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Product Liability: Change Is On The Horizon In Europe

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PRODUCT LIABILITY
CHANGE IS ON THE HORIZON IN EUROPE

There is rarely a dull moment in global product liability litigation. The US continues to dominate discussion of mass torts, with products ranging from pharmaceuticals to automotives to chemicals continuing to generate class actions. The other side of the Pacific has also seen a growth in litigiousness, however, with the Australian courts in particular having dealt with an increasing number of substantial product liability related class actions in recent years. Closer to home, the UK and certain European jurisdictions have also seen an increase in product liability class action or group claims brought in respect of medical devices and pharmaceutical products, driven in part by the rise of litigation funders who see the promise of large returns.

In the UK, recent years have seen high-profile group litigation including *Colin Gee v DePuy International Ltd* [2018] and the UK Supreme Court decision in *Hastings v Finsbury Orthopaedics Ltd & Stryker (UK) Ltd* [2022]. These cases considered the assessment of defect under the Consumer Protection Act 1987 (CPA) and culminated in landmark rulings which have clarified and shaped the law on product liability, generally in ways that have reassured producers/manufacturers. These cases may for now at least have tempered the enthusiasm of funders for pursuing product liability claims before the UK courts.

By comparison, product liability in the EU is on the cusp of major change. Consumer focused agendas and initiatives over the last decade have prompted proposals for legal and regulatory reform across the product safety and product liability spheres, as well as a legal framework to govern the risks posed by artificial intelligence (AI). These proposals, coupled with the recent implementation of EU-wide legislation designed to facilitate cross-border collective actions, and increased availability of litigation funding, have the potential to transform the product liability landscape across Europe.

The EU Consumer Agendas: a catalyst for change

The European Commission (EC) has in the last ten years launched two Consumer Agendas seeking to build a strategic framework for EU consumer focused policy and regulation:

i. The Consumer Agenda, published in May 2012, outlined key goals including the reinforcement of consumer knowledge, the stepping up of enforcement and the securing of redress. This paved the way for the “New Deal for Consumers”, announced in April 2018, the stated aim of which was to strengthen enforcement of EU consumer law against a growing risk of EU-wide infringements of consumer rights and to modernise EU consumer protection rules in view of market developments including globalisation, increased cross-border trading data-collection and e-commerce. These factors, in conjunction with the rise of high-profile mass tort litigation in parts of the EU, ultimately prompted the Directive on Representative Actions for the Protection of the Collective Interests of Consumers (EU) 2020/1828, known as the Representative Actions Directive (“RAD”), which aims to ensure that consumers are able to protect their collective interests in the EU via representative actions.

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ii. The New Consumer Agenda published in 2020 ("2020 Agenda") sets out a vision for EU consumer policy from 2020 to 2025, building upon the 2012 Agenda (which expired in 2020) and the New Deal for Consumers. It aims to empower consumers to enable them to drive a smart, sustainable and inclusive economy as well playing an active role in green and digital transitions. The 2020 Agenda's priority areas include the digital and green transitions, enforcement of consumer rights, the protection of vulnerable consumer groups and international co-operation.

A raft of legal and regulatory proposals flowed from the initiatives above including those aimed at modernising consumer protection rules, particularly around the safety of digital technologies. These include the EC's new General Product Safety Regulation (GPSR) which entered into force on 12 June 2023, and reforms the mainstay product safety regime provided for by the General Product Safety Directive. The GPSR proposal highlighted a number of areas for improvement, including market surveillance, product recalls, cybersecurity, online marketplaces and modern technologies such as connected devices and AI. Many of these areas are now subject to separate legislation.

The EU has an enthusiasm therefore for amplifying the legal framework for consumer protection and is willing to impose a greater regulatory burden on producers and other actors across the supply chain. While this might have product liability risk implications on its own, together with the RAD, it has the potential to facilitate extensive cross border product liability collective actions. EU Member States may in coming years see an increase in both the volume and value of product liability claims brought on behalf of groups or classes.

An EU-wide collective redress regime

The RAD took effect in June 2023 although some Member States are behind schedule and are yet to fully implement it into their national laws. It introduces an EU wide legal framework by which EU consumers, who are affected by the same alleged infringements of EU law, can bring a representative actions for redress and/or injunctive relief. Annex I to the RAD currently lists 66 EU laws and regulations in respect of which a collective action can be brought, including those relating to product safety and product liability

As the regulatory frameworks governing product safety and new technologies continues to evolve, the list of EU laws and regulations listed in Annex I to the RAD is expected to grow and give rise, in tandem, to an increased risk of product liability related collective actions across Europe. For example, the recently approved Artificial Intelligence Act and Green Claims Directive provide for enforcement through the RAD. The RAD may have the most significant impact in member states where there are currently no collective redress mechanisms available such as Ireland. It provides important discretion to individual Member States about how the key provisions are implemented into national laws, including whether to provide for an opt-in or opt-out system. This is likely to contribute to forum shopping across Europe, with litigants seeking to bring actions in those jurisdictions that pose the lowest barriers to starting claims or which are likely to give the most favourable outcomes. This is something borne by the experience of the Netherlands, which has established collective action mechanisms and which, in recent years, has become a hub for international class action litigation in Europe, in part because there are few restrictions on the types of actions that can be brought. The Act on Redress of Mass Damages in Collective Actions (WAMCA) – which has similarities with RAD – entered into force on 1 January 2020 and made it possible for the first time for claimants to bring collective actions for monetary damages. In

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2021, the first product liability claim was brought pursuant to the WAMCA regime on behalf of thousands of Dutch claimants involving allegedly defective breast implants.

A growing third party litigation funding market

There has been an increase of third party litigation funders in the EU, often acting in conjunction with experienced US class action law firms, particularly in the Netherlands (see above). The implementation of the RAD is likely to encourage funders to continue setting up shop in the EU, who will in future potentially be regulated (and, in some places, for the first time permitted) under the proposed EU regulation of third party litigation funding (TPLF). TPLF is currently largely unregulated within the EU, with the involvement of funders not always being disclosed to the defendants and the court. Funders can often take a large share of damages awards, leaving claimants with significantly reduced compensation.

A draft EU Directive on the regulation of TPLF was published in June 2021 and in September 2022, the EU Parliament voted in favour of TPLF regulation, proposing a "Resolution with recommendations to the Commission on Responsible private funding of litigation". The recommendations provide for greater oversight of funders as well as a cap on their profits. Whilst this is seen by many to be a significant development in supporting access to justice, some industries and organisations are concerned that the recommendations are too restrictive. It has been reported that stringent regulation of TPLF could not only hinder funder activity in the EU but also benefit the increasingly growing TPLF market in the UK.

The EC has since conducted a mapping study of the TPLF market across Member States before deciding whether to implement a regulatory framework. The EC's final report is expected to be published in November 2024.

A legal framework for the digital age

i. Proposal to reform the EU Product Liability Directive

The risks and challenges posed by new technologies, modern supply chains such as online platforms and an increasing focus on sustainability and the circular economy culminated in the EC publishing a proposal to reform the EU Product Liability Directive 85/374/EEC (PLD) on 28 September 2022 The EU institutions reached provisional agreement on the text on 14 December 2023. The new PLD is expected to come into force later this year, following which Member States will have two years to implement the legislation into national laws.

The current PLD has been in force for almost 40 years and covers a wide range of products, from medical devices to white goods. An evaluation conducted by the EC in 2018 concluded that it was generally an effective instrument and broadly fit for purpose but also identified several limitations, including in its application to complex, emerging digital technologies such as software applications and AI, and to products in the circular economy (i.e. those subject to modification or repair after they are put to market). The evaluation also considered that the burden of proof could be challenging for claimants in scientifically complex cases, such as those concerning medical device and pharmaceutical products.

Whilst the new PLD retains the substance of the current PLD, it contains a number of new and potentially far reaching provisions that could significantly change the litigation risk profile for certain types of

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products, particularly digital and AI-enabled technologies. The provisions include:

- An expanded definition of "product", bringing digital manufacturing files, software, including AI, and AI-enabled goods within scope of the 'no-fault' regime. The new regime is therefore expected to apply to products such as autonomous vehicles and AI-enabled smart assistants.
- Expansion of the potential defendants who might be liable under the PLD. Providers of software and digital services, as well as online marketplaces and fulfilment service providers (e.g. warehouses) will potentially be liable for defective products, in addition to manufacturers of hardware. This provision sits against a backdrop of developing regulation in the EU around the provision of digital services and software and the operation of online marketplaces.
- An expanded definition of "damage" to include the loss or corruption of data and medically recognised damage to psychological health. As products become more complex with functionality that is increasingly interconnected, software and cybersecurity vulnerabilities are likely to become an increasing product liability risk for manufacturers, suppliers and other actors across the supply chain.
- Rebuttable presumptions of defect and/or causation in certain circumstances. For example, where a claimant faces excessive difficulties to prove the defectiveness or a product and/or causation. In recent years, claimants have, in particular, voiced concern that the burden of proof is too high in claims involving medical devices and pharmaceutical products.

- A rebuttable presumption of defect where: (i) a defendant fails to comply with an obligation to disclose relevant evidence; (ii) the claimant demonstrates that the product does not comply with mandatory product safety requirements set out in EU or national law; and (iii) the claimant demonstrates that the damage was caused by an obvious malfunction of the product during reasonably foreseeable use.

The new PLD removes some of the hurdles encountered by claimants when bringing product liability claims, creating an easier pathway to bringing complex actions. Pharmaceutical and medical device manufacturers have been at the forefront of product liability litigation in Europe and as those industries increasingly develop products containing digital and AI-enabled technologies, they may well be amongst the first to face major test cases and collective actions brought under the new regime.

ii. Proposed legal framework for AI

Sitting alongside the new PLD is the first ever comprehensive legal framework to govern the risks posed by AI and AI-enabled products. The framework is two-fold:

i. a regulation laying down harmonised rules on AI, known as 'Artificial Intelligence Act' ("the AI Act"), which was first published in April 2021 and approved by EU lawmakers on 13 March 2024; and
ii. a proposal for a civil liability regime for AI, known as the AI Liability Directive, which was published in tandem with the PLD Proposal on 28 September 2022.

The AI Act

The AI Act adopts a risk based approach and imposes strict controls and substantial risk management for the riskiest forms of AI systems, including medical devices, vehicles and toys. Such controls include

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undergoing conformity assessments, the implementation of quality management systems, and affixing of CE-markings to indicate conformity with the proposed regulation before products are released to market. Exceptionally high risk AI-systems, such as those which are considered to pose a clear threat to the safety, livelihoods and rights of people, are prohibited. Infringements are costly, with fines of up to EUR 35m (or up to 7% of annual turnover) imposed for those in violation of the prohibited forms of AI systems. The AI Act has wide-ranging applicability and will affect AI providers and users inside and outside of the EU.

The AI Liability Directive

Complementing the AI Act is the AI Liability Directive (AILD) which aims to provide a mechanism for claims for compensation to be brought by end users of all types AI systems (such as smart home products, AI-powered software applications or AI-enabled medical devices) who have suffered harm as a result.

The AILD has been introduced owing to the EC's view that current national liability rules are not suitable or appropriate for responding to liability claims for damage caused by AI based products and services owing to their inability to account for the complex and autonomous features of AI, which can make it difficult for users to determine potentially liable parties. Against this, the AILD proposes a 'fault-based' liability regime for AI systems that includes:

i. a rebuttable presumption of causality, making it easier for claimants to demonstrate a causal link between an AI system failure and the harm caused. Crucially, a presumption may arise where the provider of the AI system has not complied with the AI Act. The risk of non-compliance is increased where obligations under the AI Act may conflict or overlap with existing obligations under other regulations that address the risks of new technologies, such as those set out in the EU Medical Device Regulations and the General Data Protection Regulation.
ii. A right of access to evidence from companies and suppliers of high-risk AI systems, giving claimants the right to ask the court to order disclosure of relevant evidence.

With the AI Act having now been approved, EU lawmakers are likely to turn their attention to the proposed AILD.

The AILD applies to claims brought by any natural or legal person against any person for fault that influenced the AI system which caused the damage. It covers any type of damage involving AI systems, including that resulting from discrimination or privacy. By comparison, the PLD Proposal applies to claims brought by private individuals against manufacturers in respect of damage to health, property and data loss caused by defective products. Together, they form a legislative package that will arm consumers with the means to seek redress, individually and collectively, in respect of harm caused by AI.

With the EU having introduced other pieces of regulation, such as the Digital Services Act, to keep big tech companies in check, there is a greater focus on holding producers and developers of AI systems accountable for harm. The appetite for AI related litigation has already manifested in the US, with Big Tech companies in the firing line for collective actions brought in respect of harms allegedly caused by the AI algorithms built in social media platforms.

ESG and sustainability

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With ESG and sustainability remaining high on corporate agendas, there has been increased focus in recent years on the environmental impact of products. Whilst ESG-type obligations are already weaved into existing product safety regulations, the EU is now seeking to incorporate them into mainstay product safety laws and regulations, as well as separate subject-matter pieces of legislation, such as the proposed Directive on Corporate Sustainability Due Diligence, which seeks to address the human rights and environmental impacts of global value chains by placing onerous obligations on EU and non-EU companies and improving access to remedies for those impacted as a result of corporate behaviour.

Products containing synthetic chemicals, such as perfluoroalkyl and polyfluoroalkyl substances (PFAS), which are found in a variety of products used by consumers and industry such as medical devices, cosmetics and cookware, are under the scrutiny of regulators, culminating in a series of international noteworthy legal and regulatory developments across the globe, because of their alleged impact on health.

PFAs related litigation in the United States and Europe is already impacting chemical producers, albeit mostly in relation to water and soil contamination. However, as regulatory scrutiny continues, actions (including product liability claims) are increasingly being brought against producers and distributors of consumer products and packaging containing PFAS across a variety of industries, including food and cosmetics.

Conclusion

For the reasons set out above, the EU may soon be entering into an era where product liability related mass tort litigation is seen on a wider scale.

Whilst the EU legal and regulatory proposals discussed in this article will not apply in the UK post Brexit, the UK government is setting out its own legal framework for the regulation of digital technologies, including AI.

The UK government has so far adopted a “pro-innovation”, sector based approach to AI regulation, as set out in its AI White Paper. However, the position could change in due course in light of the The Artificial Intelligence (Regulation) Bill, which was introduced as a Private Members’ Bill in the House of Lords on 22 November 2023 and which aims to establish a framework for AI regulation in the UK.

Whilst the UK government continues with its proposed reform of the UK’s product safety regulation, the CPA may also be subject to reform proposals to account for the risks of new technologies , as indicated in recent government consultations. It is possible, however, that UK policymakers shall wish to see how the new PLD fares in the EU, before any legislative proposals are put forward. Product liability litigation in the UK is therefore expected to remain relatively contained for the time being.

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