BEGIN

Product liability in a changing world

Navigating new risks and regulatory shifts

Tuesday | 4 March 2025 | 11.00 CET/10.00 UK

Product liability in a changing world

Contents

Regulatory changes and technological advancements are reshaping the product liability landscape, with the EU tightening safety and liability rules, particularly for AI-driven and medical devices

Meet the panel

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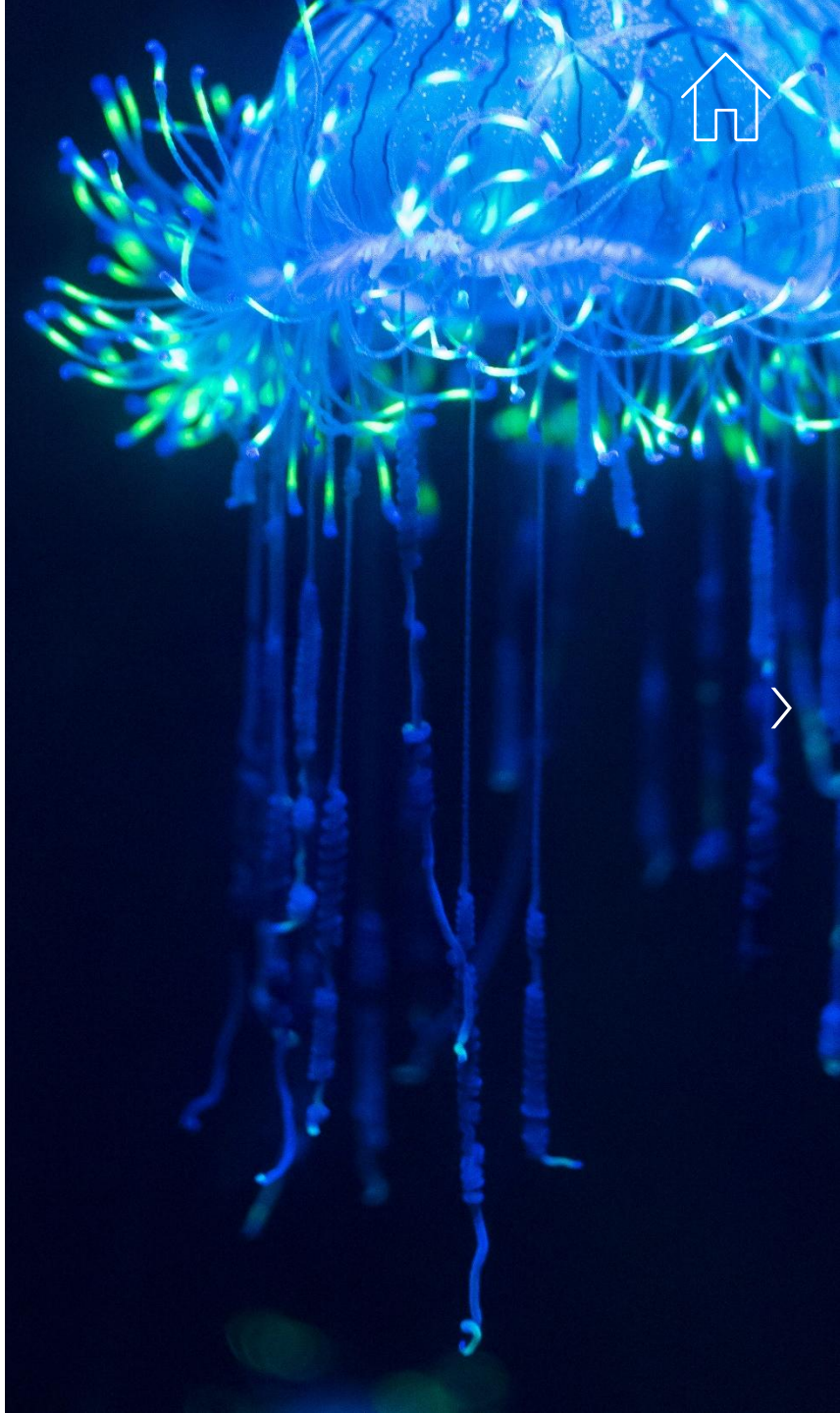
1 The importance of product safety legislation

Kiki Bink

Important outlines of the EU Product Safety Regulation

- The developments on the market required an amendment of the product safety legislation
  - Increase in online purchases
  - Use of new technologies in products
- Regulation (EU) 2023/988 on General Product Safety ("**GPSR**") has entered into force as of 13 December 2024 and replaces the General Product Safety Directive (EC) 2001/95
  - Note: from directive to regulation
- The objective of the GPSR is to improve the functioning of the internal market while providing for a high level of consumer protection
- How is this achieved?

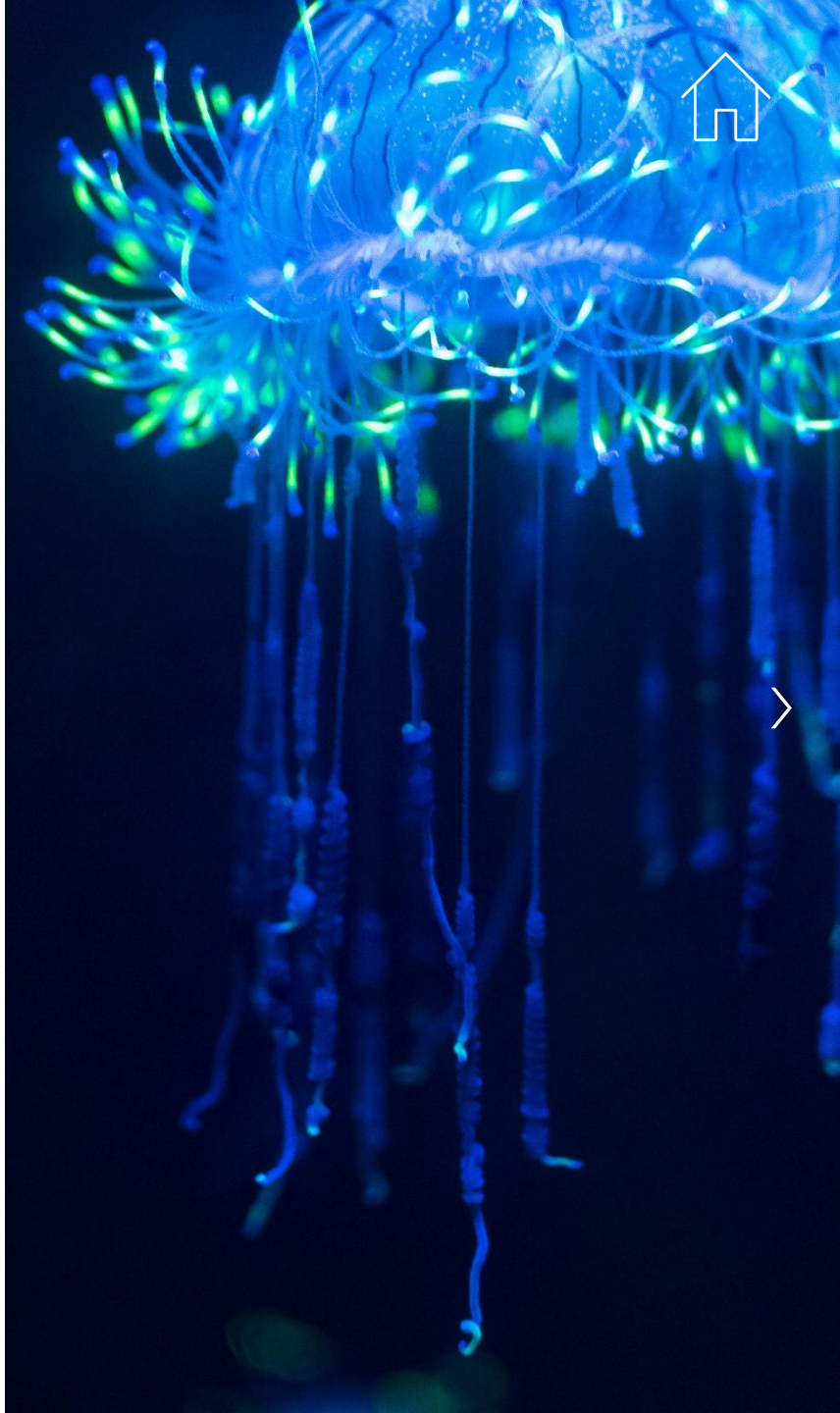


Important outlines of the EU Product Safety Regulation

1. Stricter liability and responsibility
   - Manufacturers, importers and distributors must ensure product safety
   - Mandatory risk analysis before a product is put on the market
   - An EU-based economic operator must be designated for each product

2. Improved monitoring and reporting
   - Mandatory reporting of incidents involving unsafe products
   - National authorities will have more power to remove products from the market and impose sanctions

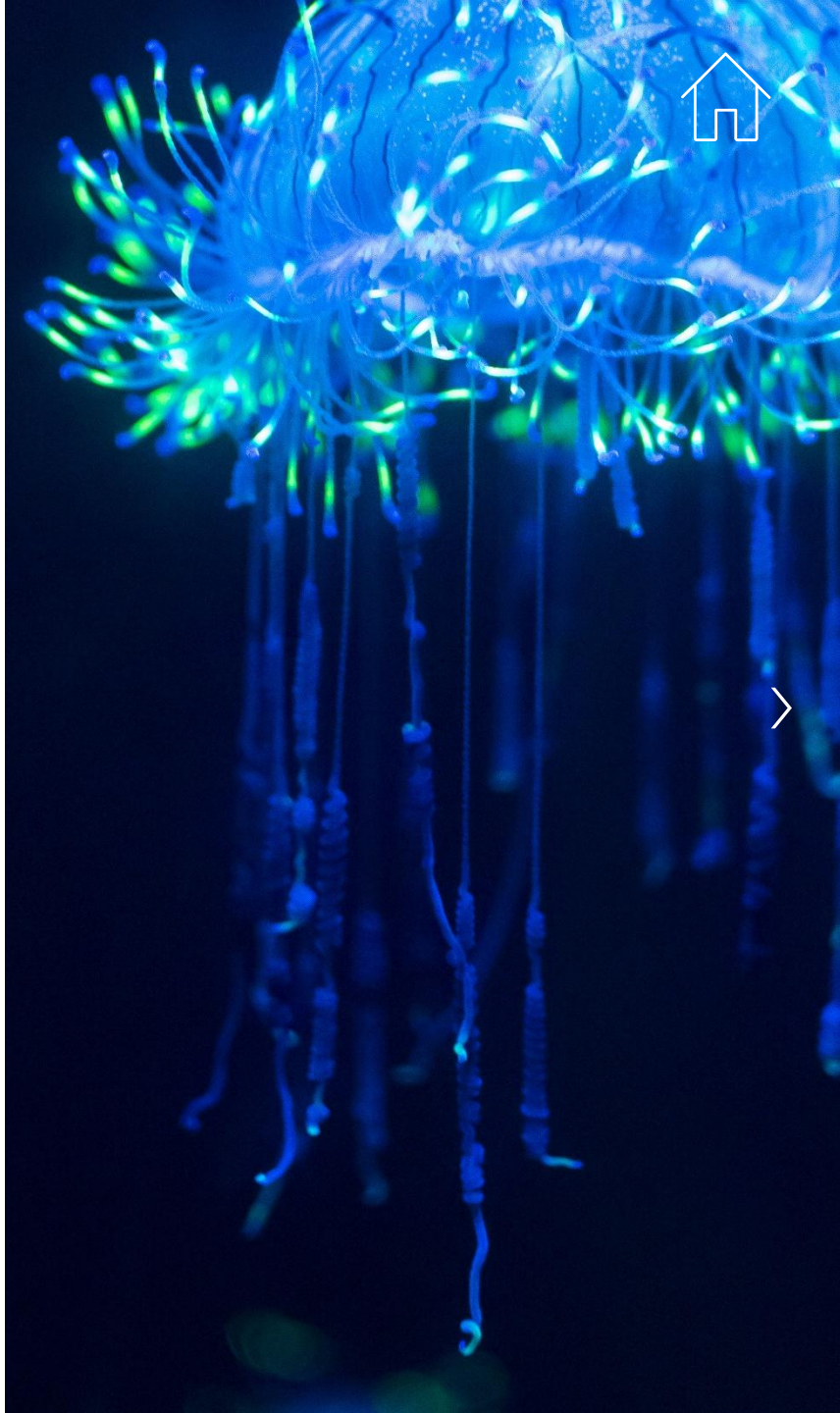
3. Responsibilities for online marketplaces
   - Providers of online marketplaces must verify seller identities
   - Required to cooperate in addressing unsafe products sold on their platforms and cooperate with market surveillance authorities



Important outlines of the EU Product Safety Regulation

4. Improved traceability and identification
   - Clear product identification marks for quick recall
   - For certain products the Commission may set up a system of traceability to which economic operators shall adhere
   - Stricter requirements for recall notices (harmonized recall procedures on EU level)

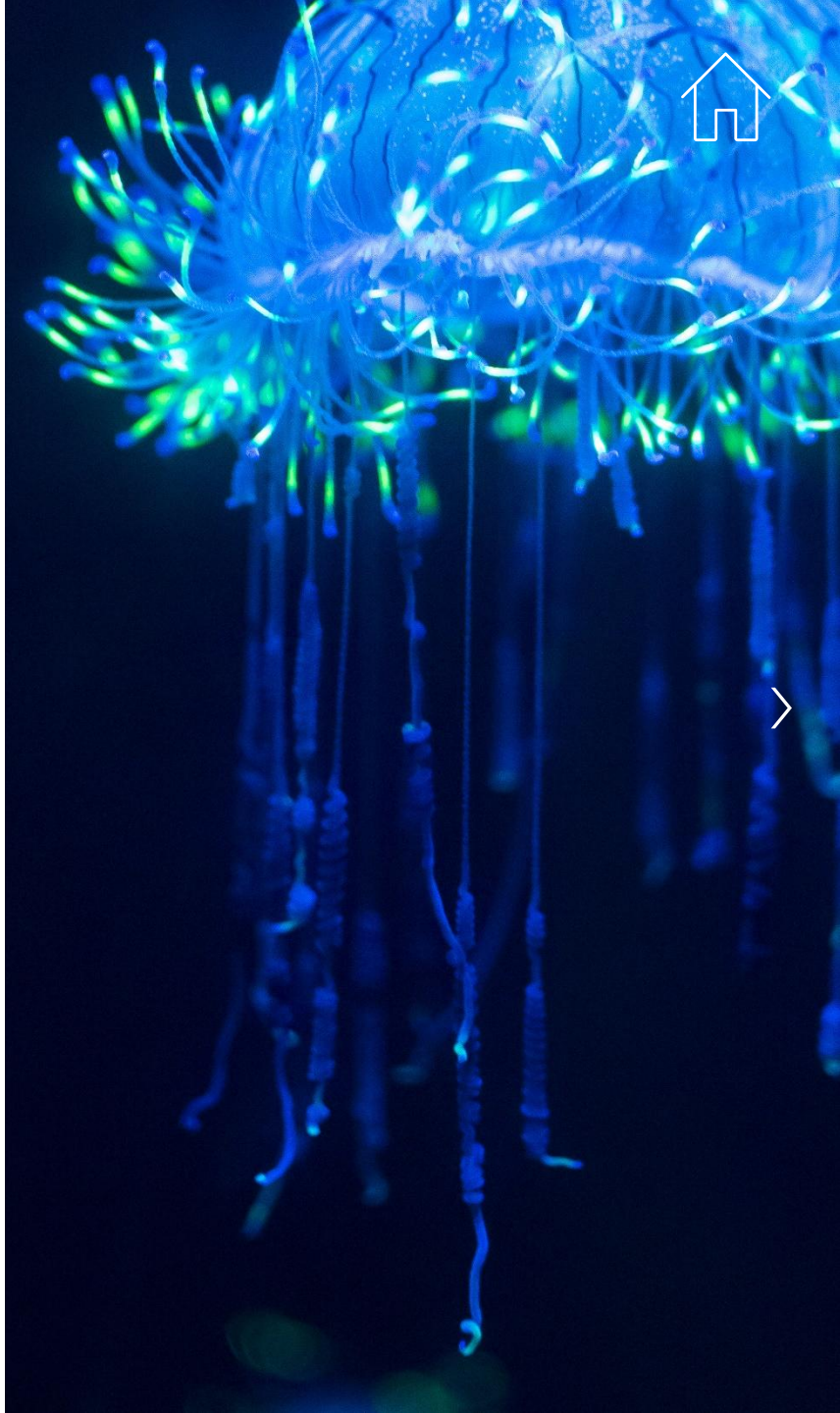
5. Stricter penalties and fines
   - Higher fines and stricter penalties for non-compliance
   - The penalties shall be effective, proportionate and dissuasive



Important outlines of the EU Product Safety Regulation

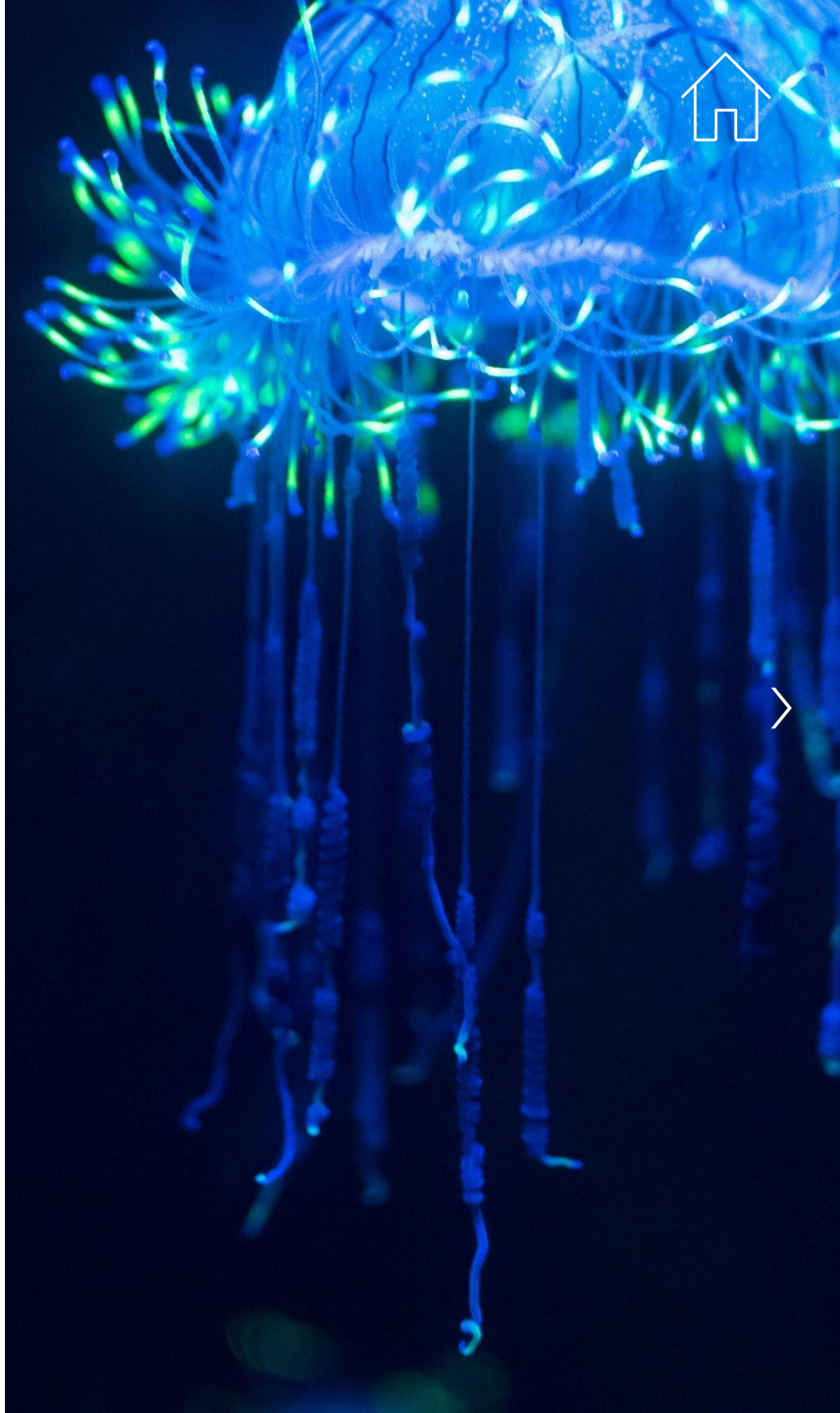
- In addition to the GPSR, there is also legislation that regulates specific characteristics of products (i.e. Toy Safety Regulation, Medical Device Regulations, Machinery Directive etc.)
  - Does a product have specific legislation with additional or deviating requirements?
  - Specific takes precedence over general

- So, for every product you put on the market or trade, check whether it is subject not only to the GPSR, but also to specific legislation!



Important outlines of the EU Product Safety Regulation

- Best practices:
  - i. Conduct a risk analysis before a product is introduced to the market
  - ii. Check products (sample check) and record the findings
  - iii. Indicate the required information on (the packaging of) the products
  - iv. Document (technical) information and manage the documentation
  - v. Create a communication channel and investigate complaints
  - vi. Establish and comply with internal policies (action plan, compliance officer, recall team)
  - vii. A manufacturer may appoint an authorised representative
  - viii. Appoint an economic operator in the EU which is responsible for product safety
  - ix. Issue the right insurances: e.g. business liability insurance, recall insurance and/or D&O insurance
  - x. Being proactive on the safety side will mitigate risks on the liability side



2 Changes in the EU Product Liability Directive and AI

Elizabeth-Anne Larsen

New Product Liability Directive

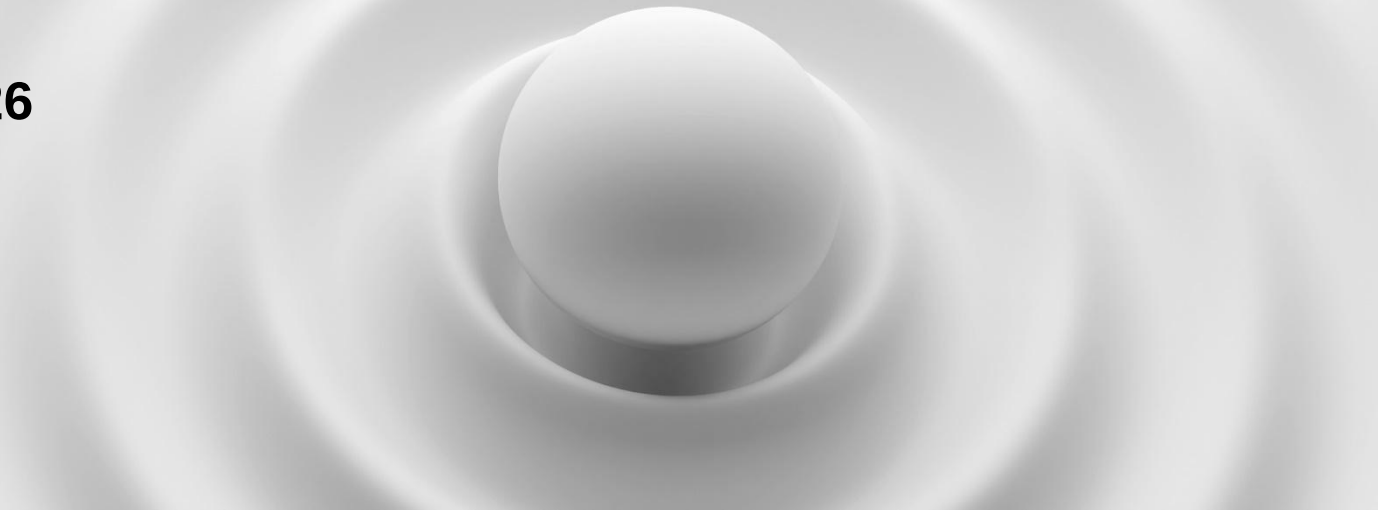
2.01 **New EU PLD**

2.02 **Considerations for insurance and LS companies**

2.01 EU PLD

Current Status:

- 9 December 2024: date new PLD went into effect
- MS have 24 months from that date to transpose it into law
- New EU PLD will apply to products placed on the market/put into service after **9 December 2026**
- No update from any MS



2.01 The changes, in short…

Expands the scope of claims (broader definition of “product”)

Expands the pool of potential Defendants

Expands the types of damages that can be sought; removes minimum threshold for damage to property

Allows Member States to derogate from the “Development Risk” Defence

Changes the test/ provides an alternative basis for “defectiveness”

Leads to heavy, early disclosure (discovery) by Defendants

Eases the burden of proof for Claimants

Extends long-stop limitation date for latent injuries to 25 years

2.01 Expanded definitions of the PLD

New Draft PLD:

This Directive applies to products placed on the market/put into service after 24 months after entry into force, i.e., after 9 December 2026.

"**Product**" definition expanded and includes:

- All movables (even if integrated into, or inter-connected with, another movable or into an immovable)
- Includes electricity
- Software (but not free and open-source software developed or supplied outside the course of a commercial activity)
- Digital manufacturing files (digital version or digital template of a movable)
- Raw materials (e.g., gas and water)

"**Damage**" definition amended:

- Personal injury now includes medically-recognised damage to psychological health
- Removal of minimum claim threshold
- Now includes destruction or corruption of data not used for professional purposes

2.01 New EU PLD

Economic operators liable for defective products

Increase in potential primary Ds:

- Manufacturer of a product
- Component manufacturer
- First importer who places the product onto the Union market from third country
- EU Authorised Representative
- FSP (Fulfilment Service Provider)

Increase in potential secondary Ds:

- **EU distributor**
- **Online platform**

2.01 New EU PLD

BOP and rebuttable presumptions

Presumption of DEFECT:

- D **fails to disclose relevant evidence (pursuant to Art 9(1)**;
- C "demonstrates" product non-compliance with mandatory PS reqs intended to protect against the risk of the damage allegedly suffered by the C; or
- C "demonstrates" the damage was caused by an obvious product malfunction during reasonably foreseeable use/under ordinary circs

Presumption of CAUSATION (causal link between the defect and the alleged damage):

- Defect of the product is established, and
- the damage caused is of a kind typically consistent with the defect in question.

Presumption of DEFECT, CAUSAL LINK, or BOTH where:

- Despite the disclosure, and in consideration of "all relevant circumstances", the C faces "excessive difficulties"—e.g., due to technical or scientific complexity—to prove the defectiveness, the causal link, or both; **and**
- C "demonstrates" it is **likely** that the Product is defective, or that a causal link between defectiveness/damage/both exists

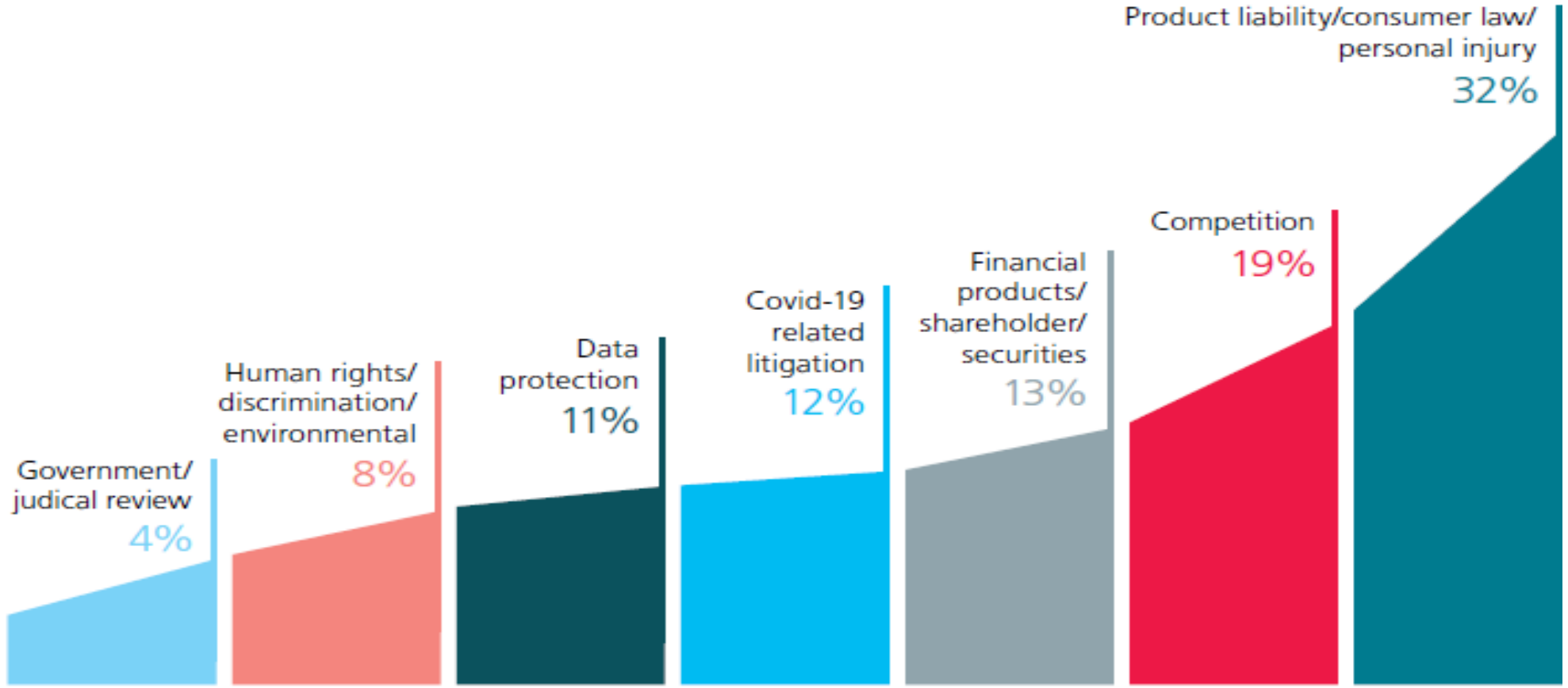
New EU PLD

Impact of PLD and the RAD

Adding fuel to the  …

The RAD and PLD reforms combined can encourage PL class actions being brought against companies doing business in the EU.

2.01 Class action trends in types of claims 2023



2.01 New EU PLD: What can we expect?

Expect:

- More onerous disclosure
- Significant front-loading,
- and increase of, defence costs

Takeaways:

- Tipping of balance of risk in favour of consumers (and their funders!)
- BOP exception becoming the rule for Ds
- Settlement Pressure on Ds can further fuel unmeritorious claims
- Supply chain re-allocation of risk
- Increased importance of TD for acquisitions
- Increased risk of litigation growth, including class actions

2.02: Considerations for insurance and LS companies

Discussion Points: How do these changes affect companies?

The removal of the EUR 500 threshold, increased scope of Ds, increased form of damages, will lead to a rise in liability insurance costs/insurers' risks

The front-loaded disclosure requirements lead to increased legal costs for Defendants. So…

Encourage early settlements?

- Consequence of encouraging unmeritorious claims
- Encouraging high volumes of claims

Uncertain liability risks are difficult to insure against

Expected inconsistency of handling across EU Member States

Considerations

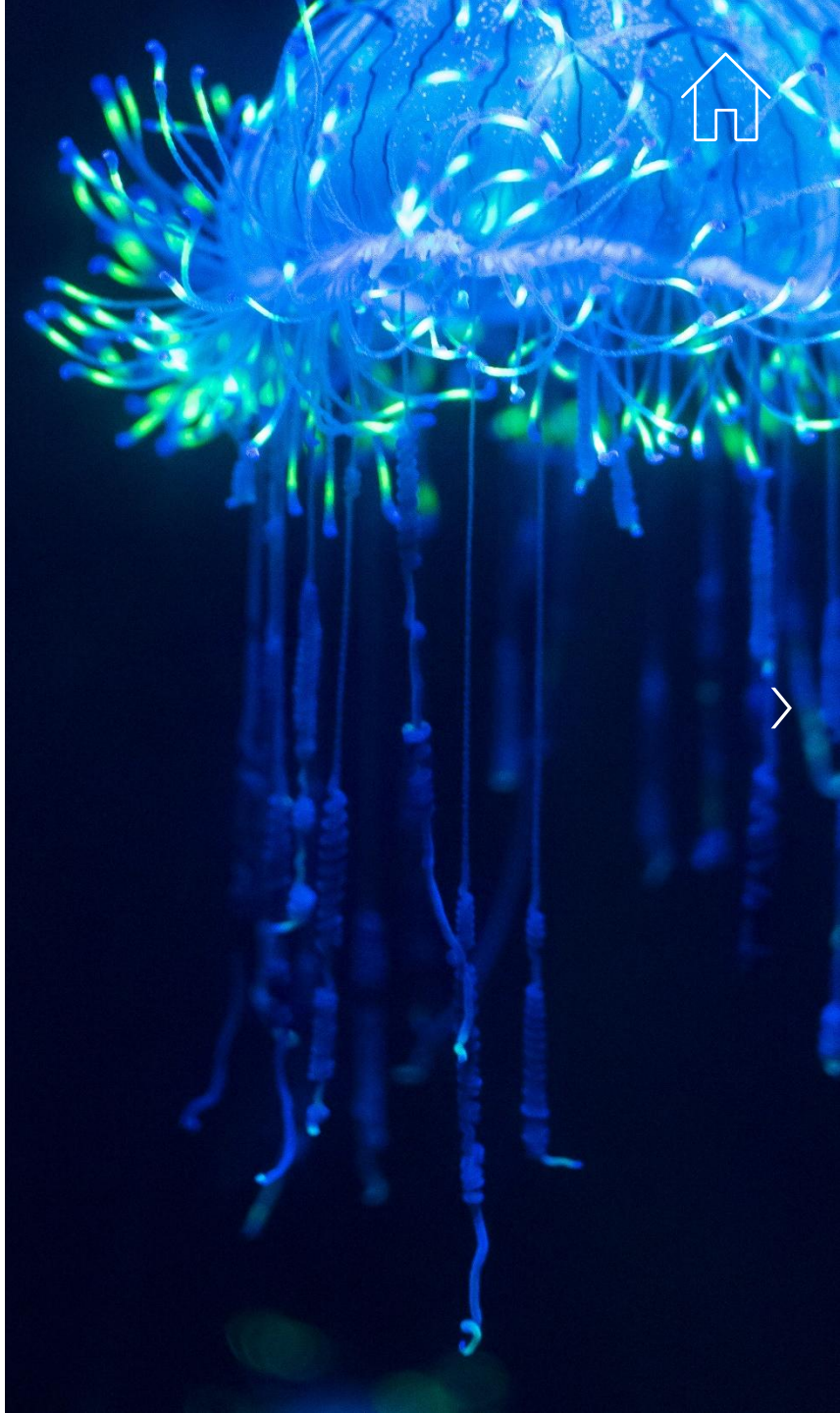
3 Product liability and developments in the Medical Devices Directive

Laura Opilio

Product liability and developments in the MD and IVD Regulations

The legal framework

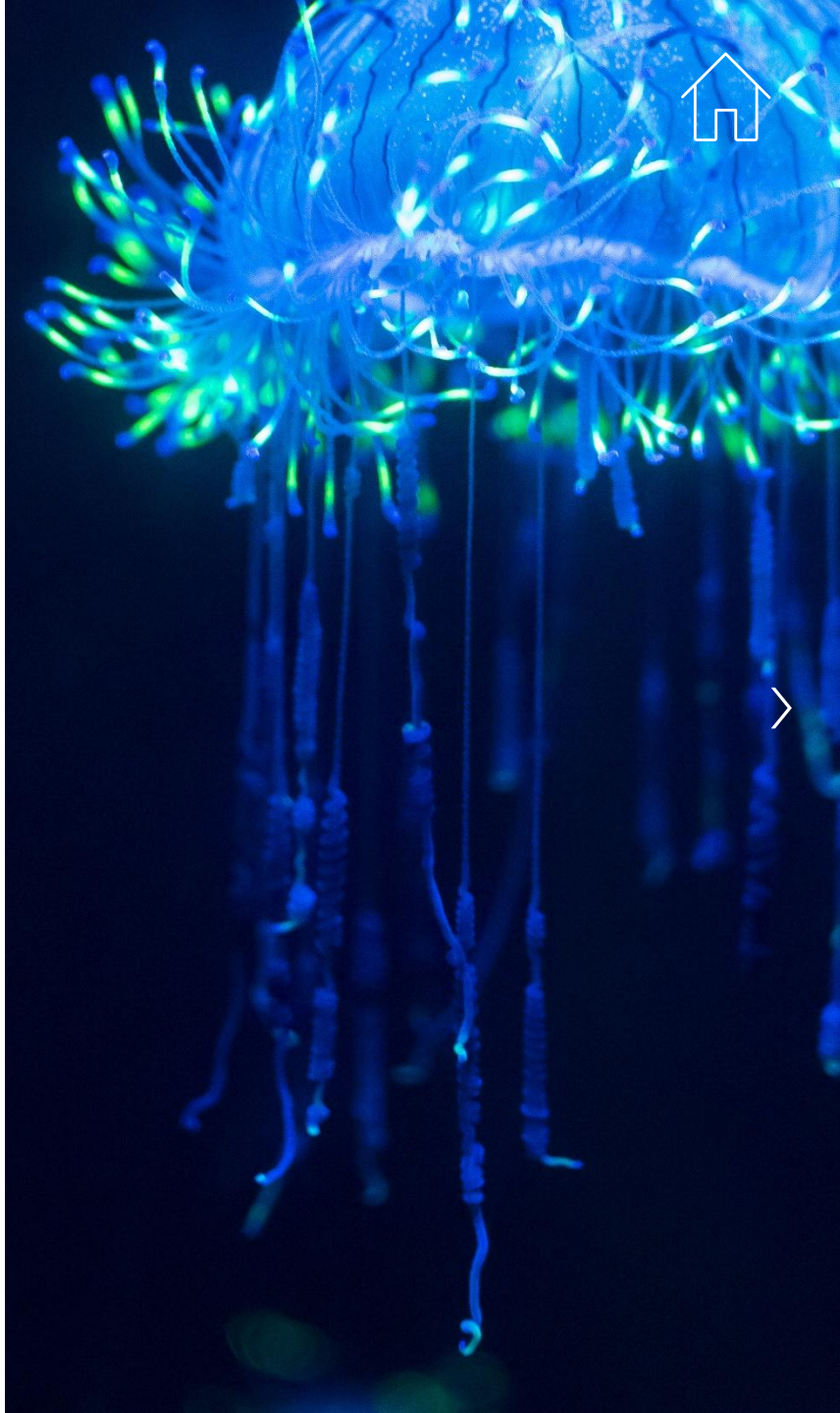
- Regulation (EU) 2023/988 on General Product Safety (“GPSR”)
- Regulation (EU) 2024/2853 on Product Liability Directive (“PLD”)
- Regulation (EU) 2017/745 on Medical Devices (“MDR”)
- Regulation (EU) 2017/746 on In Vitro Diagnostic Devices (“IVDR”)
- Directive (EU) on Consumers Rights 2011/83



Product liability and developments in the Medical Devices Regulation

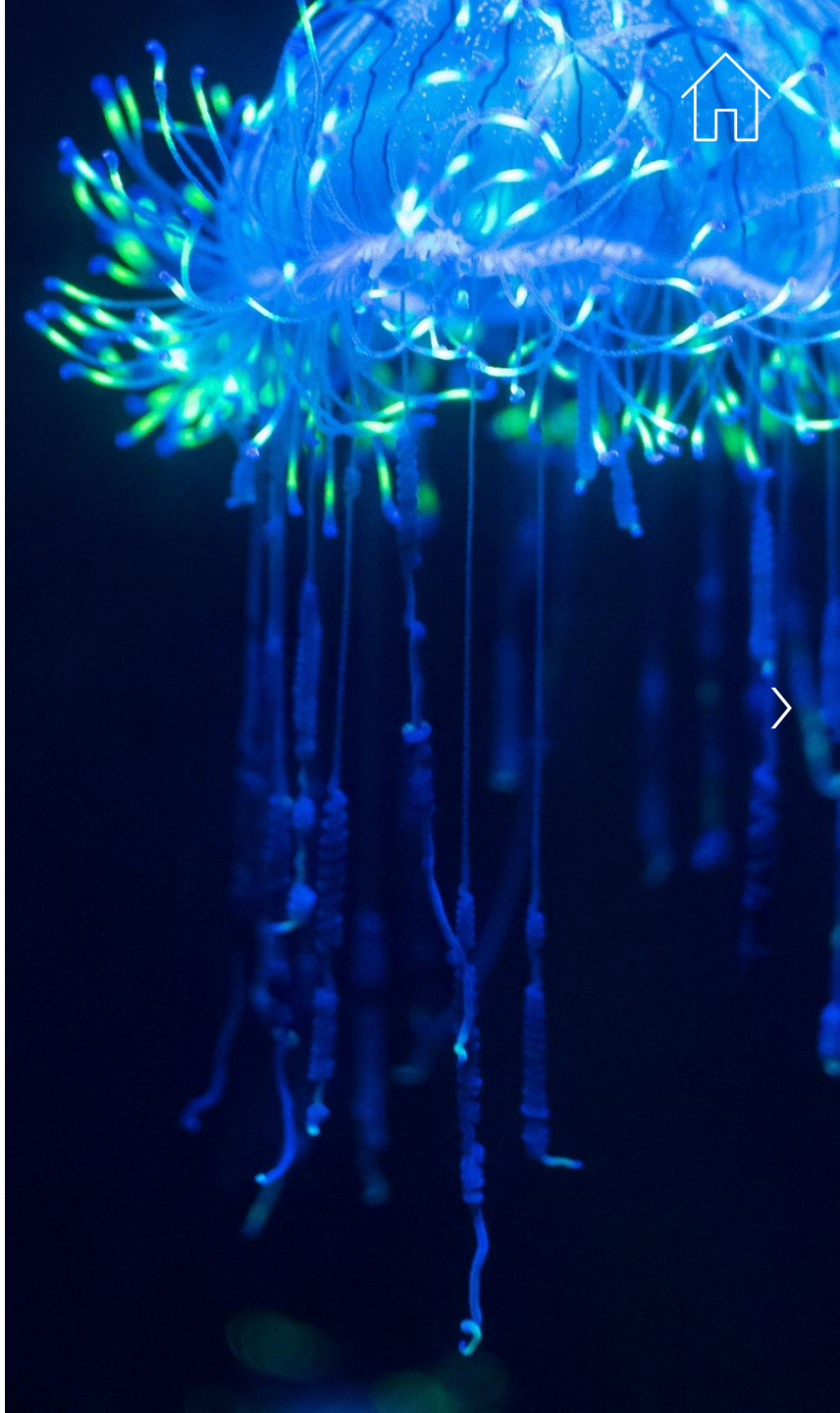
Evaluation of Council Directive 85/374/ECC Final Report (January 2018)

- Most product liability claims are related to Pharmaceutical and MD products: 16,1%
- 67% of CJEU decisions on product liability concern pharmaceutical products and medical devices
- The most frequent reason for rejecting a claim for a defective product in the medical/pharmaceutical sector concerns the burden of proof: proof of the defect and of the link between defect and damage (including costs for collecting sufficient and valuable evidence)



Product liability and developments in the Medical Devices Regulation

- Definition and obligations of economic operators
- Financial requirements
- Risk management, post-market surveillance and incident reporting system
- Compliance with clinical data
- Clinical Evidence
- UDI (Unique Device Identification) system: Transparency and Traceability
- EUDAMED
- Notified Bodies



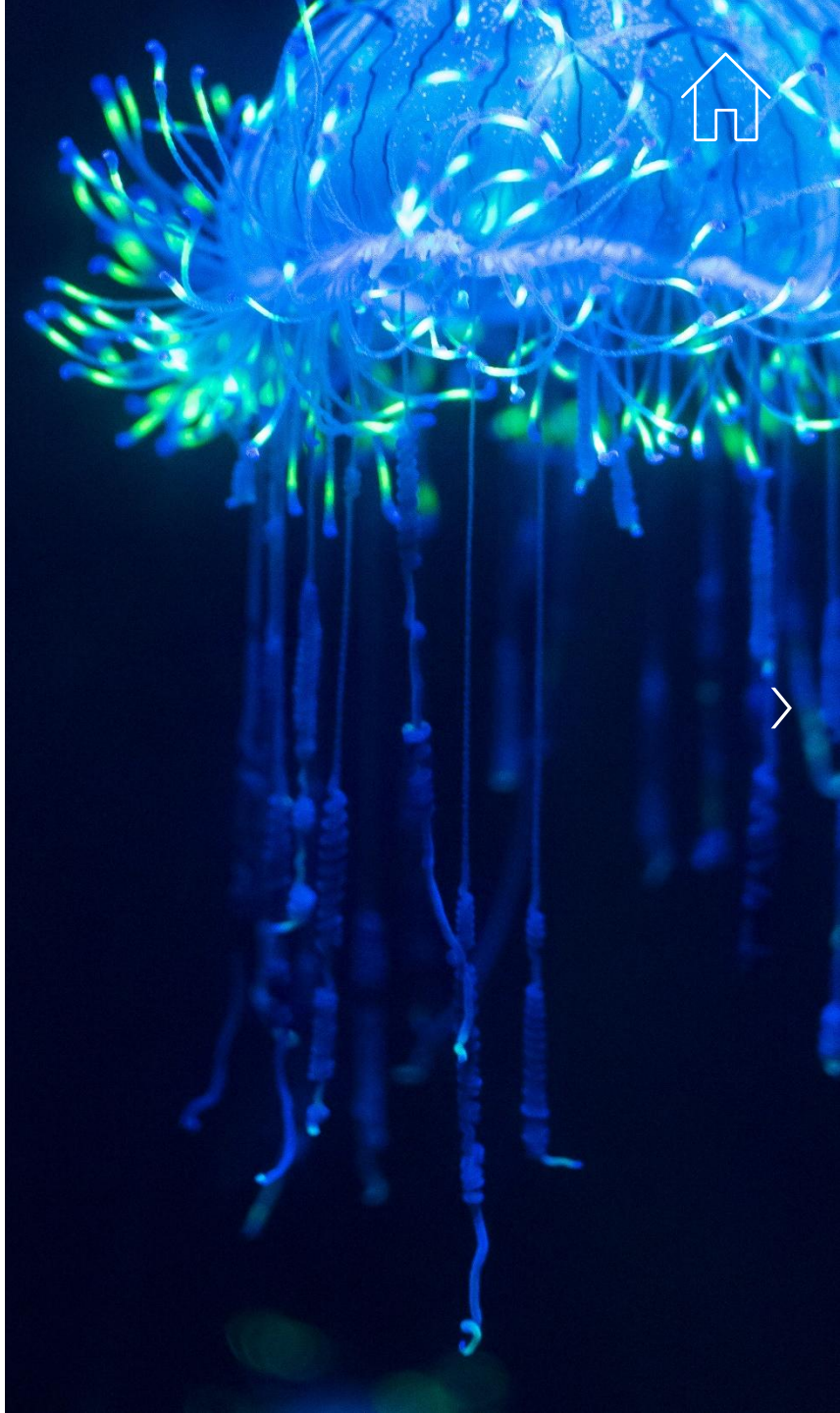
3. Product liability and developments in the Medical Devices Regulation

Definition of defect (art 2)

“Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer”

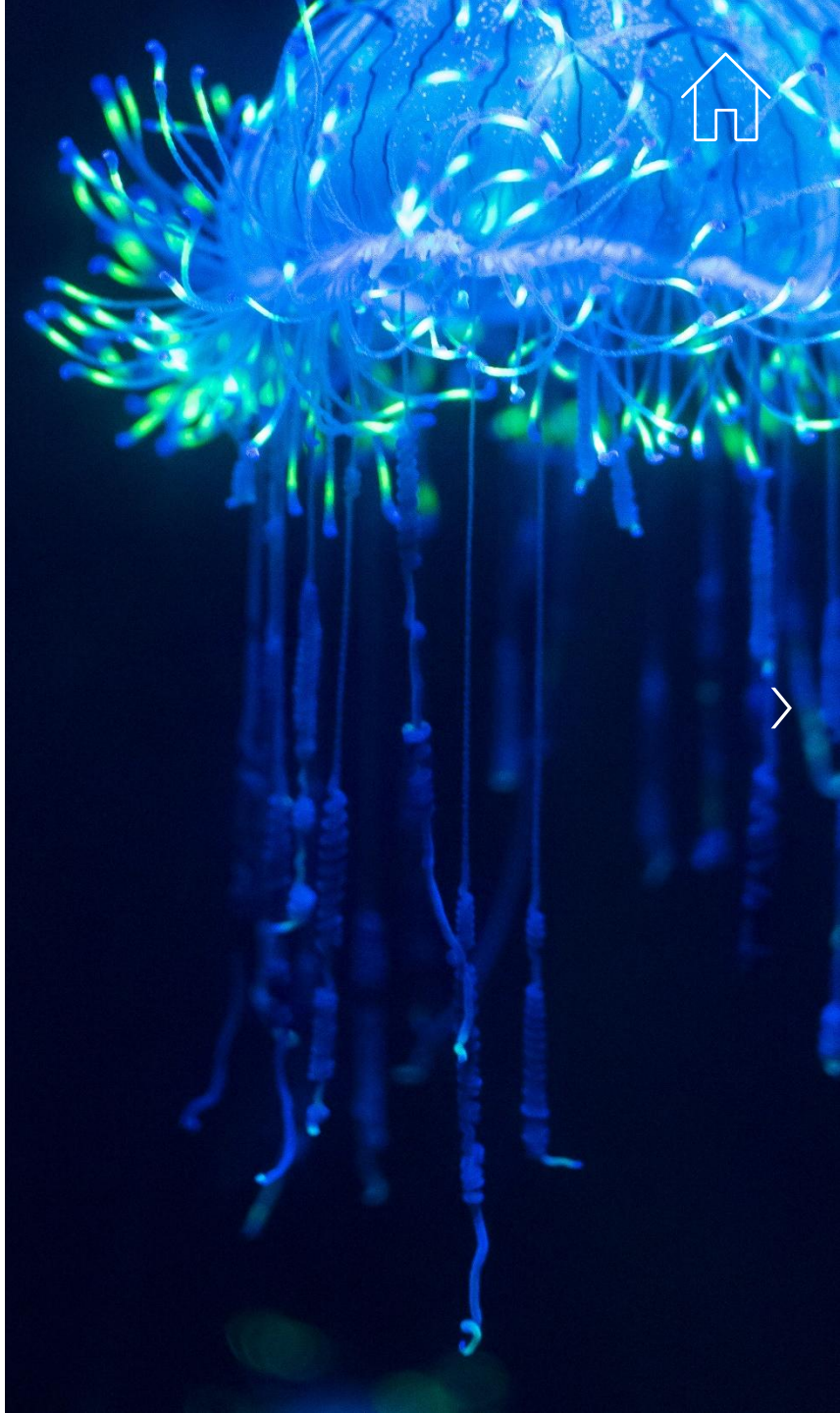
Clinical performance means the ability of a device to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.

Clinical benefit means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.



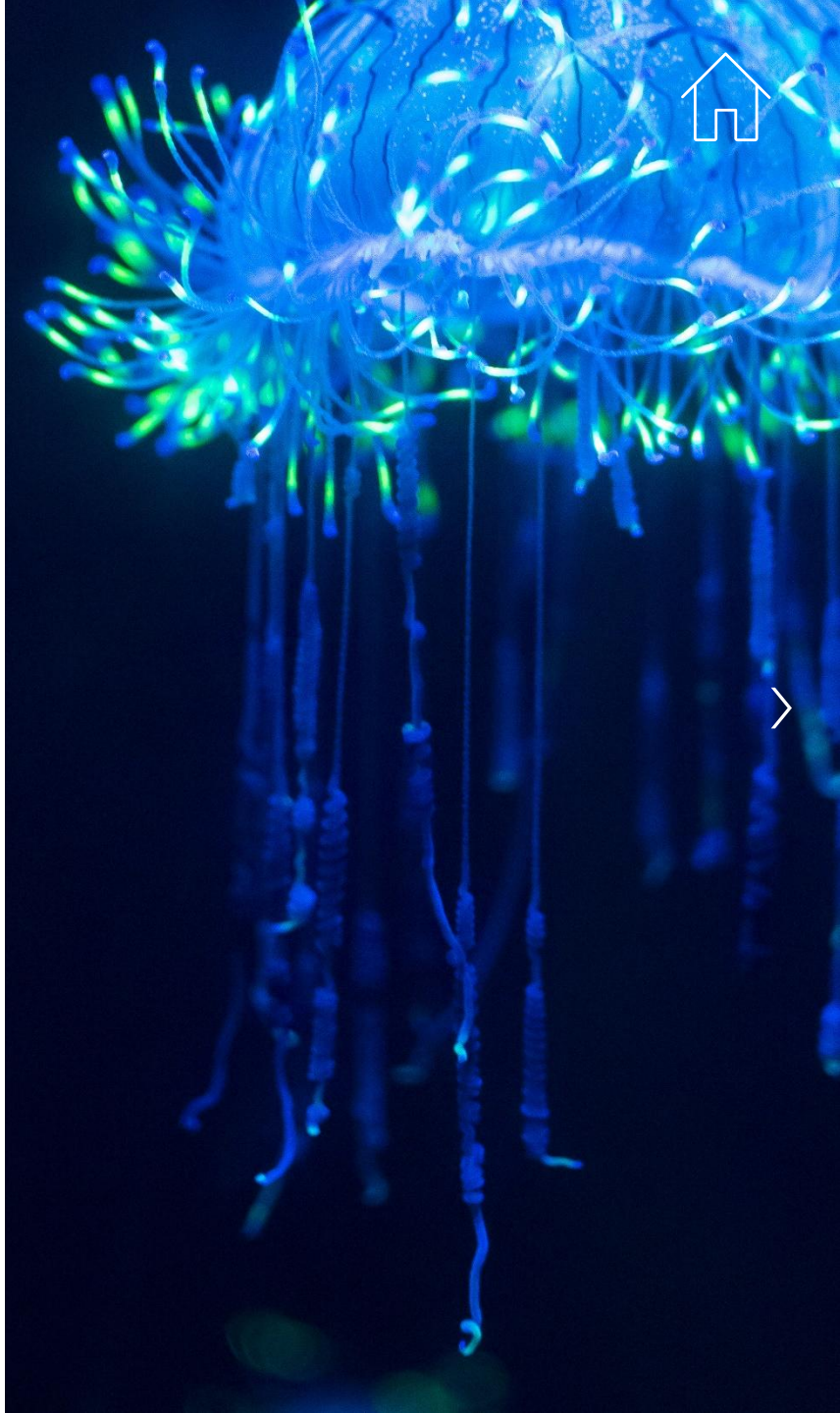
Product liability and developments in the IVD Regulation

- New classification (higher classes of risk)
- Clinical evidence
- Certificates issued by a Notified Body
- Declaration of Conformity
- Post market surveillance system
- EUDAMED



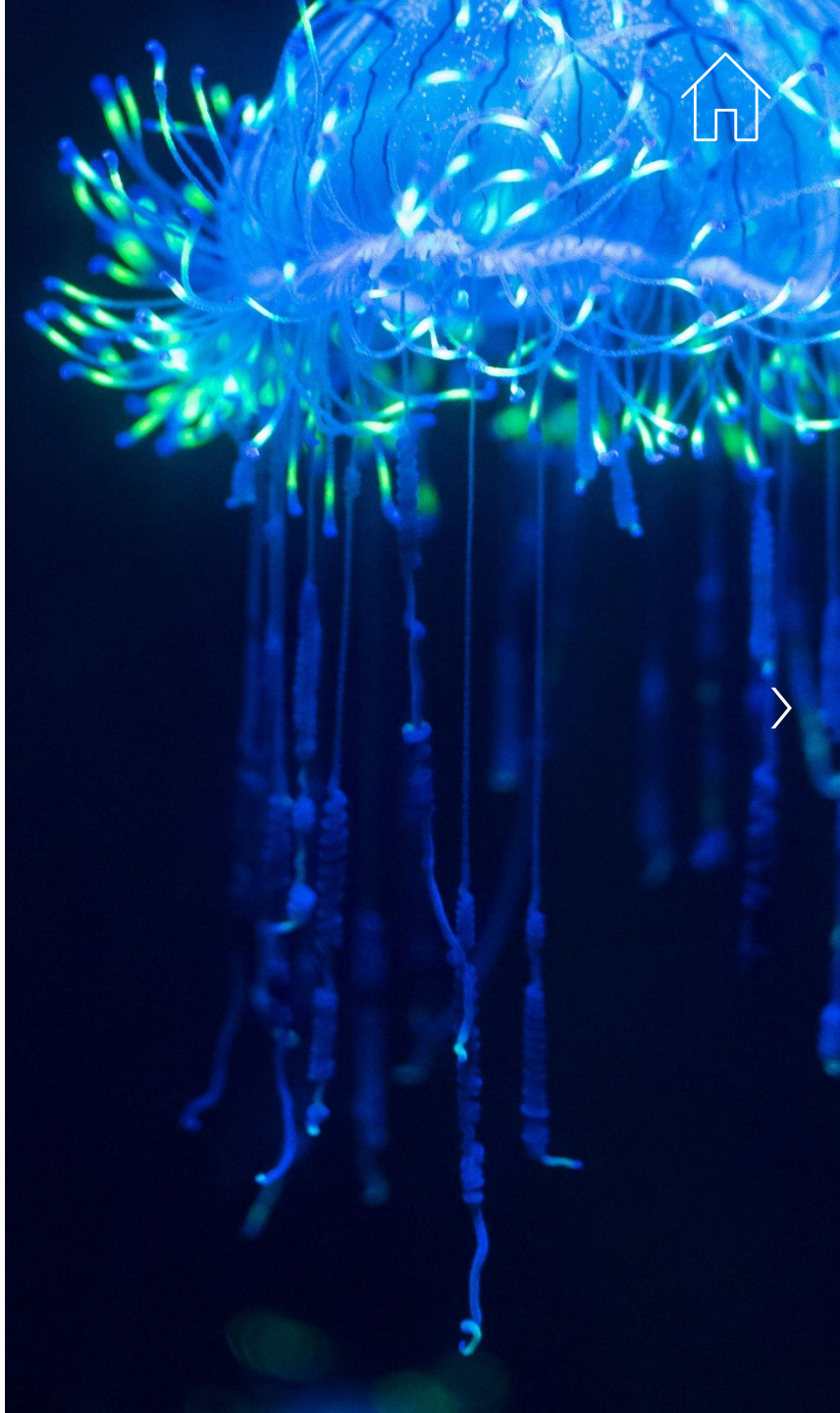
Financial Requirements

- Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law
- Measures: internal asset (reserve) or insurance policy (see EC report on PL Directive n.85/374 31/1/01, 3.2.5)
- Financial limits not set by the Regulations
- Italy: pecuniary sanctions from Euro 26.000 up to 120000 for not compliance



Financial Requirements

- Self assessment on **risk class, MD type and size of company**
- Shared regime of liability between manufacturer and importers/distributor, confirmed by the complementary regulation in art. 8 (c) of the new PLD
- According to MDCG (Medical Device Coordination Group) 2020-14 the notified body may focus their surveillance audit on specific MDR/IVDR requirements, including manufacturer financial coverage in respect of potential liability



4 Product liability South Africa

Sihle Bulose

Consumer Protection Act, 2008 ("**CPA**")

In terms of section 55 of the CPA **consumers have the right** to receive goods that are –

- are fit for the purpose
- are of good quality, in good working order and is free of any defects
- will be useable and durable for a reasonable period; and
- comply with the applicable standards set under the Standards Act, 1993

National standards

The standards set for products under the Standards Act, 1993 often incorporate EU standards or standards that are similar to the EU standards for products that fall under the South African National Standards Specification.

Products may only **carry the SABS mark if the product meets the specified standards**, which requires the product to be tested in accordance with the relevant standards. This allows consumers to make informed decisions when purchasing products.

Product labelling

In terms of section 22 **product notice must be in plain language** and in a prescribed form (if the form of the notice is prescribed in any legislation).

Further labeling requirements for Foods, Cosmetics and Disinfectants can be found in the Foodstuffs, Cosmetics and Disinfectants Act, 1972, while labeling requirements for **textiles and footwear** can be found in the Guide to Importers of Clothing, Textiles, Footwear (Shoes) and Leather Goods (001/05/2022).

Consumer Protection Act, 2008 *continued*

Section 56 of the CPA provides for an **implied warranty.** If the goods fail to satisfy the standards in section 55 then the consumer may return the goods to the supplier, without penalty at the supplier's risk and expense, within 6 months after the delivery of the goods to the consumer. The supplier must refund, repair or replace the defective goods.

In terms of section 58(2) of the CPA, anyone that **packages hazardous or unsafe goods** must provide the consumer instructions on the safe handling and use of the goods.

The **National Consumer Commission** may by written notice require that the supplier/producer to conduct an investigation in respect of such goods or implement a recall programme in terms of section 60(2) of CPA.

In terms of section 61 of the CPA the **producer, importer, distributor or retailer are jointly liable** (strict liability) for harm caused as a result of –

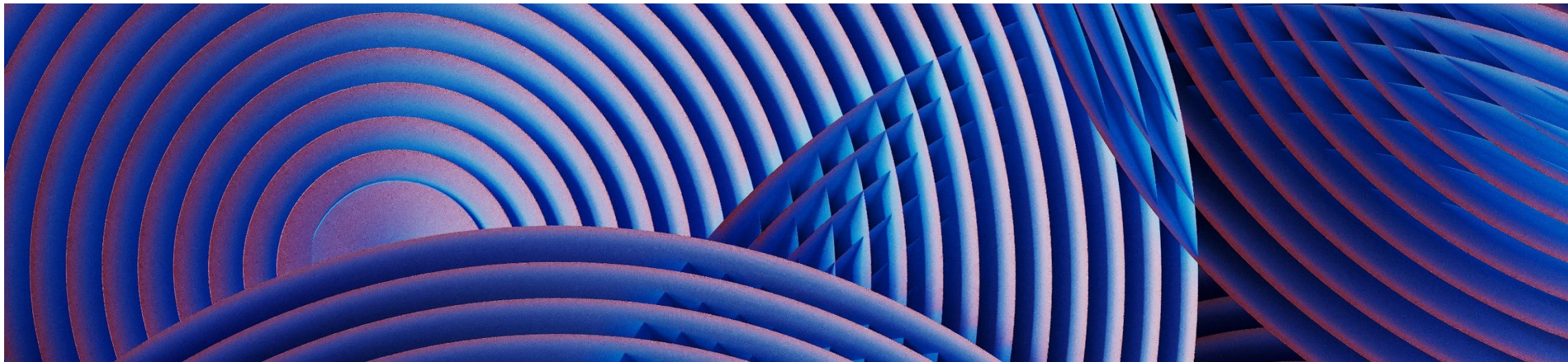
- supplying unsafe goods
- a product failure, defect or hazard in goods; or
- inadequate instructions or warnings provided to the consumer pertaining to hazards associated with the use of the goods

National Consumer Commission ("**NCC**")

- On 12 August 2024 the National Consumer Commission ("**NCC**") issued a guidance note in light of a recent case where a car was returned to defects in terms of the CPA. The purpose of the guidance note was to confirm the passing of risk on the return of defective goods
- The NCC confirmed that where a consumer returns a vehicle that does not meet the standards set out in sections 53 and 55 of the CPA and the seller/distributor refuses to accept the return goods then the risk associated with any use, depletion or deterioration of the vehicle will shift to the supplier/distributor despite their refusal to accept the returned goods

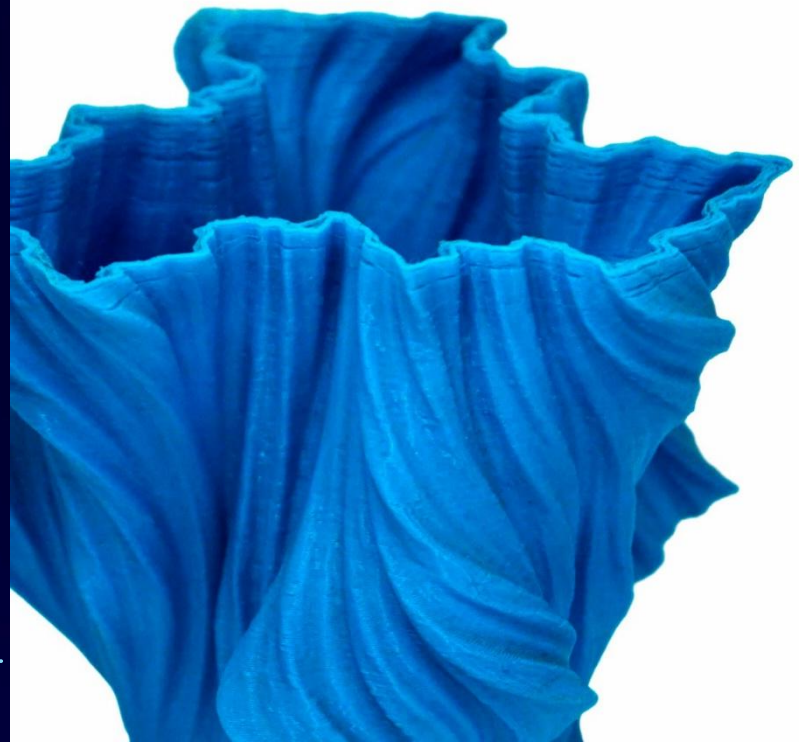
In terms of section 72 of the CPA the **NCC when receiving a complaint** may –

- issue a notice of non-referral if the complaint in frivolous or does not constitute grounds for relief
- refer the complainant to alternative dispute resolution or another regulatory authority; or
- direct an investigator to investigate the complaint as quickly as practicable



Medical Devices

The Medicines and Related Substances Act, 1965 regulates medical devices which includes any machine or software intended by the manufacturer to be used for diagnosis, treatment, monitoring or alleviating of any disease or injury, and the prevention of any disease. The South African Health Products Regulatory Authority ("**SAHRPA**") is tasked with regulating health products and was involved in the recall of defective birth control tablets in November 2024.



- Current framework does not provide for the provision of telemedicine service through an AI system without the intervention of a registered medical practitioner
- Practitioners and hospital groups remain liable
- Devices using AI systems such as robotic surgery assistants, nursing aides and nano-robots if used for these purposes, must be registered with SAHRPA

Medicine and medical devices

Product labelling

The Medicines And Related Substances Act, 1965 prescribes that no one may sell –

- **medicine or scheduled substances** if the container or package does not have a label setting out the prescribed particulars; and
- **medical devices or IVD** unless the device or its packaging bears a label, where practicable, setting out the prescribed particulars

The above-mentioned labels must be approved by the SAHRPA.

- The **prescribed particulars for the labeling** of medical devices and medicines are set out in the regulations of the Medicines And Related Substances Act, 1965

From 4-6 February 2025, SAHRPA and the World Health Organization hosted a workshop to address the threat of substandard and falsified medical products across Africa, with the aim of developing a handbook for the action plan on substandard and falsified medical products. The pilot programme will take a year to develop and implement strategies to address the threat of substandard and falsified medical products.

SAHRPA has previously in 2023 warned the public against the use of unlicensed medicines, such as products purporting to be *Ozempic*.

5 Product liability China

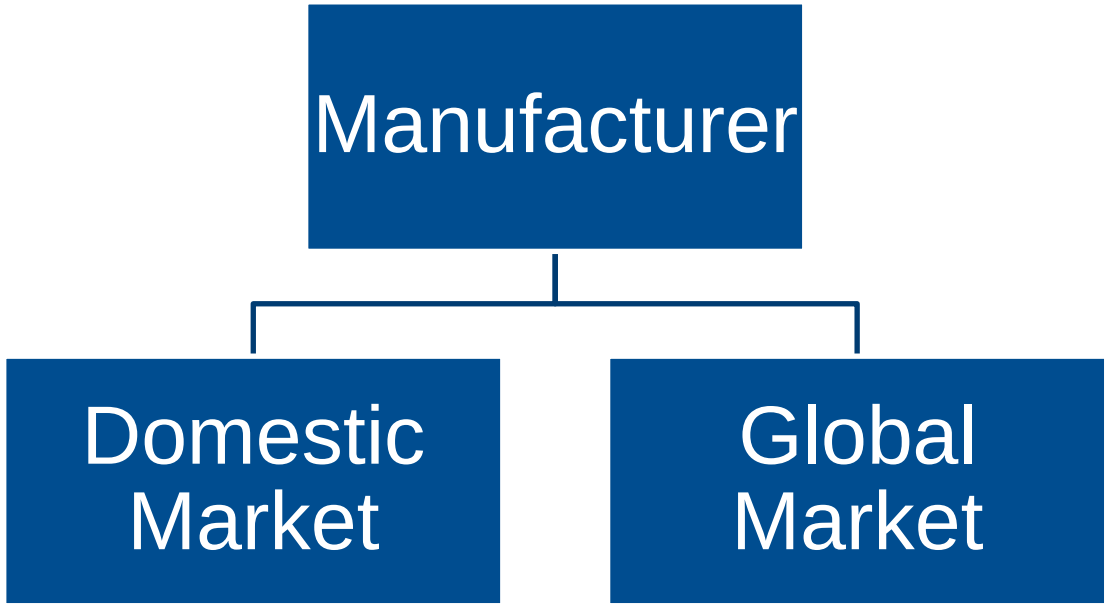
Jonathan Chu

The Growing Importance of Product Liability in China

Many of the “products” in terms of product liability starts with China

- China contributed approximately 30% of the global manufacturing added value in 2024
- Manufacturing accounts for 24.86% of its GDP, which was RMB33.5507 trillion (EUR4.420 trillion)
- Manufacturing covers everything from consumer electronics to heavy machinery

Domestic and Global Market



China manufactures for its own consumption, as well as for global consumption.

E-Commerce Growth

- eCommerce revenue projected to reach USD1.38 trillion in 2025
  - ➢ Most is generated in China
- Growth rate of 7.62%
- Number of users is expected to amount to 1.4billion by 2029
- Key regions are USA, Asia, Japan, S. Korea, and India

E-Commerce Rise

SHEIN

Taobao

TikTok Shop

JD.COM

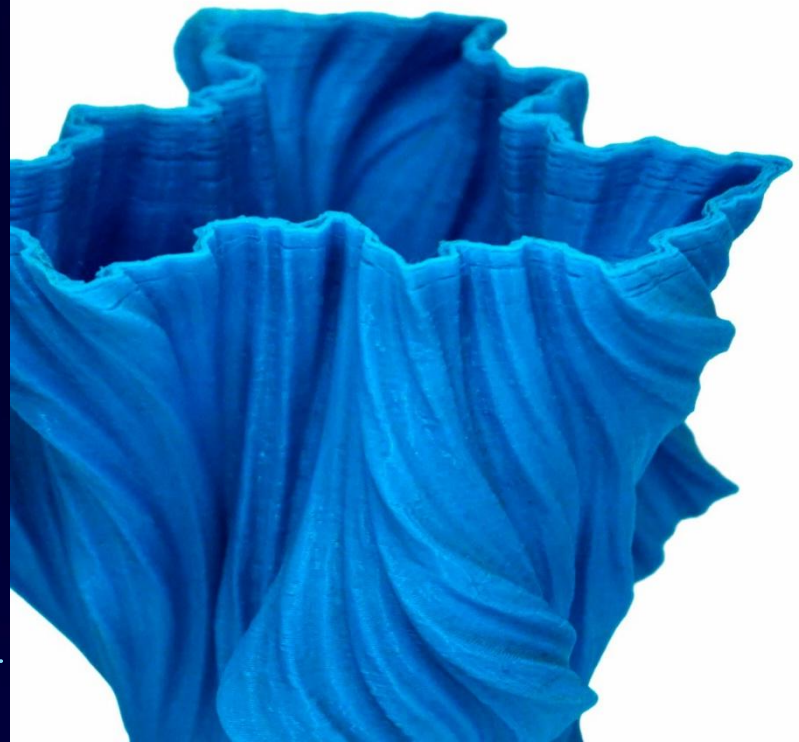
TEMU

拼多多

AliExpress

Why is this Important to Product Liability?

With a growing domestic market and increased interest in global market, regulations and laws will be shaped



- Rise of E-commerce has had a profound impact on the evolution of product liability laws
- Supply chains affected, bypassing traditional retail channels – manufacturers are closer to consumers
- Blurred lines of responsibility makes it crucial to clarify the liability of platforms, sellers and manufacturers

Key Laws

E-Commerce Law of the PRC

- Took effect in 2019
- Addresses rights and obligations of operators, consumer protection and IP protection
- Electronic contracts, online payments and data protection

Product Quality Law of the PRC

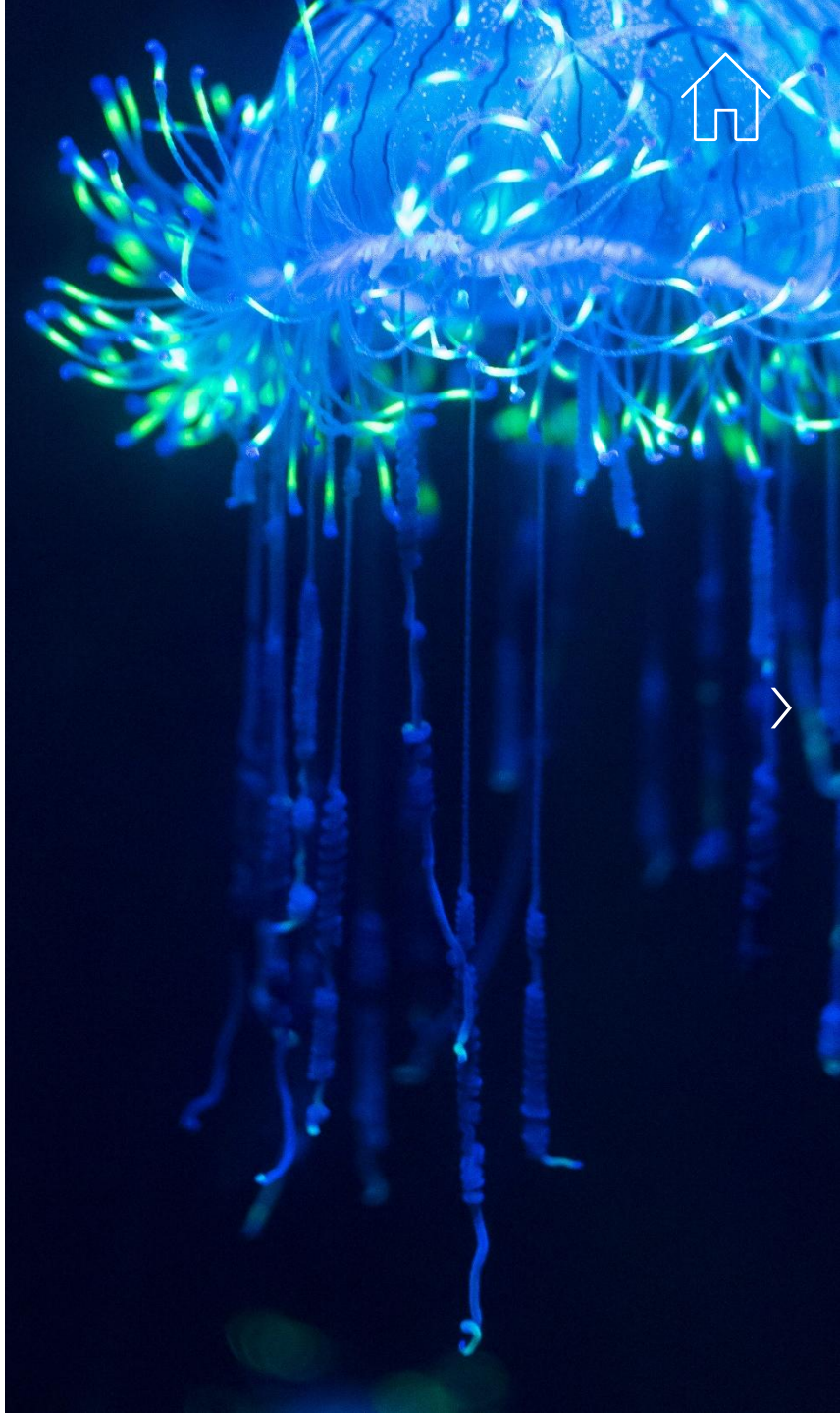
- Online and offline sales - addresses

Civil Code of the PRC

- *Interpretation of the Application of Tort Liability of the Civil Code of the PRC* took effect in 2024.

Law of the PRC on Protection of Consumer Rights and Interests

- Implementing regulation took effect in 2024.



Recent Developments

The scope of damages that consumers can claim has widened.

- *Interpretation of the Application of Tort Liability of the Civil Code of the PRC*, Article 19

Sellers shall be liable for the damages caused by giveaways.

- *Regulation on the Implementation of the Law of the PRC on the Protection of Consumer Rights and Interests*, Article 7

More specialised regulations have been released to clarify the liability of platforms and sellers in e-commerce.

- *Provision of the Supreme People's Court on several Issues Concerning the Application of Law in the Trial of Cases of Disputes over Online Consumption (I)*, Article 4, 12, 14 - 17

Prevent sellers and platforms from unreasonably exempting themselves from liability by methods such as standard terms.

- *Provision of the Supreme People's Court on several Issues Concerning the Application of Law in the Trial of Cases of Disputes over Online Consumption (I)*, Article 1, 3

Questions

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