CMS Insurance Sector Group webinar programme

Product Liability

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Your speakers today

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What we will cover

01 Impact of the EU Directive for collective redress on PL claims from an Italian perspective

02 The impact of new legislation regarding product safety and product liability

03 New legislation regarding medical devices in Spain

04 Proposal for a Directive on non-contractual civil liability rules to AI

05 Recent developments of PL insurance in Austria: series loss clause

06 Q&A

1 The impact of new legislation regarding product safety and product liability

The new European framework on product safety: Comment on GPSR

- The EU Regulation 2023/988 has introduced a new General Product Safety Regulation (GPSR), that will enter into force from 13 December 2024
- Regulation instead of directive
- Obligations to comply with high safety standards
- Digitalisation and online marketplaces
- Member States will have to implement the new rules within 18 months
- Objectives:
  - Strengthen safety standards for products sold both offline and online
  - Strengthen the supervision of unsafe products and consequently consumer rights

The cornerstones of GPSR

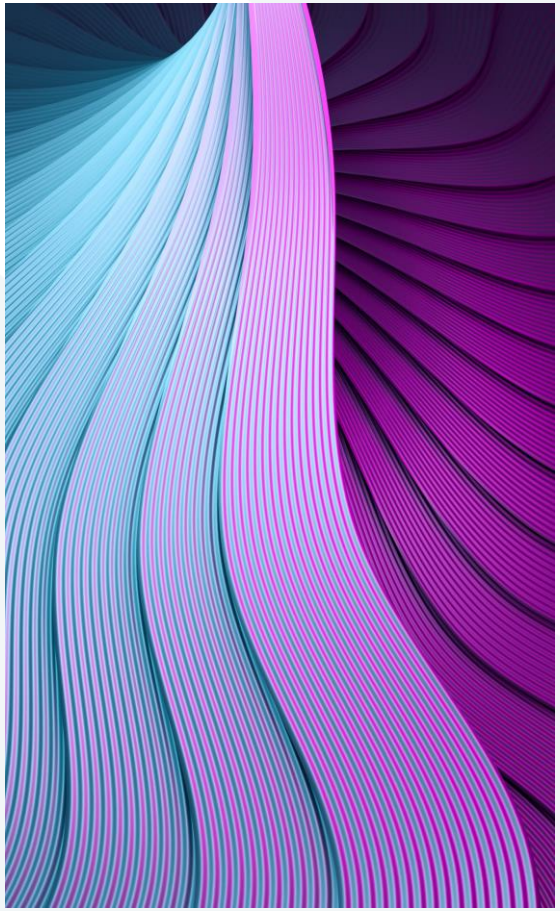
- Introduction of a person in charge of sold products
- Obligation to remove dangerous products
- Introduction of the principle of a stay-down clause on illegal products
- Right of consumers to request repair, replacement or refund of a good (being able to choose from at least 2 of these options) in case of a product recall
- The following points deserve special attention:
  - Safety Gate and Recall
  - Representative actions
  - European class action

Safety Gate is a warning system that allows information on measures taken against dangerous non-food products to be quickly circulated among national authorities responsible for product safety in single market countries

The Safety Gate system also includes the establishment of a web portal designed to inform the public and enable them to file complaints

Manufacturers and importers shall have and verify the establishment of appropriate channels of communication to consumers to file their own complaints

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



Current directive adopted on 25 July 1985

The Parliament and Council are currently working on establishing their respective positions on the draft legislation

Potential substantial changes and extended scope: follow the EU legislative process

Amendments product liability directive

- Directive not only applicable to goods and electricity, but also to software
- So cyber safety requirements within scope directive
- Changes regarding new directive product safety
- Everyone who substantially changes a product within scope

Amendments product liability directive

- Not only to comply if a product is brought to the market, but also if able to check/control the product
- Software updates and digital services
- Authorised representative of the producer and fulfilment service provider within scope
- Causal connection implied between defective product and damages
- Mandatory disclosure of documents, burden of proof
- Next steps?
- Compliance due to collective redress directive?

2 Impact of the EU Directive for collective redress on PL claims from an Italian perspective

Representative action

Art. 39: "Directive (EU) 2020/1828 applies to representative actions brought for violations of its provisions“
Implemented in Italy by Italian Legislative Decree No. 28/2023, into force from 25 June 2023

National representative action (brought by an Italian qualified entity in Italy)

New action to protect the collective interests and individual rights of consumers (amendment of the Consumers Code)

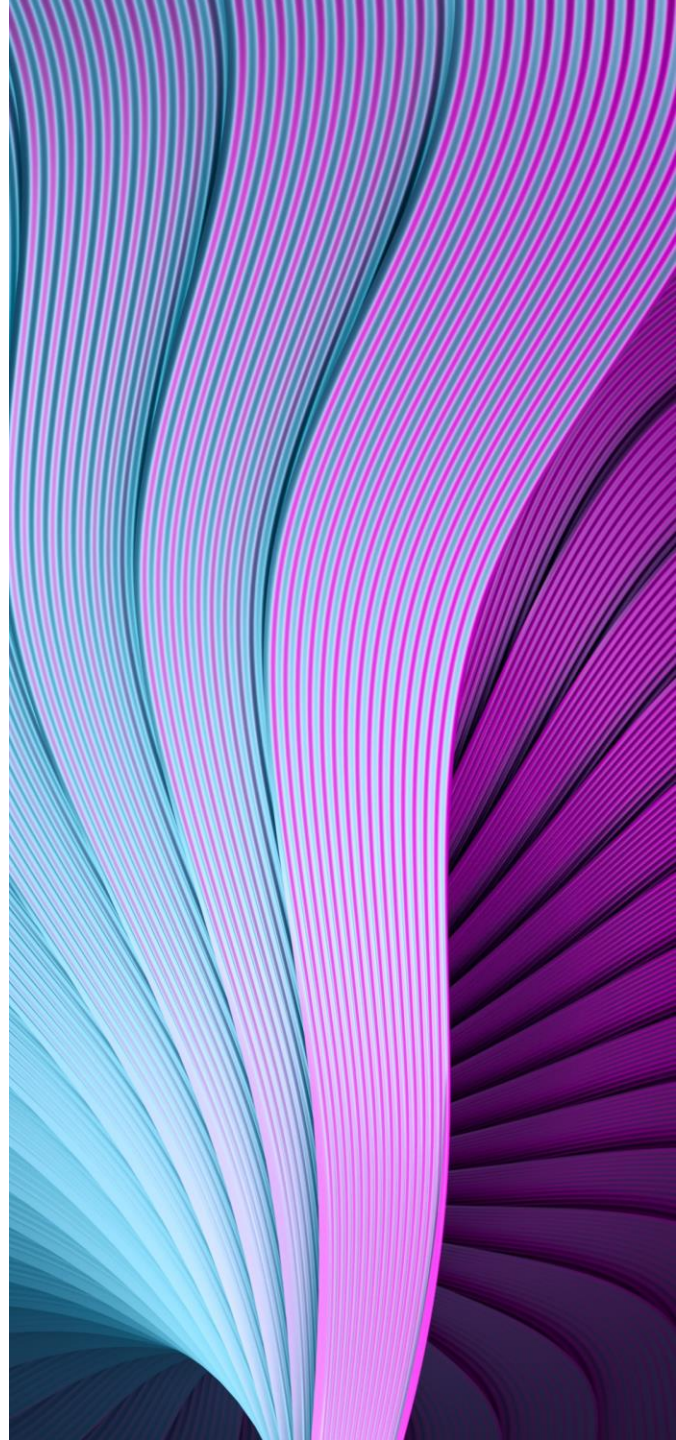
This action is in addition to and alongside the class action under Article 840 bis c.p.c., but covers only the 68 matters governed by regulations

European representative action (brought in a different Member State When the member state by a qualified entity

One or more entities, qualified by other member states and included in the list of Art. 5(1) of the Directive, will be able to take legal action before the Italian authority, as well as bring representative action in another member state

Representative action

- Opt-in mechanism
- Compensable damages
  - Patrimonial
  - Non-Patrimonial (without a tolerance threshold and regardless of size)
- Expenses
  - The Court shall determine the amount to be paid by each member as an expense allowance



European representative action: how does it work?

- Who — The qualified Entity (even without a mandate)
- Why cross-border — When the infringement injures or is likely to injure consumers from different member states, the representative action may be brought jointly by several qualified entities from different member states
- How — In this regard, there is no specific cooperation mechanism, which is therefore left to the initiative of the entitled entities. (see “Whereas (31)”)
- Which law — In Italy, Italian Legislative Decree No. 28/2023, into force on 25 June 2023

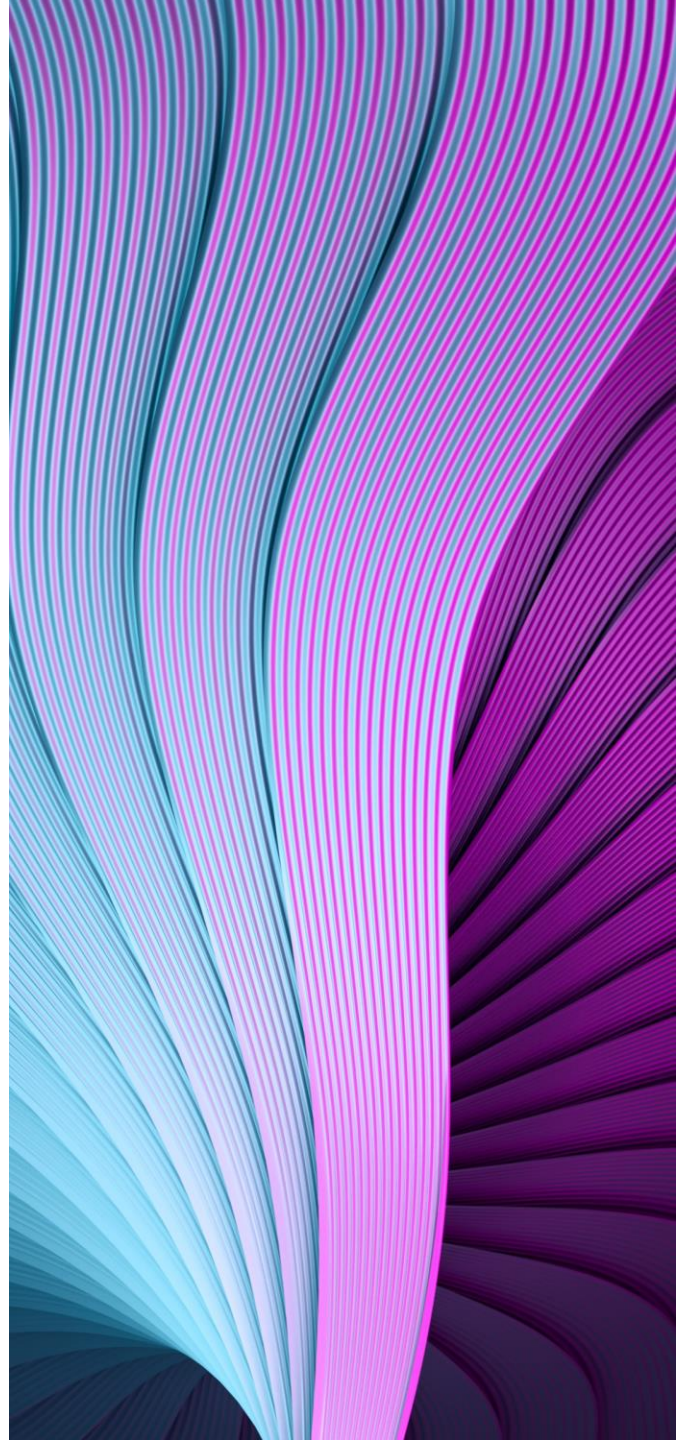
Whereas (31): “*Member States should ensure that cross-border representative actions can be brought before their courts or administrative authorities by qualified entities that have been designated for the purpose of such representative actions in another Member State. Furthermore,* ***qualified entities from different Member States should be able to join forces within a single representative action in a single forum, subject to the relevant rules on jurisdiction****. This should be without prejudice to the right of the court or administrative authority seized to examine whether the representative action is suitable to be heard as a single representative action*.”

Class action vs Representative action

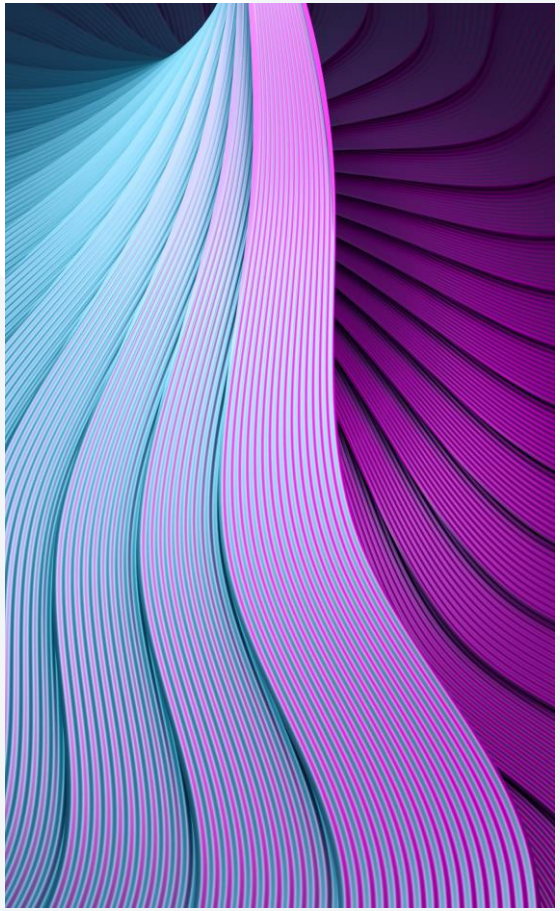
- Protected rights are different:
  - For representative actions (domestic and cross-border) the protected rights are collective consumer interests in specific matters exhaustively listed
  - For class actions the protected rights are homogeneous individual rights without any matter restriction

Class action in Italy

- Opt-in mechanism
- Compensable damages
  - Patrimonial
  - Non patrimonial if:
    - The interest is constitutionally relevant
    - The injury is serious
    - The prejudice is concrete, common to all members of the class and does not result in mere inconvenience, annoyance or disappointment



Registers of qualified entities



Representative actions

Ministry of Enterprises and Made in Italy

European class action

European Commission

Class action

Ministry of Justice

3 New legislation regarding medical devices in Spain

New regulation in Spain on medical devices

Law 192/2023 regulating medical devices

Entered into force on 22 March 2023

Implementation of EU Regulation 2017/745

Repeals previous Spanish Laws

New regulation in Spain on medical devices

- Competent Authority: Spanish Agency on Medicines and Medical Devices
- Proceedings to grant installation licenses for certain operators
- Regulates the single use medical device reprocessing
- Creation of:
  - Medical Devices Commercialisation National Registry
  - Responsible of Custom-made medical Devices Registry
- Develop the requirements for manufacturing in-house medical devices by hospitals
- Clarifies which medical devices can not be sold online

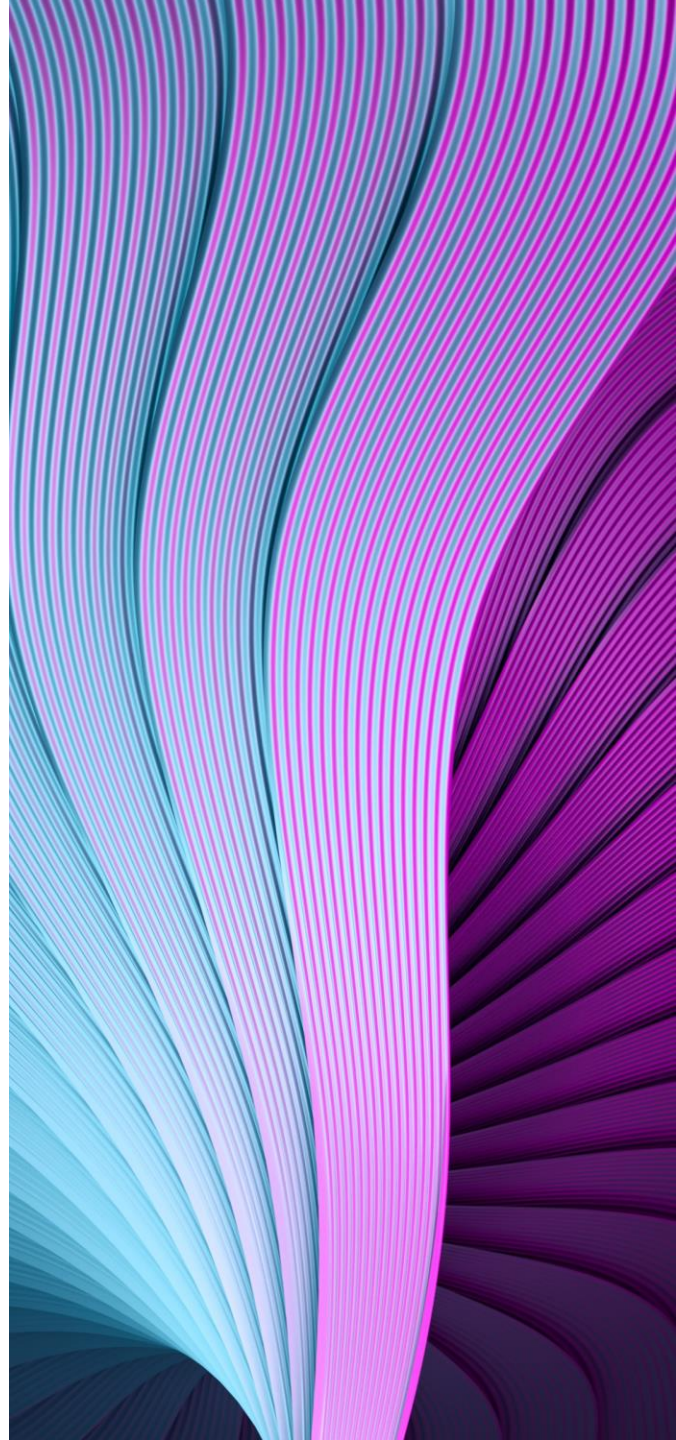
New regulation in Spain on medical devices
Liability regime of clinical trials

- Mandatory insurance policy to cover participants
- To be taken out by the clinical trial promoter
- Covering damages and expenses
- Due to promoter, main investigator, collaborators and hospital/centre liability
- Minimum insured sum of €250,000 per participant
- Maximum insured sum of €2,500,000 per year per clinical trial
- Presumption provision: damages caused by the clinical trial during it and 1 year after
- Spanish vs Austrian requirements

4 Proposal for a Directive on non-contractual civil liability rules to AI

Proposal for a Directive on adapting non-contractual civil liability rules to AI (AI liability Directive)

- Seeks to harmonise current national civil liability rules
- Due to AI systems failures not covered by PL Directive
- Lays down common rules on:
  - Disclosure of evidence - presumption of non-compliance
  - Burden of proof – presumption of causal link
- Claimant definitions: includes subrogation
- Potential mandatory insurance



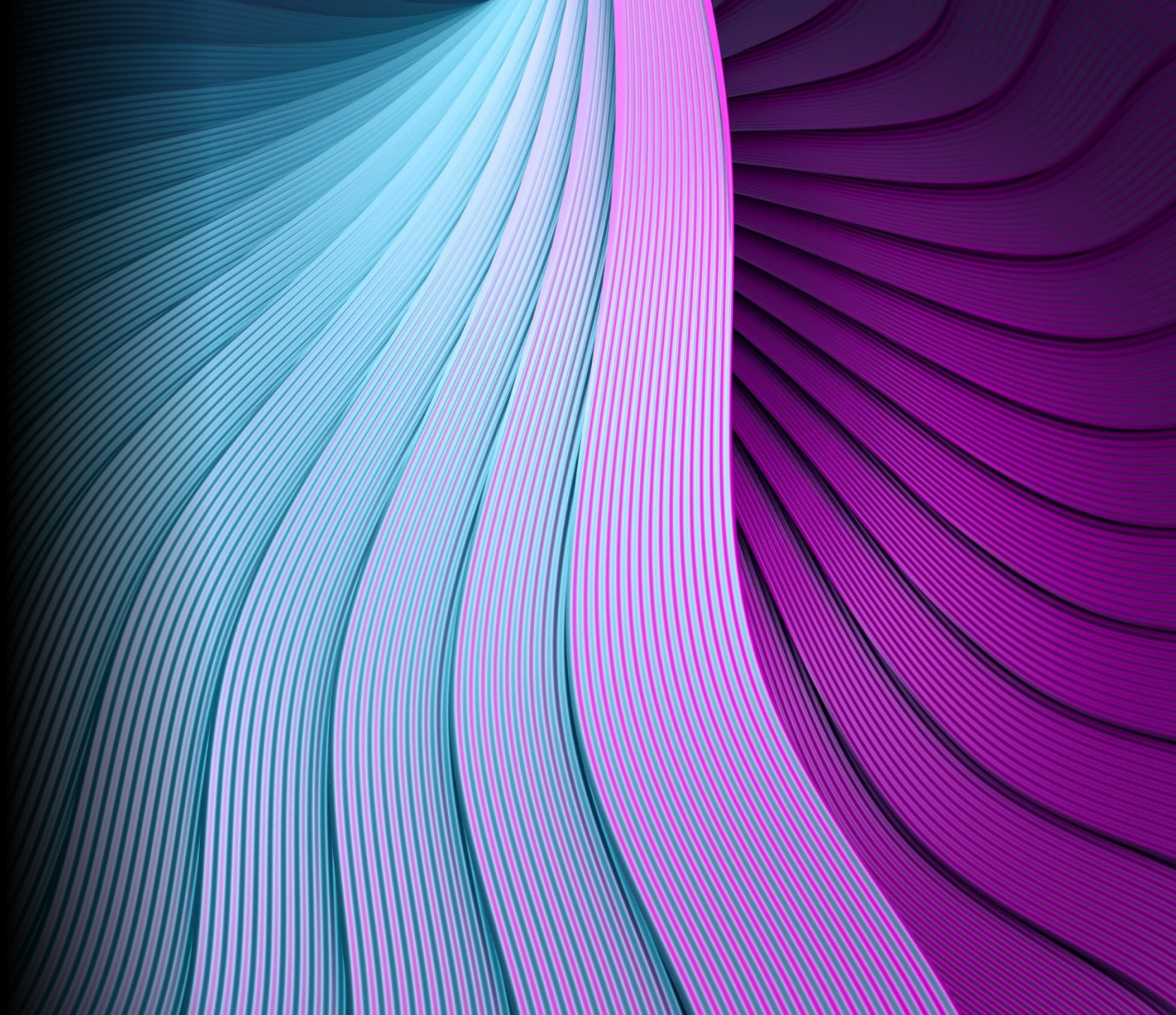
5 Recent developments of PL insurance in Austria: series loss clause

Series loss clause in PL insurance in Austria

- Business liability insurance typically include product liability risk coverage
  - i.e., losses caused by a defective product after delivery
- Extended product liability coverage available only if explicitly agreed and provided that certain conditions are met
- Series loss clause in the extended product liability coverage
  - Several deliveries are considered as one insured event if they cause losses for the same reason
  - Aggregate limit and not policy limit applies
  - What is the “same reason”?

6 Concluding remarks & forecast for future

Questions?



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