directive (*AD v PACCAR Inc and*

39 Article 10(2)(a).
40 Article 10(2)(b).
41 Article 10(3).
42 Article 10(4).
43 Article 10(5).

Others [Case C-163/21])[44] which found that the disclosure of "relevant evidence" within the meaning of EU law includes documents that a party may be required to create for the purposes of the disclosure request, by compiling or classifying information, knowledge or data in its possession.

This means that a defendant may have to assist the claimant to understand the science relevant to their claim by creating new documents, rather than simply providing documents which had already been created. In Ireland, an index of the documents is provided with the documents, which is usually divided into categories/topics, and documents are usually provided in searchable format. However, the requirement in the new PLD goes further, and may require operators to, for example, compile or explain adverse event reports in a way which is understandable to a lawyer or consumer. As the overall object of the new PLD is to remedy a perceived asymmetry of information between producer and consumer, the CJEU and national courts will likely interpret these provisions in favour of broad disclosure, subject to the disclosure being proportionate in terms of costs and effort for the producer, as required under Article 9(6).

More generally, it is important for organisations who are not accustomed to document disclosure to understand the type of documents that may need to be disclosed. In Ireland, where there is a long history of expansive disclosure obligations, it is not unusual in significant product liability claims to see tens of thousands of documents disclosed by operators to claimants. This is more than simply the technical documentation on a product and can extend to internal emails, meeting notes, instant messaging data, mobile phone messages, correspondence with regulators, pharmacovigilance data and analysis, etc.

This new obligation comes with a major sanction for non-compliance. If operators fail to disclose relevant evidence, their product will be presumed to be defective.[45] It is not yet clear how strictly this provision will be interpreted in practice; for example, whether the failure need only be minor (inadvertently not disclosing one email out of thousands) or something deliberate and significant (refusing to hand over documents that are known to exist).

Disclosure creates other risk, as careless internal communications might be misinterpreted in litigation or could attract uncomfortable media publicity if referred to in court, leading to reputational risk.

Standard legal protections will apply to disclosed documents, like protection for confidentiality, trade secrets, personal data and legal privilege. The documents should also only be used for the pursuit of the specific legal claim in which they are disclosed, and not shared with media or lawyers in other jurisdictions without consent.

Because of this new disclosure obligation, and subject to any specific local law requirements, it is good practice that as soon as a claim is threatened a notice is issued to relevant employees informing them of the claim and the need to preserve potentially relevant material for the claim. It is also a good idea to ensure a record is kept of any decisions about document retention or destruction generally, so that if any documents are unavailable for disclosure the reasons can be explained to a court later if necessary.

E. The increasing relevance of regulatory intervention

In the language of economic theory, we are in a policy era where *ex post* liability and *ex ante* regulation are used as complements, not substitutes.[46] In the life sciences sector, both are used in parallel in the EU to advance the interests of consumers: the safety of products is regulated, and if products are unsafe there is a liability system to compensate the injured.

The definition of defectiveness under Article 7 links these two policy tools. As before, the test is based on the entitled expectation of safety, but now is also broadened to provide that: *"A product shall be considered defective if it does not provide the safety … that is required under Union or national law"*.

The interpretation of this provision is uncertain. Medicinal products and medical devices are assessed by their risks and benefits. They are not 'safe' or 'unsafe', but rather have 'an acceptable safety profile'. If the benefit/risk balance switches to unacceptable, is the product then automatically deemed to be defective under the new PLD because the product does not provide the safety required to be marketed under Union law, even if the shift is because benefits diminished rather than because risks increased?

A recall of the product or *"any other relevant intervention by a competent authority"* relating to product safety will also be considered when assessing defectiveness.[47] The expertise of regulators may therefore guide a court's assessment of defect, which may be seen by some as a good thing if judges lack scientific expertise.

However, there is a downside to this provision, because regulatory intervention can also occur for reasons that do not prove a product is unsafe. For example, EU regulators may feel compelled to apply the precautionary principle to ban certain substances or products where there is not robust scientific evidence

44 Judgment available at: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:62021CJ0163.

45 Article 10(2)(a).

46 For a law and economics analysis on the dual use of liablity and regulation see for example Schmitz, Patrick W. (2000), "On the Joint Use of Liability and Safety Regulation," International Review of Law and Economics, Vol. 20, pp. 371–382. Page 3 notes that the joint use of liability and safety regulation can be optimal if wealth varies among those who cause injury.

47 Article 7(2)(g).

to prove safety.[48] Judicial review will rarely annul such regulatory decisions due to respect for the regulator's discretion.[49]

The new PLD therefore creates an ironic situation where a precautionary regulatory decision to pause the use of a product would not be overturned on judicial review due to a lack of evidence that the decision was incorrect, but that same regulatory action could be relied upon to assert that the product is defective.

This shows the potential danger of seeking to blend two policy tools which have different standards of evidence and different purposes. Regulators may be more concerned about ensuring there is enough evidence to prove a product is safe; whereas in product liability litigation there ought to be evidence that a product is unsafe.

Again this change is particularly relevant to life sciences, a heavily regulated industry, where judges may feel less confident in the subject matter and defer to the expertise of regulators.

This provision also generally increases the risk of 'follow-on' product liability litigation, where a regulatory finding acts as the stimulus for litigation claims.

Article 7(2)(g) confirms that actions taken by operators themselves (such as issuing a recall or safety notice) will be taken into account when assessing defectiveness. While of course litigation risk should not be a factor when deciding whether or not to issue a recall, it is important for operators to be aware that when a recall is issued, a court could later find that the recall is proof of the product's defectiveness.

F. Product warnings and risk assessments

Recital 31 explains how warnings in product literature will be assessed by a court. It states: *"warnings or other information provided with a product cannot be considered sufficient to make an otherwise defective product safe … Therefore, liability under this Directive cannot be circumvented simply by listing all conceivable side effects of a product"*.

Life science operators should therefore continue to draft product literature based on a careful assessment of actual evidence.

Recital 31 also confirms that the reasonable misuse of a product will be a consideration when assessing defect. This could mean that even if a patient does not precisely follow product instructions they could still succeed in their claim, if it is reasonable that they could have made that error (for example if dosage instructions are overly complicated or unclear and the claimant overdosed).

Recital 32 states that the assessment of a product's safety should take into account the reasonably foreseeable effects of other products on the product in question. This could apply to medicinal products which are used with a medical device, and vice versa. It is conceivable that even if the medicinal product itself is safe when assessed in isolation, if its use requires interactions with unsafe surroundings, it could be found to be defective. It is therefore prudent that a safety assessment of a product considers all reasonably foreseeable interactions around its use.

Finally, amongst the new circumstances that will be taken into account when assessing defectiveness, is: *"…a product whose very purpose is to prevent damage, any failure of the product to fulfil that purpose"*.[50] Recital 33 provides the example of a warning system like a smoke alarm. By analogy, this could apply to many medical devices whose purpose is to monitor or warn; if the device is not effective it could be found to be defective. It could also be argued that the purpose of a vaccine is to prevent damage, but it seems unlikely that a court would interpret this in an extreme way if a claimant alleged that they contracted a disease despite being vaccinated (perhaps unless the manufacturer had provided some assurance that the product would be 100% effective). The purpose of the PLD is to facilitate compensation for products which are unsafe, not those which are not effective, albeit there is not always a neat line between those two metrics.

G. EU form of class action for product liability cases

The PLD revision has occurred within a broader policy in the EU of 'A New Deal for Consumers', the goal of which is to strengthen consumer rights.[51] As well as the new PLD, the Representative Actions Directive (2020/1828)[52] increases product liability risk for operators in the life sciences sector.

The directive has been transposed by almost all Member States over the last year.[53] It creates a restricted form of class action in the EU where a so-called 'qualified entity' (for example a non-profit interest group like a consumer or patient representative body) can bring a claim against a manufacturer alleging product liability defect on behalf of a group of patients.[54]

The directive has cross-border scope, as it allows a qualified entity from one Member State to bring an action in another Member State. Amongst the entities who have registered to bring such an action to

48 See De Smedt, K., Vos, E. (2022). 'The Application of the Precautionary Principle in the EU'. In: Mieg, H.A. (eds) The Responsibility of Science. Studies in History and Philosophy of Science, vol 57. Springer, Cham. https://doi.org/10.1007/978-3-030-91597-1_8.

49 Ibid.

50 Article 7(2)(i).

51 https://ec.europa.eu/newsroom/just/items/620435/en.

52 Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020L1828.

53 Just Estonia and Luxembourg remain to transpose the directive – https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=celex:32020L1828.

54 The directive also applies to other types of cases, see Annex I of the directive for the full list of potential actions.

date are the Danish Medicines Agency and the Finnish Medicines Agency.[55] More qualified entities are likely to be registered in the coming year.
The law is a further example of a blending of public and private enforcement and may be used for product liability cases to overcome some of the costs and difficulties which one individual faces when trying to sue a manufacturer in a complex case.

IV. Practical steps to take

This article has outlined a number of ways in which product liability risk is increasing in the life sciences sector. For operators, it is preferable to take a series of smaller risk-minimisation steps rather than needing to react to a crisis. The passing of the new PLD is a good time to take stock and assess an organisation's legal risk profile.
This can be done by: identifying the possible risks; estimating their likelihood and severity; assessing how the risks can be controlled (for example, contractual terms with suppliers, insurance, internal governance, training, oversight); and ensuring a regular re-assessment is done to check whether any anticipated or unanticipated risks emerged. A blend of legal and technical expertise is required so that the mixture of views are incorporated.
This assessment can be done both for individual products and the organisation as a whole. Legal risk assessment is not of course the same as the product's benefit/risk assessment. Indeed even where a product has a favourable benefit/risk profile, the potential for litigation could lead to a commercial decision that a product should not be marketed.
This article has also outlined a number of issues to consider at product development stage, including any risk of psychological harm, foreseeable misuses of the product, and any interconnecting products, while carefully drafting product literature will remain essential.
The prospect of document disclosure may be a new one for operators not accustomed to litigation in common law jurisdictions. It is prudent for operators to plan for this possibility, for example by understanding how employees communicate with each other, where company data is stored, how key decisions are recorded, by providing training and informing employees that there is a prospect that their communications could be disclosed in litigation, et cetera. It is also important that any training does not instil fear in creating documents at all; for example when a key decision is made at a meeting it can be useful later in litigation that there is a record of the decision and a short summary of the reasons why it was made. That can be useful not only as a reminder for any employees who may need to give evidence at trial but also to demonstrate to a judge that the company is professional.

V. Conclusions

An organisation must try to balance commercial risk-taking with legal risk-minimisation. That balance is becoming increasingly difficult.
Litigation risk will vary between jurisdictions, between organisations, and between products sold by the same organisation. An organisation needs to know its own profile and its risk appetite.
Product liability law is an interesting and evolving field of study, with a confluence of law, economics, innovation, science and regulatory theory. The policy options selected by the EU in the new PLD shift the landscape in favour of consumers. The wider impacts of the changes on the life sciences industry should continue to be discussed and monitored as the new law evolves.
The implementation of new procedural rules on presumptions and document disclosure in the new PLD will vary between Member States. It is likely the new rules will encourage more claims against manufacturers, as that is what they are designed to do. There are practical steps that organisations can take now to minimise risk.
The continuing pro-consumer trend in the EU might appear to be negative for manufacturers, but despite how some debates are framed, it is not inevitable that one side must succeed while the other loses. Improving patient safety can be a competitive advantage, and if an unexpected event does happen, the current system retains key safeguards for defendants who acted carefully.
Product liability risk does not, therefore, need to be feared. However, it does need to be acknowledged and addressed.

55 A list of qualified entities registered to bring cross-border actions is at: https://representative-actions-collaboration.ec.europa.eu/cross-border-qualified-entities.