The new perils of product liability regulation

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12 September 2024

The Background to the Product Liability Directive (PLD)

Existing PLD

- 40 years old (adopted in 1985)
- Adopted in the context of high-profile cases such as Thalidomide

The new PLD

- Adopted on **12 March 2024**
- WHY CHANGES?
  - Reflect the nature of products in the digital age
  - Ensure that individuals are better protected and can prove their claim in complex cases

How the PLD works in practice?

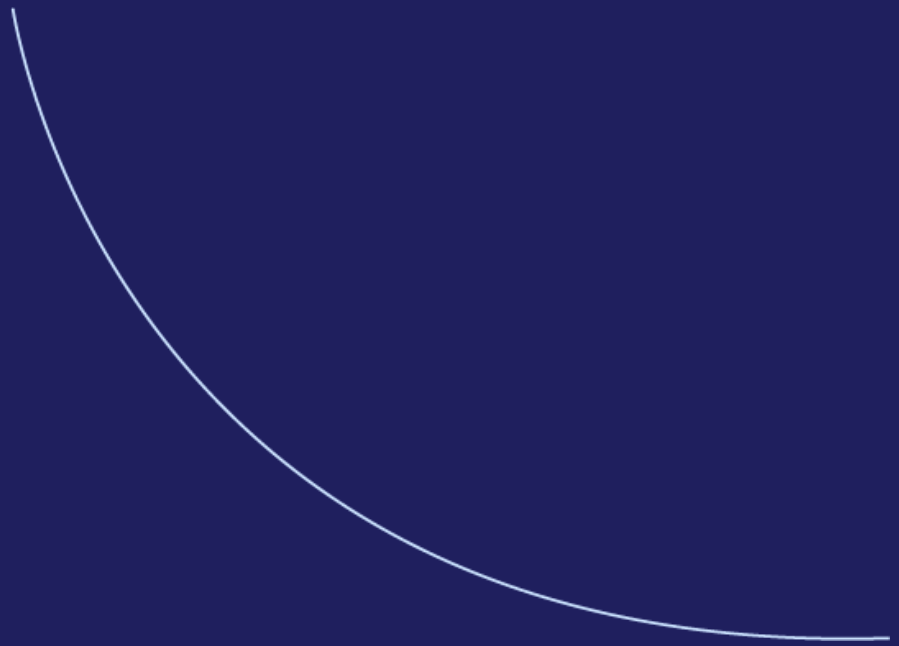
What is the essence of the PLD

- Consumers can claim compensation for **personal injury or property damage** resulting from a product defect
- Makes it **easier for consumers to recover damages** caused by defective products
- No need to prove the manufacturer's negligence (also called **'strict liability**‘)

How rights of consumers are enforced

- Consumers can file lawsuits in national courts
- Consumers have to prove: (i) the product was defective; (ii) damage was suffered; (iii) a causal link exists between the damage and the product's defectiveness.
- Class actions mechanisms are available

For whom in the Life Sciences sector the PLD is relevant



- Pharmaceuticals
- Medical devices - Technology
- Food – food supplements
- Cosmetics
- Biocides

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How much PLD is relevant to Life Sciences sector?

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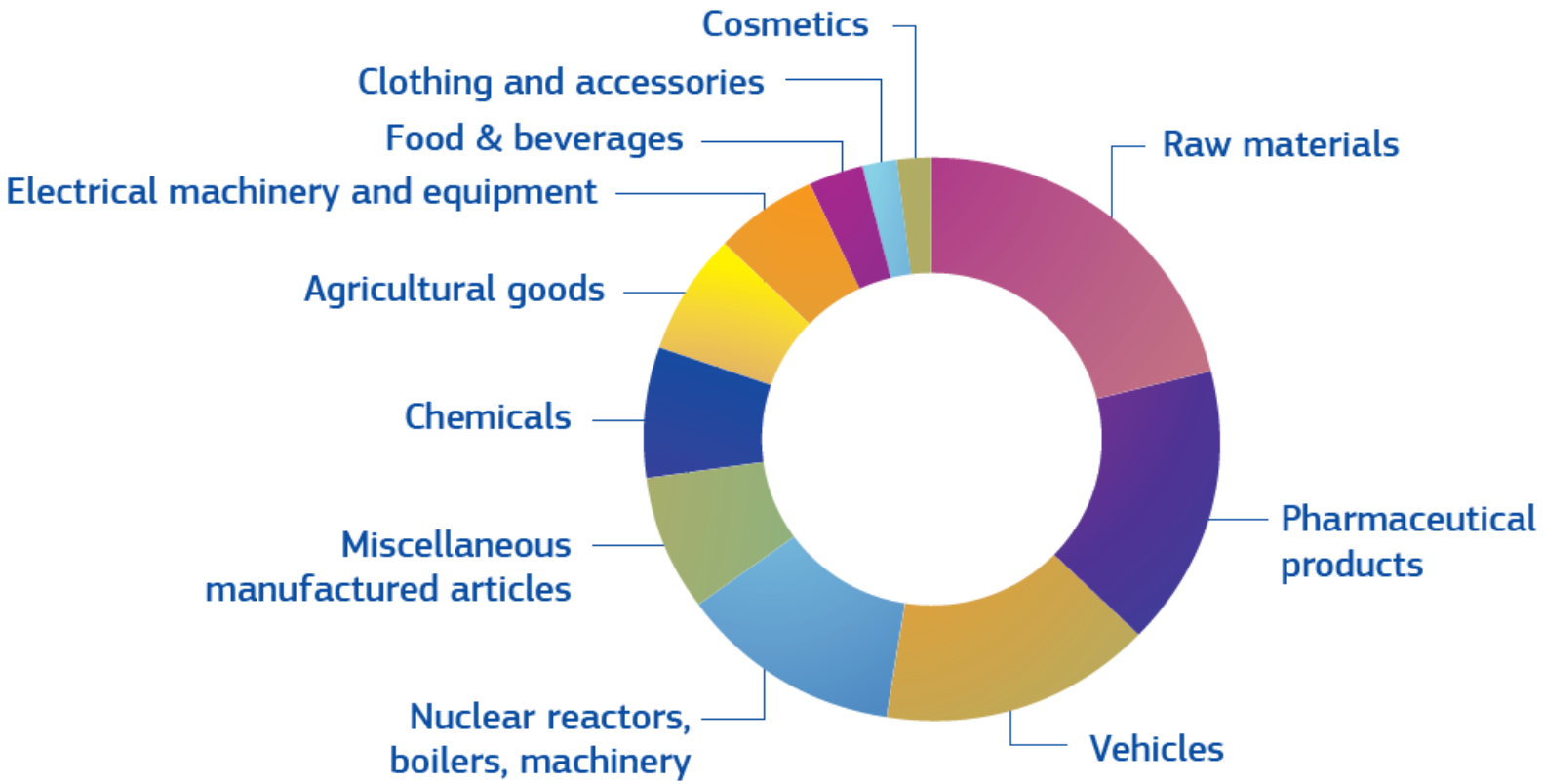
Claims for damages under the PLD in 2000-2016 → Pharmaceutical products – TOP 2



Claims in EU litigation:
breast implants, vaccines, pacemakers, metal-on-metal hips

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How much consumers have used PLD in the Baltics

Lithuania

(1) Sports club was found liable for client's death caused by bacteria found in the swimming pool (2012, compensation for non-pecuniary damage 40 000 EUR)

(2) The seller of fertiliser is found liable for the farmer's damages, where the instructions on how to use the fertiliser were incorrect and the fertiliser had no effect on the plants (2018, 40.000 EUR damage)

Estonia

(1) Victim has the right to file a claim for damages against the manufacturer of the vaccine (2024)

(2) The plaintiff developed tooth enamel pigmentation as a result of consuming the defendant's product "Children's iron syrup" (2023; compensation for non-pecuniary damage 1000 EUR)

(3) A piece of plastic plate in the sausage – resulted in loss of tooth (2021, material and non-pecuniary damage totalling 14.901 EUR)

Latvia

Damage resulting from dental services:

(1) Case 1: 2014, 405 EUR;

(2) Case 2: 2021, 3.750 EUR.

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The news things in the new PLD

New **products** in scope*	Software, AI systems and digital services (medical devices that rely on AI, medical apps).
More potentially liable **entities**	Manufacturer → Importer / Authorized representative → Fulfilment service provider (e.g. warehousing, packaging) → Distributor / Provider of online platforms
New **disclosure** requirements	Following a request, manufacturers will have to disclose necessary and proportionate evidence in its possession **that the claimant can use to support its claim for compensation**. Impact / risk: disclosure of confidential documents.
Presumed defectiveness*	- Where there is **noncompliance** with relevant EU product safety regulations (e.g. MDR); - If it is excessively difficult on account **of the technical or scientific complexity** of a product for a claimant to prove either that: (A) A product is defective; or (B) There is a causal connection between the defect and the damage.
New types of **damage***	Medically recognized damage to **psychological health** and damage resulting from the **destruction or corruption of data** (such data is not used for professional purposes).
The **minimum damage** and **limits for compensation** is cancelled	The minimum thresholds (500 EUR) and maximum limits for compensation claims are removed. The impact of this change, particularly when combined with the introduction of the EU's new class actions mechanism, is likely be to a significant risk of mass claims for relatively trivial claims of data destruction or corruption.
Extension of **claims period***	The claims period is extended from 10 years following placement of the product on the market under the existing rules— to 25 years in certain cases.

* For medicinal products and medical devices – significantly increased liability risks

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Why the business is concerned about the new PLD

- May undermine Europe's **competitiveness**.
- Growing number of unregulated, profit-motivated, claims, also taking advantage of **class actions**.
- Imposes **disproportionate disclosure requirements** on producers. Easier for producers to pay-out or settle the claim rather than comply with the disclosure obligations – "blackmail settlements".
- Even a minor technical breach of a pharmacovigilance obligation may be sufficient to allow a product to be **presumed defective**, even if the competent regulatory body had made no such determination.

Producers will likely have to:

- spend more on insurance premiums and legal fees;
- 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.**

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When will the new PLD apply?

- Not yet entered into force: PLD is adopted by the Parliament → waiting for adoption of Council
- PLD will apply after it is transposed into national laws by EU Member States → **before the end of 2026?**
- PLD will apply to products placed on the market 24 months after entry into force of the PLD

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What needs to be done by the market players?

- Monitor the implementation of PLD to local laws
- Review supply chain contracts that allocate liability risks
- Review internal procedures, e.g. documents' retention periods in line with GDPR
- Assess manufacturing and marketing systems and processes
- Monitor interpretation of the new PLD by the courts
- Prepare for an increase in the claims?

Thank you!

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