
The changing EU legal landscape for health and wellness apps in the EU

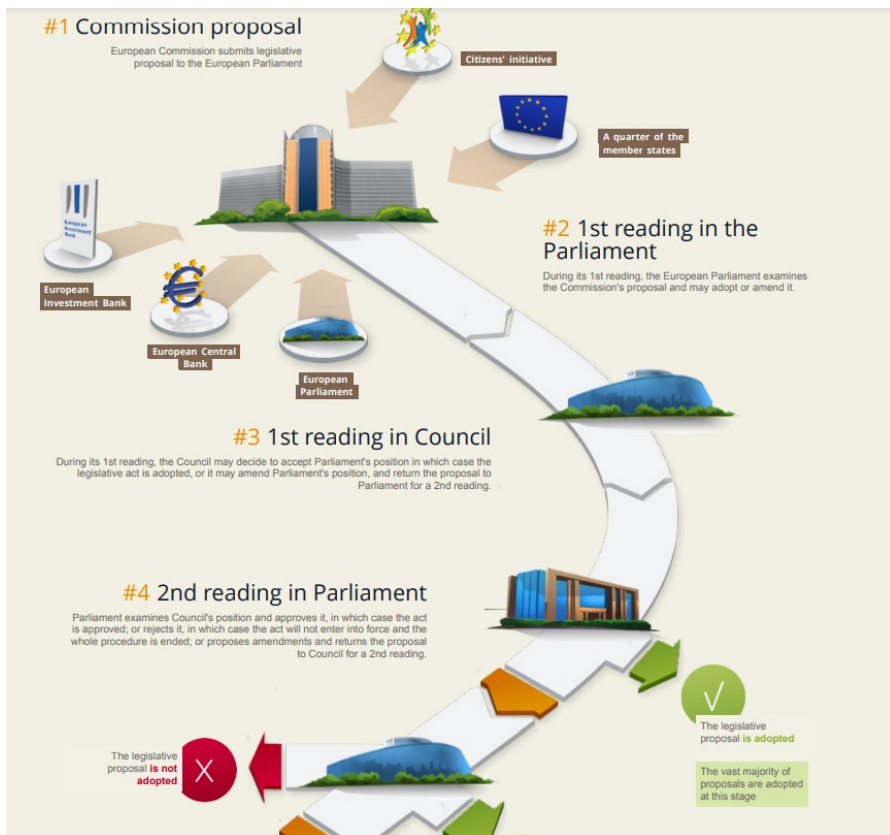
Petra Wilson – Brussels, Nov 3, 2023

- European Health Data Space
- Cybersecurity
- Artificial Intelligence
- Liability
- Other relevant legislation

Apps in the EHDS proposal

- EHDS is primarily a tool for data sharing for care (primary use) and for research and policy making (secondary use).
- It recognises that **wellness apps** are a source of data which could be added to the EHDS - note it addresses wellness apps, **not health apps** which could be classified as medical devices.
- Article 31 addresses the **interoperability of data collected or generated by apps with EHRs**.
- The label proposed for wellness apps in Article 31 is primarily about the **interoperability of the data, rather than a quality assurance** of the app itself.
- Annex II set out the essential requirements for EHRs which shall apply mutatis mutandis to products claiming interoperability with EHR systems.
- This includes concepts of safety and security - and will be further developed in implementing legislation.

Update on the EHDS legislative procedure



- A vote is due on the ENVI-LIBE amendments on 9 November and plenary vote scheduled for 11 December
- Council will discuss at WP level on 9-10 November and info session by the Presidency on 30 November
- Aim is to finalise discussions in Council this year, have trialogues in January-March and approval of the text in Parliament during the final plenary of this mandate in April.
- But there are still significant sticking points – including:
 - Opt in/out for secondary use
 - EHR conformity assessment
 - Protection of IP and trade secrets



3 schemes under development

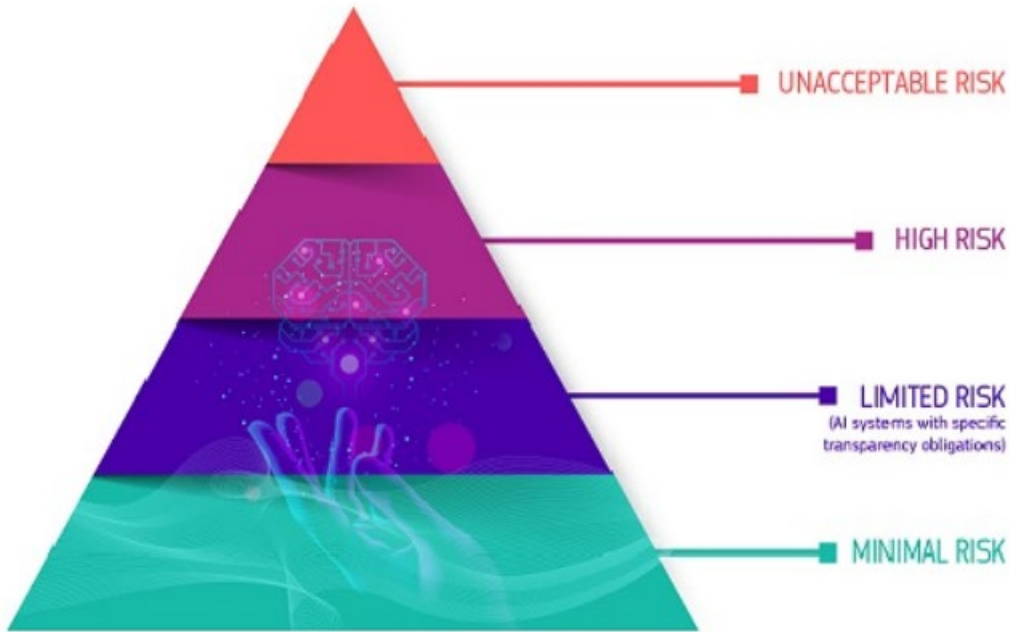
- *ICT products called 'EUCC'*
- *Cloud services called 'EUCS'*
- *5G networks called 'EU5G'*

EU Cybersecurity Act

- Adopted and entered into force in 2019
- Strengthens the EU Agency for cybersecurity (ENISA) and establishes a **cybersecurity certification framework** for products and services.
- **Voluntary**, but in future **may be mandated through other legislation** - possibly NIS 2 Directive (Network Information Security Dir.) , which seeks to boost the overall level of cybersecurity in the EU by focusing on key industries, inc. healthcare (healthcare providers, manufacturers of medical devices)

EU Cyber-resilience Act

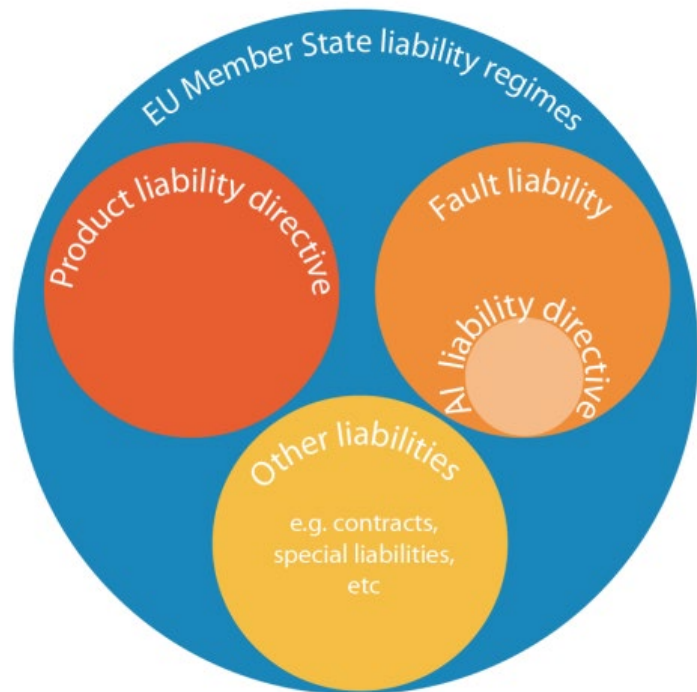
- Draft legislation, interinstitutional negotiations ongoing.
- Obligations on **all products with digital elements** with direct or indirect data connection to a device or network
- **Cybersecurity by design** and by default principles and imposes a duty of care for the lifecycle of products.
- Will apply to apps



AI Act

- Not yet adopted, co-legislations aim to reach agreement by the end of 2023.
- Limited applicability for healthcare (diagnostic, clinical decision support, disease monitoring)
- **4 risk categories:**
minimal, limited, high, unacceptable
 - **Certification of high-risk** AI Systems through a mandatory CE-marking procedure
 - **Transparency obligations for limited risk** AI Systems
- Covers medical devices which require third party certification under MDR (EU Medical Device Regulation): **Class II and above**

Liability for harm



Source: European Commission, 2022.

- National level liability systems/laws apply – both as statutory protection and in contract or tort law.
- At EU level currently two complementary draft directives to adapt the existing liability rules to new digital technologies, including AI are being developed.
- **Revision of the Product Liability Directive (PLD)**
 - Existing PLD is being revised – co-legislative procedure ongoing.
 - It is to enlarge the **scope of the legislation to include software.**
- **AI Liability Directive**
 - Co-legislative procedure ongoing
 - **Non-contractual civil liability rules:** ensure that persons harmed by AI systems enjoy the same level of protection as persons harmed by other technologies in the EU

NOTE No overlap is intended between claims brought under the proposed no fault-based PLD and the fault-based AI liability directive.

- **Medical Devices Regulation**

- When an app is a Medical Device, the CE marking process, quality management system and registration requirements apply as for a physical medical device

- **EU Product Safety Regulation (GPSR)**

- Applicable for non-food consumer products from Dec 2024. Stand-alone software is not in the scope, so will not apply to apps

- **EU Digital Markets Act and Digital Services Act**

- Both acts are in force. Primarily concern: online intermediaries and platforms.
 - It identifies “gatekeepers” - Alphabet, Amazon, Apple, ByteDance, Meta, Microsoft - large digital platforms providing so called core platform services, such as online search engines, app stores, messenger services.
 - For example: Products and services offered by the gatekeeper itself can't be more favourable in ranking than similar services or products offered by third parties on the gatekeeper's platform.
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Conclusions

- **EHDS and AI legislation proposed legislation** does not provide a direct avenue for general quality labelling health and wellness apps as such but acknowledges the **role of health and wellness apps**.
- **Voluntary labelling of apps that interoperate with EHRs is foreseen in EHDS**
- **Both EHDS and AI Act proposals are interconnected with other pieces of EU legislation** on the cybersecurity and liability as well as the existing **Medical Device Regulation (MDR)**, and **General Data Protection Regulation (GDPR)** – all of which combined **will have profound impact on the development and market launch of health and wellness apps in the EU**.

THANK YOU FOR YOUR ATTENTION

**please do get in touch if you have questions:
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