Interplay between AI Act & sectoral regulations

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Demystifying AI novelty

*"**Big Data and AI developments don't necessarily create new challenges**" (EIOPA - report on AI Governance)*

AI is not new …

Machine Learning is used for years in **insurance** and **health** sectors:

- **Pricing**
- **Risk assessment**
- **Actuarial studies**
- **Claims management**
- **Quality Control**

… Generative AI is

The **real novelty** lies with Gen AI in:

- **Distribution Model**
- **Availability**
- **Accessibility**
- **Deployment Costs**

Parallel with SaaS ?

Similar to SaaS industry revolution:

- Technological shift
- Industry mutation
- Changes are structural more than material

Market seeking **maturity** on:

- **Responsibility allocation**
- **Usage scoping**
- **Risk Limitation**
- **Standardisation**

Room for self-regulation and fair competition equilibration?

AI Act: a risk based approach. Only ?

A dual approach?

Risk-based: risk presented by a usage

Sectoral: material scope of a sector as a risk factor

Provisions added throughout AI Act negotiations

Sectoral application

Insurance	**Article 6(2) and Annex 3 art 5(c)**
Health	**Article 6(1) and Annex 1**

Sectoral application is more an additional layer than a different factor

AI Act & Insurance Sectoral Regulations

Capturing only **health** and **life** insurance

High risk: **pricing** and **risk** assessment

Explicitly **not high risk**: **fraud** and **prudential** purposes

What about the rest ?

Recital 58

*"AI systems intended to be used for **risk assessment** and **pricing** in relation to natural persons for **health and life insurance** can also have a significant impact on persons' livelihood and if not duly designed, developed and used, can infringe their fundamental rights and can lead to serious consequences for people's life and health, including financial exclusion and discrimination."*

*"However, AI systems provided for by Union law for the purpose of **detecting fraud** in the offering of financial services and for **prudential purposes to calculate credit institutions' and insurance undertakings' capital requirements** should not be considered to be high-risk under this Regulation."*

AI Act & Insurance: a concrete application

Under **article 6 (3)** AI Act, an **AI system is not high risk where it is intended to:**

- perform a **narrow procedural task**;
- improve the result of **a previously completed human activity**;
- **detect decision-making patterns** or deviations, without replacing proper human review**;**
- **perform a preparatory task**

Support

- Previously handled by **support agents**, **FAQ**, and more recently **chatbots**
- **No sensitive** or **personal** data
- No **decision / impact** for individuals

✓ **Not high risk**

Document Recognition

- **Procedural tasks**
- **Previously handled by humans**
- **Preparatory tasks**
- Potential **sensitive data** (prescription)
- **No decision / impact** for individuals

✓ **Not high risk**

Claims management

- **Not covered** by AI Act
- **No impact** on individuals security or fundamental rights
- **Potential impact on health**
- **Potential significant impact on decision making**

? **High Risk ?**

AI Act & Health Regulation: the example of medical devices

Risk classification interplay and complementarity

Medical Device Regulations **approach risks** through **different classes of medical devices**

AI Act high-risk criteria for Annex 1 Regulations:

1. the **AI system** is intended to be **used as a safety component** of a product, or **is itself a product**
2. the product is required to **undergo a third-party conformity assessment,** with a view to the **placing on the market**

Recital 51

*"The **classification of an AI system as high-risk** pursuant to [the AI Act] s**hould not necessarily mean that the product** whose safety component is the AI system, or the AI system itself as a product**, is considered to be high-risk under the criteria established in the relevant Union harmonisation legislation** that applies to the product.*

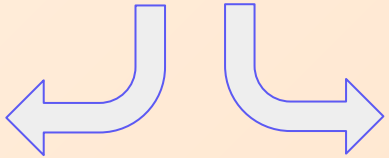
This is, in particular, the case for Regulations (EU) 2017/745 and (EU) 2017/746, where a third-party conformity assessment is provided for medium-risk and high-risk products."

AI Act & Sectoral Regulation: interplay and friction

Interplay with Sectoral Regulations main criteria : **impact on the "*New Legislative Framework*"**

Positive takeaways on existing sectoral regulations

Taken into account : not starting from scratch



Reducing compliance costs

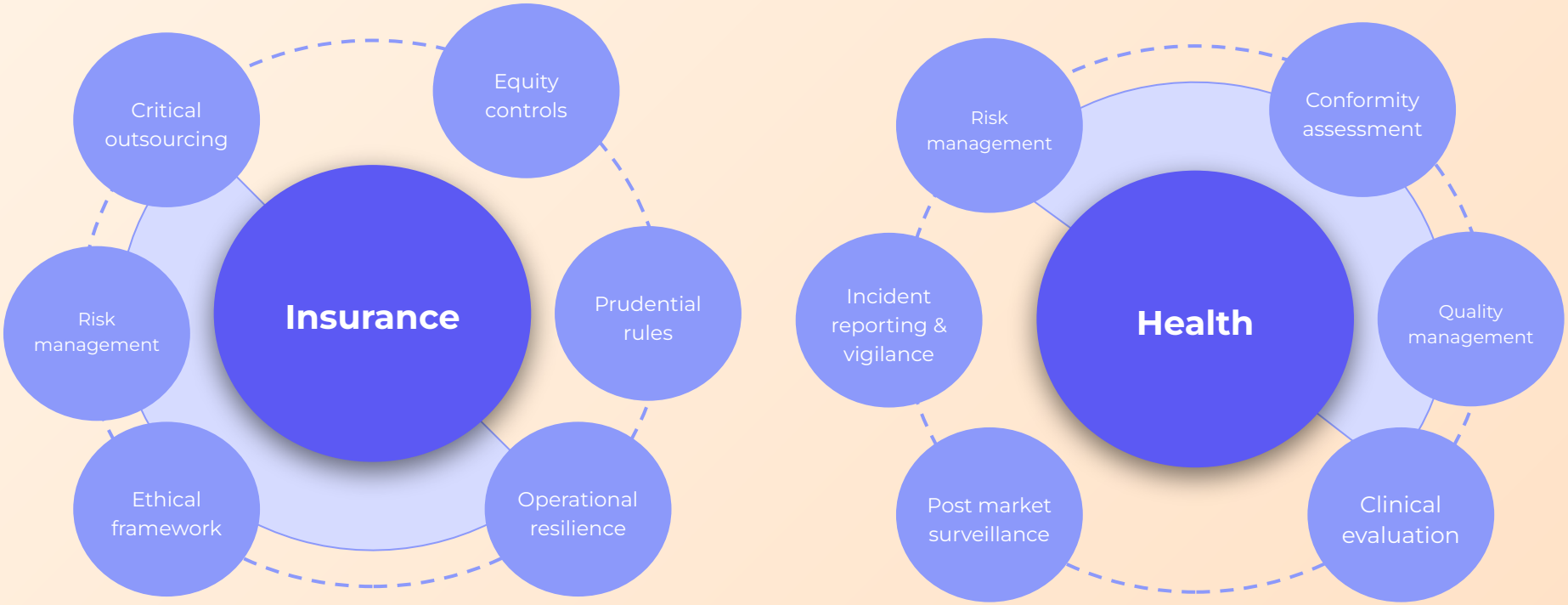
Recital 64

*"The **general rule** is that **more than one legal act** of Union harmonisation legislation **may be applicable to one product**"*

*" This calls for a **simultaneous** and **complementary application** of the various legislative acts"*

*"To **ensure consistency** and to **avoid** an **unnecessary administrative burden** and **unnecessary costs**, providers of a product that contains one or more high-risk AI system,[...], **should have flexibility** with regard to operational decisions **on how to ensure compliance"***

AI Act & Sectoral Regulation: Gap Analysis



What is really new with AI Act: **bias mitigation, explainability and fairness**

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Thank you for your attention