2024 CMS Insurance Sector Group
Webinar Programme

Product liability

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Moderator:
Bas Baks (CMS Netherlands)
Panel:
Rowena Williams (CMS UK)
Laura Opilio (CMS Italy)
Jorge Etreros (CMS Spain)
Annelies Zwart (CMS Netherlands)
Hugues Marxuach (CMS France)
Yushanta Rungasammy (CMS South Africa)
Sihle Bulose (CMS South Africa)

Your speakers today

Bas Baks | Partner
T: +31 20 301 62 49
E: bas.baks@cms-dsb.com

Laura Opilio | Partner
T: +39 06 47 81 51
E: laura.opilio@cms-aacs.com

Yushanta Rungasammy | Partner
T: +27 (0) 72 464 1722
E: yushanta.rungasammy@cms-rm.com

Sihle Bulose | Partner
T: +27 (0) 82 776 2038
E: sihle.bulose@cms-rm.com

Annelies Zwart | Senior Associate
T: +31 20 301 6267
E: annelies.zwart@cms-dsb.com

Rowena Williams | Senior Associate
T: +44 131 200 7319
E: rowena.williams@cms-cmno.com

Jorge Etreros | Senior Associate
T: +34 91 452 00 32
E: jorge.etreros@cms-asl.com

Hugues Marxuach | Associate
T: +33 1 47 38 41 93
E: hugues.marxuach@cms-fl.com

What we will cover

01 The impact of the new General Product Safety Regulation (EU) 203/988

02 Obligations/guidelines regarding the notification of dangerous products

03 Amendments to Directive Product liability (85/374/EEC)

04 UK, respectively South African perspective on product liability

05 Legislation regarding liability for defective medical devices

06 Q&A

1 The impact of the new General Product Safety Regulation (EU) 203/988

General Product Safety Regulation (EU) 2023/988 (I)

General Product Safety Regulation (EU) 2023/988

- Replacing the General Product Safety Directive (2001/95/EC)
  - Impact assessment

- Objectives of the GPSR
  - Applicability to digital products, like software, AI
  - New tools to surveil/impact online marketplaces which have become ubiquitous
  - Harmonized recall procedures on the EU level

- The new General Product Safety Regulation (2001/988) **(“GPSR”)**
  - Legislative status: enforceable starting **13/12/2024**
  - Harmonized definitions, products and procedures

General Product Safety Regulation (EU) 2023/988 (II)

Market participants

The GPSR expands the scope of market participants to introduce ‘providers of online marketplaces’ (article 3(14)), which have **specific obligations**:

- Article 22 GPSR:
  - Single point of contact through the Safety Gate Portal
  - Removal of dangerous products
  - Suspension of traders

- Mandatory EU representative
  - Tasks set out in in Article 4(3) of Regulation 2019 1020 ('Market Surveillance Regulation’), e.g: Availability of technical documentation, compliance checks and risk identification

- Insurance opportunities: **new market participants/increased recall rates as intended by the EC**

General Product Safety Regulation (EU) 2023/988 (II)

(Pre-market) Safety assessment

- **Strict obligations imposed on ‘economic operators’**
  - Internal risk analysis (art. 9(2)): general description and characteristics relevant for safety, as well as possible risks and the solutions adopted
  - Technical documentation (art. 9(3))
    - To be kept up to date and at the disposal of Market Surveillance Authorities for 10 years by the manufacturer (art. 9(3)), and/or the importer (art. 11(6)).

- **Improved traceability and identification**
  - Art. 9(5): traceability duty: type, batch number, serial number
  - Art. 9(6): contact information of the manufacturer to be placed on the product

General Product Safety Regulation (EU) 2023/988 (III)

Penalties

- Stricter penalties for non-compliance
- Implementation in accordance with national law (art. 44(1))
- *“Deterrent effect” & “Effective, proportionate and dissuasive.”*

- **Penalties in case of breach are yet unknown.**
  - *Original legislative proposal: max. 4% of annual turnover.*

2 Obligations /guidelines regarding notification of dangerous products

Obligations regarding notifications of dangerous products (I)

- Accident/dangerous product on the market
- Obligations (manufacturer, importers/distributors & online marketplaces) (e.g. article 9(8)):
  - Corrective measures
  - Inform consumers
  - Inform market surveillance authorities

Obligations regarding notifications of dangerous products (II)

Dangerous product available on the market; informing consumers & authorities

- Notification obligation to consumers (article 35):
  - *(1) "direct and without undue delay"*
  - *(4) "appropriate channels"*

- Specific obligations regarding **recall notices** (article 36), for example:
  - *"Language of the Member State" (2)*
  - Headline consisting of the words *"Product safety recall" (2a)*
  - Clear description of the product, the hazard and the actions a consumer should take
  - Remedies (article 37): R.R.R.

- Notification obligation to authorities (article 20 (1))

Practical guidelines regarding notifications of dangerous products (III)

Safety Gate

- Former: RAPEX

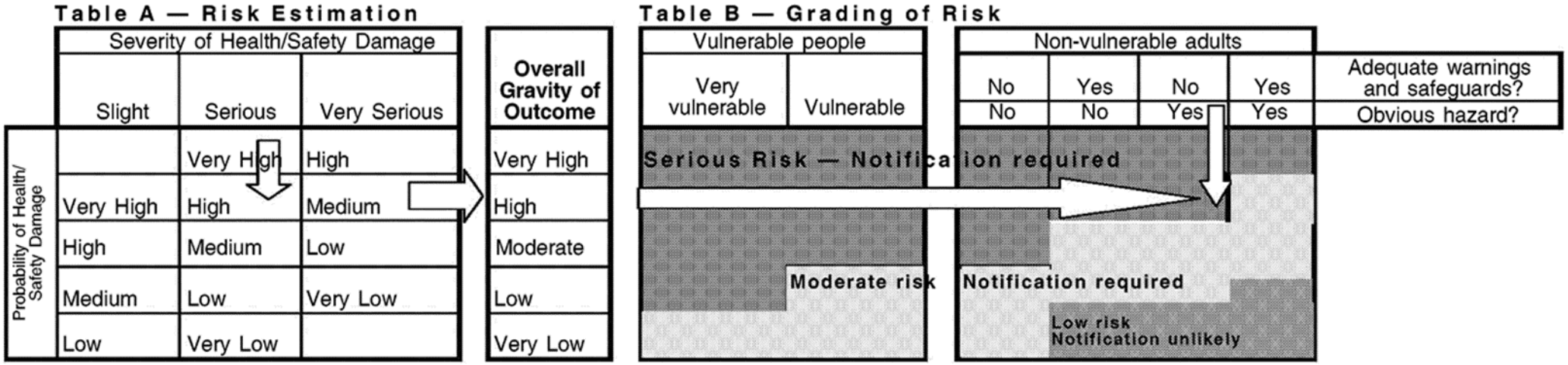
- Consisting of 3 elements:
  - Safety Gate Rapid Alert System
  - Safety Gate Portal
  - Safety Business Gateway

- Consumer Safety Network (article 30)

Practical guidelines regarding notifications of dangerous products (IV)

Risk assessment

- Risk assessment: model EU Commission Decision 2004/905/EC



Practical guidelines regarding notifications of dangerous products (V)

Practical guidelines

- Reporting to authorities in practice
  - Observations
  - Differences between Member States?

- Proactive approach
  - Prepared recall/withdrawal plan

3 Amendments to Directive Product liability (85/374/EEC)

Amendments to Directive Product liability (85/374/EEC) European Commission Proposal September 2022

- No fault-based liability of producers for damage caused by defective products
- Software must be considered a product (defectiveness for lack of software updates)
- Liability also for products refurbished or manufactured outside EU
- Damage also harms to psychological health and corruption of data

Amendments to Directive Product liability (85/374/EEC) Council Proposal June 2023

- Add raw materials (including gas and water)
- Presumption of defectiveness based on expectations of public at large
- Wide definition of manufacturer
- Development risk defence (no longer subject to Member State derogations)
- Compensation period (20 years)

Amendments to Directive Product liability (85/374/EEC) Parliament Proposal October 2023

- Add raw materials (including gas and water)
- Medically recognised harm to psychological health
- Loss of data compensated (not if not used for professional purposes under Euro 1000)
- Presumption of defectiveness based on expectations of the average person
- Wide definition of manufacturer
- National schemes to compensate damaged persons
- Exemption for micro or small enterprises producing software

Amendments to Directive Product liability (85/374/EEC) Text approved December 2023

- Any product, including electricity, raw materials and software, digital manufacturing files and digital services
- No free software and open source outside commercial activity
- Cascade of attributable liability for the economic operators: manufacturer of a product or component; provider of a service; authorised representative; importer; fulfilment service provider; distributor (including online platforms)
- Damages: death, personal injury **and** medically recognised harm to psychological health; property damages (no more threshold of Euro 500) and loss or corruption of data not used for professional purposes

Amendments to Directive Product liability (85/374/EEC) Text approved December 2023

- Compensation of material damages and non-material losses (on the basis of national legislation)
- Burden of proof on the damaged party (alleviated by presumption of defectiveness and casual link)
- Manufacturer’s obligation to disclose all relevant information
- Liability period 10 years and 25 years for personal injuries if symptoms are slow to emerge
- Claim time barred after 3 years from the date the defect was discovered, the damage occurred and the manufacturer was identified

Timing for approval

- Parliament approved in March 2024
- Council still to approve
- New rules applicable to products placed on the market 24 months after the Directive comes into force

4 United Kingdom, respectively South African perspective on product liability

Product liability: United Kingdom

Applicability

- Will the new Product Liability and its caselaw apply in the UK*?
- Outlook for the future of UK legislation

Product liability: United Kingdom

Development of the Current Law

- UK Legislation: Consumer Rights Act 1987, based on the Product liability Directive 1985
- Cause of action = Before or after 31 December 2020?
  - Before 31 December 2020:
    - Product Liability Directive 1985;
    - its existing caselaw;
    - new caselaw;
    - and caselaw on the new Directive if it relates to a common concept
  - From 1 January 2021:
  - Product Liability Directive 1985;
  - and existing caselaw only

Product liability: United Kingdom

What will the courts do?

- Post-Brexit rules on European caselaw:
  - To follow or not?

- TuneIn v Warner Music UK Limited [2021] EWCA Civ 441
- ICE Limited v IEC Holdings Co Limited [2023] EWCA Civ 1451

Product liability: United Kingdom

Future developments

- No full review of the PLD and GPSR planned
- Office for Product Safety and Standards: Smarter Regulation consultation
- Extended use of CE marks – what if regulations diverge?
- Intra-UK divergence

Product liability: United Kingdom

To conclude

- Will the new Product Liability Directive and its caselaw apply in the UK?
  - No, but…

- Unclear how the current law will develop, and whether the UK Courts will choose to stay aligned with the EU?

Consumer Protection Act, 2008 (“**CPA**”)

When does the CPA apply?

The CPA applies to every transaction, agreement, advertisement, production, distribution, promotion, sale or supply of goods or services (local and international suppliers).

What is a good or service

- Goods
  - Anything marketed for human consumption.
  - Immovable Property and other tangible goods.
  - Intangibles – literature, music, data, software, code, and any other intangibles.
- Services
  - Any work or undertaking for the benefit of another.
  - Education, banking services, transportation, accommodation, infrastructure and others.

CPA continued

When does not CPA apply?

- Monetary and non-monetary exclusions.

Exceptions:

- Goods or services promoted or supplied to the state.
- A transaction that constitutes a credit agreement under the National Credit Act, 2005.
- Employment contracts.
- Collective bargaining agreements.
- Where the Minister of Trade and Industry has given exemption to the transactions
- Where the consumer is a juristic person whose annual turnover or asset value exceeds or equals ZAR2 million.
- Financial services under the Insurance Act, 2017 and Financial Advisory and Intermediaries Act, 2002.

CPA continued

Consumers' rights to safe, good quality goods - section 55 of the CPA

- Consumers have the right to receive goods that are:

- are fit for the purpose;
- are good quality, in good working order and free of any defects; and
- will be useable and durable for a reasonable period, having regard to the use to which they would normally be put and to all the surrounding circumstances of their supply.

CPA continued

Implied warranty of quality - section 56 of the CPA

Within six months after the delivery of any goods, the consumer –

- may return the goods to the supplier without penalty
- at the supplier's risk and expense
- if the goods fail to satisfy the requirements and standards contemplated in section 55, then:
  - the supplier must (at the discretion of the consumer) either –
    - refund the consumer the price paid for the goods or
    - repair or replace the failed, unsafe or defective goods

CPA continued

Liability for damage caused by goods - section 61 of the CPA

- The producer or importer, distributor or retailer of any goods is liable for any harm caused as a result of:
  - supplying any unsafe goods;
  - a product failure, defect or hazard in any goods; or
  - inadequate instructions or warnings provided to the consumer pertaining to any hazard arising from or associated with the use of any goods.

CPA continued

Strict Liability - under the CPA the producer, importer, distributor and retailer are jointly and severally liable (local and international parties may be liable, as long as there is a supply of goods or services in South Africa/to a consumer based in South Africa).

Burden of proof – on a balance of probabilities, depending on applicable law. No presumptions, one way or the other. Standard common law position – the consumer would have to prove damages.

CPA continued

Safety monitoring and recall - section 60 of the CPA

- The National Consumer Commission ("**the Commission**") is empowered to develop a practice and framework where goods are determined to be unsafe, to recall those goods for repair, replacement or refund.

- If the Commission has reasonable grounds to believe that any goods may be unsafe or that there is a potential risk to the public, and the producer or importer of those goods has not taken any steps, it may by written notice require that:
  - the supplier/producer to conduct an investigation in respect of such goods; or
  - The supplier/producer carries out a recall programme on any terms required by the Commission, in terms of section 60(2) of CPA.

Consumer Product Safety Recall Guidelines

The general steps to be followed for a recall process are:

- Step 1 - Mitigating a product safety risk;
- Step 2 - Determining an appropriate course of action (if any);
- Step 3 - Notification of recall to the Commission;
- Step 4 - Submission of recall strategy to the Commission;
- Step 5 - Communication plan and communication with consumers;
- Step 6 - Retrieval of the affected product; and
- Step 7 - Reporting on the recall to the Commission.

5 Legislation regarding liability for defective medical devices

Medical Devices and in vitro diagnostic medical devices

- Regulations (EU) 2017/745 and (EU) 2017/746
- In March 2023, Regulation (EU)) 2023/607 extends the validity of certificates and extends the transitional periods based on product risk class
- Regulation (EU) 2017/745:
  - 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
  - Notified Bodies

Medical Devices and in vitro diagnostic medical devices

- Strengthens the use of the European Database of Medical Devices (EUDAMED) Risk management, post-market surveillance and incident reporting system
- Withdraws conformity assessment procedures that were based on product quality assurance and statistical verification.
- introduces new classification rules (more stringent classification criteria).

– Regulation (EU) 2017/746:
  - Changes in the labels
  - Instructions for use
  - Certificates issued by a Notified Body
  - Declaration of Conformity
  - Classification
  - Certificates of free sale

MD and IVD Regulations
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 3171/21, 3.2.5)
- Financial limits not set by the Regulations
- Italy: pecuniary sanctions from Euro 26.000 up to 120000 for not compliance

6 Questions?

Upcoming webinars

Litigation trends
Tuesday 9 July, 11.00 CET/12:00 UK

Main trends and traps when handling professional indemnity claims (European and not European jurisdictions)
Wednesday 11 September, 11.00 CET/12:00 UK

Claims handling
Wednesday 6 November, 10.00 CET/09:00 UK

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