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Guest contribution

ROB STEVENSON, ASSOCIATE, *SIMMONS & SIMMONS*





Risks, challenges, and outlook for the European pharmaceuticals industry

 **ROB STEVENSON**, ASSOCIATE, *SIMMONS & SIMMONS*

There are a number of regulations ahead that will present considerable risks, challenges, and opportunities for the European pharmaceutical industry. They reflect lawmakers' desire to ensure patients have access to innovative medications but also have tools to act if they are harmed.

EU Directive on Liability for Defective Products

On 10 October 2024, the EU adopted its new [Directive on Liability for Defective Products](#) (the PLD). The PLD replaces the existing regime, which has been in place since 1985. EU Member States must implement the new rule by 9 December 2026. Astute pharmaceutical businesses are already preparing to comply.

The PLD represents a departure from the previous regime on several key issues which appear likely to influence the risk assessment, quality control, and supply-chain measures being adopted by pharmaceutical manufacturers. It will also impact the factors companies consider when deciding whether to initiate pre-emptive or voluntary recalls and the potential consequences of initiating a recall for both manufacturers and competent authorities.

Presumptions as to defectiveness and cause of damage

The new directive is a paradigm shift compared to the former regime when it comes to the burden of proof, both for establishing a product's defectiveness and when demonstrating the existence of a causal link between a product defect and alleged damage. The PLD creates several circumstances where there will be a rebuttable presumption that a product is defective, including where a product does not comply with mandatory product safety requirements.

In anticipation of this risk, pharmaceutical manufacturers may choose to adopt more proactive philosophies around quality control and reporting procedures. These steps may minimise the risk of non-compliance with the more stringent mandatory product safety requirements.

Drug makers may also take a more aggressive stance when responding to adverse events, including initiating a recall. For example, if a quality control issue is identified in a drug or manufacturing line, a manufacturer may be more likely to initiate a recall of affected batches rather than risk a presumption of defectiveness and eventual litigation and damages exposure. This is true even when the issue initially appears to be only marginally significant and/or unlikely to cause injury or illness.

Once the PLD has been implemented by EU Member States, there may be an increased tendency to accept that the financial and reputational risks associated with public litigation under the PLD outweigh the costs of an early recall. This is because the new regime heavily favours consumers and places an increased burden on manufacturing companies as defendants.

In the pharmaceuticals industry, product recalls are taken very seriously due to the potential impact on patient health and brand reputation, especially in the context of non-generic drugs. The introduction of these presumptions of defectiveness may prompt broader, more frequent, and earlier recalls.

Consideration of product recalls in assessing product defectiveness

Another prominent change is in how the defectiveness of a product is assessed under the PLD. EU Member States' national courts are now directed to consider any recall of the product in question by a competent authority or a manufacturer, together with any other relevant intervention relating to product safety.

Under the new regime, a manufacturer's crisis response procedures and/or a decision to voluntarily recall a product may create new avenues for claimants to eventually establish defects in that product in subsequent litigation.

We expect that this will be another factor for pharmaceutical companies to consider when deciding if they will voluntarily recall their products in the absence of mandatory regulatory intervention.

Steps to prepare for the new PLD regime

Companies that operate in the pharmaceutical supply chain should adopt a multifaceted approach to prepare for the new PLD regime. In particular, they should take steps to mitigate the need for, and consequences of, a greater number of product recalls.

Pharmaceutical companies already face significant regulatory scrutiny. Given the PLD's broader scope and consumer-friendly presumptions, drug makers should refine not only their quality assurance and manufacturing processes, but also their post-market surveillance and risk management programs.

There are a range of measures that would help manufacturers achieve this, such as standardising processes to meet or exceed regulatory requirements; regularly validating production methods, manufacturing equipment, and storage and transportation facilities to minimise variability that might later lead to a presumption of "defectiveness" under the PLD regime; and continuously evaluating supply chain vulnerabilities and opportunities to mitigate the risk of contamination or improper/unsafe storage.

Other preventative actions include expanding and strengthening laboratory testing protocols to detect marginal variations in the quality of active ingredients and finished products; investing in systems to capture real-time data on product performance and adverse event notifications; and enhancing the ability to analyse post-market data and quality attributes for each production batch to allow for targeted recalls rather than broader, and more costly, recall actions. This could potentially be done with the assistance of emerging AI technologies.

In addition, companies could establish systematic channels for healthcare professionals and patients to report product issues. This would allow for swifter assessments of whether alleged defects are isolated or indicative of broader manufacturing or distribution issues.

We anticipate that developments in technology may prove to be useful tools for pharmaceutical companies in mitigating the risks and challenges posed by the new PLD regime. This is particularly true for the integration and embedment of AI into the systems and protocols to help reduce risk.

UK point-of-care (POC) manufacturing

The UK's Human Medicines (Amendment) (Modular Manufacture and Point of Care) Regulations 2025 (the Regulations) provide a new regulatory framework to allow medicines with a very short shelf life or highly personalised medicines to be manufactured more easily in or near hospital and community settings at the point of care (POC).

A new Statutory Instrument (SI) was [signed into law on 25 January 2025](#). It makes the UK the first country in the world to introduce what has been described as “[a tailored framework for the regulation of innovative products manufactured at or close to the location where a patient receives care](#).”

The Regulations permit medicines to be manufactured in small, portable units that can be set up close to patients who are too sick to travel, whose reduced immunity precludes travel, or where rapid medicinal availability is required.

The pharmaceutical sector will need to adapt quickly to the challenges and opportunities presented by the Regulations. It is a significant shift from the tightly controlled manufacturing, storage, and distribution procedures that are a critical part of the industry and where variations in quality or dosage can pose serious risks to patient health.

Manufacturers and suppliers of pharmaceutical products and/or ingredients may have concerns regarding the controls in place in the envisaged “modular” units to ensure homogeneity in the manufacturing process. The decentralisation of the manufacturing and distribution processes outlined in the Regulations presents obvious risks regarding quality control, contamination, and product safety. This is especially true for a patient population that is not well enough to travel.

We expect that the Regulations will lead to higher numbers of adverse events, contaminations and, ultimately, the initiation of product recalls.

At first blush the modular manufacturing and distribution of pharmaceuticals may appear to increase the risk of

contamination or heterogeneity of the products in question. However, manufacturers, suppliers, and practitioners may be able to more precisely isolate contaminated batches or products. This would allow them to avoid large-scale recalls of entire product lines.

Conversely, a broader product defect discovered at any modular site could affect products or ingredients at all other modular sites and trigger a recall. The risk could be posed by ingredient contamination, a packaging or storage error, or process deviation. The fragmentation of the supply chain—and consequently the “recall chain”—is expected to vastly increase the logistical complexity of a recall.

Rather than withdrawing products from a centralised factory or storage facility, manufacturers will be required to coordinate the simultaneous withdrawal of products from potentially hundreds or even thousands of hospital or community settings. The potential costs associated with a modular recall may affect the availability of product recall insurance coverage, as well as the terms on which insurers are willing to offer policies.

Furthermore, speed and bedside delivery, which are the very qualities that make POC manufacturing and distribution attractive, also mean that, once a defect is flagged, there may be insufficient time to notify all administering health professionals and remove affected doses before they are administered to patients.

To mitigate this risk, it would be sensible for manufacturers and other parties involved in the process to develop and strengthen “rapid-alert” procedures tailored to these ultra-short shelf-life products. These may include automatic digital notifications to and from each modular POC site.

The new regulations come into effect on 23 July 2025. Pharmaceutical companies with an interest in POC manufacturing should be watching for guidance from the Medicines and Healthcare products Regulatory Agency on how the rule will be interpreted and enforced.

The views expressed in this article are those of the author and do not necessarily reflect the opinions of Sedgwick.



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