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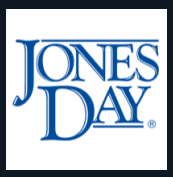

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Introduction

Product liability litigation continues to evolve at pace. The United States remains the epicentre of the global mass tort landscape, with pharmaceuticals, medical devices, cosmetics, chemicals and automotive products continuing to generate high-value class actions. However, the dynamics that have long driven large-scale product litigation in the US are increasingly being replicated in other jurisdictions.

In particular, the United Kingdom (UK) and several European jurisdictions have experienced an uptick in collective claims relating to allegedly defective medical devices, pharmaceutical products and cosmetics.

This trend has been fuelled in part by the expansion of the litigation funding market, as funders are increasingly drawn to the potential for substantial financial returns in large-scale product claims. At the same time, broader structural developments are reshaping the landscape. These include reforms to existing product liability regimes and the introduction of a harmonised framework for collective redress across EU Member States.

Taken together, these developments suggest that product liability litigation is entering a new phase of internationalisation. With procedural mechanisms for collective redress expanding, and third-party funding continuing to grow, we may be on the cusp of a significant shift in how product liability claims are pursued and defended across multiple jurisdictions.

Potential reform in England and Wales

Turning first to the UK, a number of high-profile product liability cases have played a pivotal role in shaping the modern interpretation of defect under the Consumer Protection Act 1987 (CPA), which imposes strict liability on producers for damage, death or personal injury caused by defective products. Notable decisions include Colin Gee v DePuy International Ltd (2018), concerning metal-on-metal hip implants, and the Supreme Court's judgment in Hastings v Finsbury Orthopaedics Ltd (2022).

These cases have clarified the legal test for defect and provided important guidance on how courts assess consumer safety expectations under the CPA, offering a greater degree of certainty for both producers and claimants. In particular they confirmed that the test as to whether a product is defective (i.e. whether the safety of a product meets the level of safety persons are generally entitled to expect) is an objective one and should be assessed having regard to all the circumstances which are factually or legally relevant to the evaluation of safety. Further, the assessment of risk associated with a product, which might inform entitled expectation, is to be done at the time the product is supplied, and not with the benefit of hindsight.

Notwithstanding this well-developed body of UK case law on product liability, the Law Commission of England and Wales is now undertaking a review of the UK's product liability framework. The review reflects growing concerns that the CPA has not kept pace with the evolution of modern products and markets. In particular, critics argue that:

- the current regime does not adequately address the rise of digital technologies and online marketplaces;
- it has not always provided a straightforward route for consumers seeking compensation; and
- in practice, claimants face significant evidential hurdles in proving defect and causation when attempting to bring successful claims.

This marks the first comprehensive review of the CPA since its introduction nearly 40 years ago. According to the Law Commission's terms of reference1, the review will examine a number of fundamental questions, including whether and to what extent:

- the CPA's definition of "product" should expressly encompass intangible digital technologies such as software and AI;
- the burden of proof placed on claimants is too onerous, particularly where emerging and complex technologies such as AI make it difficult to establish defect;
- the concept of "defect" should be reformed, particularly in light of the evidential challenges posed by complex and emerging technologies;
- the definition of "producer", and the scope of economic operators who can be potentially found liable, should be expanded;
- the current ten-year longstop limitation period should be extended in cases of latent harms or products that are iteratively updated (for example, software);
- the "state of the art" defence where the producer is protected if the state of scientific or technical knowledge at the relevant time did not allow them to discover the defect- should be available or be amended in light of iterative technologies; and
- the definition of "damage" should be broadened to include harms such as data destruction or corruption.

The Law Commission's initial scoping questionnaire officially closed on 31 December 2025, and a formal public consultation on reform proposals is expected in the second half of 2026. A report with recommendations to the government is anticipated in late 2026 or early 2027.

Although the review focuses primarily on England and Wales, the Commission has indicated that it will consult with stakeholders in Scotland and Northern Ireland and will liaise with the relevant devolved administrations. Whether this ultimately leads to greater alignment across the UK or to a degree of divergence in product liability regimes remains to be seen.

A key question arising from the review is whether the UK will follow the direction of travel in the EU. While the Commission's mandate is formally limited to examining the operation of the existing CPA framework—particularly in the context of digital products and emerging technologies such as AI2—the breadth of the issues under consideration suggests that more significant reform may ultimately be on the table.

Against this background, it will be important for manufacturers, distributors, insurers and consumer groups to engage proactively in the consultation process in order to help shape a regime that strikes an appropriate balance between effective consumer protection and the continued competitiveness and innovation of UK businesses.

Relevance of product liability reforms in the EU

As referenced above, the Law Commission's review takes place against the backdrop of significant reform at European level. In particular, its terms of reference overlap substantially with the areas addressed by the new EU Product Liability Directive 2024/2853 ("the new PLD"), meaning developments in the EU could influence the UK debate.

The new PLD entered into force on 8 December 2024, replacing the original EU Product Liability Directive 85/374/EEC, which has long formed the foundation of product liability regimes across the EU and UK. EU Member States must transpose the new PLD into national law by 9 December 2026, with products placed on the market before that date remaining subject to the existing regime. Early adopters leading the implementation process include Germany and Sweden.

Under the Windsor Framework, Northern Ireland will also be required, subject to certain exceptions, to implement the changes introduced by the new PLD into its product liability regime.

The new PLD (i) introduces a number of significant changes that modernise the EU's product liability framework, (ii) broadens the scope of potential liability and (iii) introduces measures intended to ease the evidential burden on claimants. These reforms are widely expected to make it easier for individuals who suffer injury or loss arising from defective products to bring successful claims, including collective or group actions, and against a broader range of economic operators.

The key issues presented by the new PLD are as follows:

Broadened definition of "product": The new PLD expands the definition of a "product" to expressly include software, including AI systems and AI-enabled goods, reflecting the increasing integration of digital technologies into consumer products. While services remain outside the scope of the regime, the new definition also captures digital manufacturing files, such as those used in 3D modelling and 3D printing.

Expansion of potential defendants: There has also been a significant expansion of the range of economic operators who may be liable for defective products. In addition to traditional defendants such as manufacturers, importers and distributors, liability may, in some circumstances, now extend to:

- Online platforms & marketplaces that facilitate the sale of products;
- Fulfilment service providers, meaning entities that provide at least two of the following services without taking ownership of the product: warehousing, packaging, addressing or dispatching; and
- Authorised representatives that act as intermediaries between non-EU manufacturers and EU authorities and are responsible for ensuring regulatory compliance when products are placed on the EU market.

The purpose of these changes is to ensure that there is always an EU-based entity that can be held liable where a defective product causes harm.

In addition, any entity that substantially modifies a product outside the control of the original manufacturer, and subsequently places it on the market or puts it back into service, will be treated as the manufacturer of the modified product and may therefore incur liability.

Expanded definition of recoverable damage: The concept of compensable damage has also been broadened. Compensation for personal injury may now include damages for medically recognised psychological harm. Damages can also be awarded for destruction or corruption of non-professional data, which means that software failures and cybersecurity vulnerabilities may increasingly give rise to product liability claims.

Extended limitation period for latent injuries: The existing 10 year longstop limitation period acts as a final cut-off to protect producers from liability, commencing from the date on which the product was placed on the market. The new PLD provides that this period may be extended to 25 years in cases involving latent personal injuries. This may expose businesses to long-tail liability risks, particularly in sectors such as healthcare and life sciences where some injuries may take many years to manifest.

Revised criteria for assessing defect: The new PLD also introduces additional criteria that courts must consider when determining whether a product is defective.

Under the existing framework, courts must assess defect by considering "all relevant circumstances." The new PLD builds on this by expressly requiring courts to consider factors such as (i) compliance with relevant product safety requirements and (ii) whether the product has been subject to a recall or other intervention by a competent authority or economic operator. These provisions aim to provide greater clarity as to how defectiveness should be assessed in complex technological environments.

Enhanced disclosure obligations: There are new provisions enabling courts to order the disclosure of necessary and proportionate evidence where a claimant presents a plausible claim. The aim is to address information asymmetry between claimants and defendants.

While broad disclosure obligations are familiar in jurisdictions such as the UK, they represent a significant shift for many EU Member States where disclosure is traditionally much more limited. As a result, businesses may face requests for potentially sensitive or confidential commercial information, subject to any safeguards provided under national procedural laws.

Potential limitation of the "state of the art" defence: The new PLD allows individual Member States to derogate from the "state of the art" defence, which currently enables producers to avoid liability where the defect could not have been discovered based on the scientific and technical knowledge available at the time the product was placed on the market.

If Member States choose to restrict or remove this defence, economic operators could face liability even where the defect was not discoverable at the time, potentially increasing litigation risk in sectors involving complex or evolving technologies.

Lower burden of proof for claimants: Perhaps the most significant change introduced by the new PLD is the creation of rebuttable presumptions of defect and causation in certain circumstances, which may substantially ease the evidential burden on claimants.

Under the current regime, claimants must prove that (i) the product was defective; (ii) they suffered damage; and (iii) the defect caused that damage.

Under the new PLD, a rebuttable presumption that a product is defective may arise where:

- the defendant fails to disclose relevant evidence under the new disclosure rules;
- the damage results from an obvious malfunction of the product during reasonably foreseeable use; or
- the product does not comply with mandatory safety requirements intended to prevent the type of harm that occurred.

In addition, courts may presume defect, causation, or both where—despite disclosure of evidence—the claimant faces excessive difficulties in proving their case due to technical or scientific complexity. The recitals to the new PLD specifically refer to medical devices, pharmaceuticals and AI or machine-learning systems as examples of situations where such difficulties may arise.

While these reforms provide greater clarity in several areas, and aim to improve consumer access to compensation, they also significantly expand the scope of potential liability on potential defendants and reduce evidential barriers for claimants. As a result, industry stakeholders may face increased litigation exposure, higher insurance costs and greater regulatory scrutiny, particularly in sectors involving complex products and supply chains. Close attention to these developments will be essential, both in terms of litigation risk and regulatory compliance.

Class action landscape

Alongside the recent reforms to the EU product liability framework and the ongoing review of the regime in England and Wales by the Law Commission, broader legal and market developments across Europe are increasing the likelihood that economic operators across many sectors will face large-scale product liability claims.

At present, the UK continues to present one of the highest litigation risks in Europe for collective actions. Its relatively well-developed procedural mechanisms—including Group Litigation Orders and representative actions—have made it an attractive forum for claimants, particularly in relation to product liability and personal injury claims. However, developments within the EU may gradually narrow this gap.

In particular, the implementation of the EU Representative Actions Directive (RAD)3, the growing availability of third-party litigation funding across Europe, and the forthcoming changes under the new PLD are all expected to drive an increase in collective product liability litigation across EU Member States in the coming years.

EU Representative Actions Directive (RAD)

The RAD establishes a legal framework enabling consumers within the EU to bring collective actions for redress arising from alleged infringements of EU law. Although product liability and product safety claims fall squarely within its scope, the RAD also extends to a broad range of regulated fields including data protection, financial services, travel and tourism, energy, telecommunications, environmental protection and healthcare.

The RAD is intended to improve access to justice for consumers while introducing a more harmonised

procedural framework for collective actions across the EU. Key features include:

- Mandatory collective redress mechanisms: All EU Member States must establish a system allowing collective actions, although they retain discretion to adopt either an opt-in or opt out4 model;
- Wide range of remedies: Courts may award remedies including injunctive relief, compensation, repair, replacement, price reduction and contract termination;
- Qualified Representative Entities (QREs): Actions must be brought by designated organisations on behalf of consumers. QREs are appointed by Member States and typically include consumer protection bodies or similar organisations. Individual consumers will generally not be formal parties to the proceedings and will face limited cost exposure, except in exceptional circumstances; and
- Flexible funding mechanisms: Collective actions may be financed through multiple sources, including third-party litigation funding, donations, crowdfunding or legal aid.

Since its implementation, a number of Member States (Italy, Germany) have reportedly issued actions under the RAD in a range of consumer protection cases.

Third party litigation funding:

The implementation of the RAD in all EU Member States is also expected to make Europe increasingly attractive for third-party litigation funding (TPLF). Under TPLF arrangements, external investors who are not parties to the dispute, finance legal proceedings and associated costs in exchange for a share of any damages ultimately recovered. Such funding can significantly reduce the financial risk for claimants and facilitate large-scale litigation that might otherwise be economically unviable, although concerns have been raised in various jurisdictions about how it operates in practice.

Outside the United States, the UK currently represents the largest litigation funding market, supported by a well-established collective litigation framework. However the European funding market is expanding rapidly.

Notably, TPLF remains unregulated in both the UK and EU, which may further encourage investment by funders seeking opportunities in emerging mass tort and collective redress claims. As these developments converge with the broader liability reforms introduced by the new PLD, they are likely to contribute to a more active and sophisticated class action environment across Europe.

Conclusion

For the reasons set out above, we may soon be entering an era in which product liability- related mass tort litigation becomes significantly more widespread. In particular, the imminent changes to the EU product liability regime, the Law Commission's review of the product liability regime in England and Wales, the introduction of a new EU collective redress mechanism and growth of third-party litigation funding are all likely to contribute to an increase in product liability group actions across a range of sectors in the UK and the EU.

That said, the pharmaceutical, MedTech and software industries may see the most pronounced rise in claims. The recitals of the new PLD specifically identify such products as scientifically or technically complex. These sectors are also amongst the most heavily regulated industries. As a result they may be

particularly vulnerable to presumptions of defect, particularly where there is any non-compliance with applicable product safety regulations.

Some of the EU legal initiatives discussed in this article will not apply directly in the UK following Brexit. Nevertheless, the Law Commission is likely to examine closely how the new PLD is implemented across the EU, including its impact on caselaw, consumers and industry more broadly, before advancing any concrete legislative recommendations.

In the meantime, stakeholders should remain alert to the evolving litigation landscape across Europe and ensure they stay informed of, and compliant with, relevant regulatory developments in the markets in which they operate.

The views and opinions set forth herein are the personal views or opinions of the authors; they do not necessarily reflect views or opinions of the law firm with which they are associated.

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