LABEL2 ENABLE

Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

EU legislation on labelling, reimbursement, and payment of health apps

Anett Molnar (HIMSS) – Label2Enable 1st Roundtable on Reimbursment of health apps,

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LABEL2 ENABLE

- EHDS
- MDR
- AI Act
- Pharma Legislation
- Conclusions

Apps in the EHDS proposal

- EHDS is primarily a tool for data sharing for care (primary use) and for research, innovation and policy making (secondary use).
- It recognises that **wellness apps** are a source of data which could be added to the EHDS - note that it addresses wellness apps, **not health apps** which could be classified as medical devices.
- **Article 31:** interoperability of data collected or generated by wellness 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.
- **Article 13:** supplementary cross-border digital health services and infrastructures
  - Member States may provide through MyHealth@EU supplementary services that **facilitate telemedicine, mobile health, access** by natural persons to their translated health data,
- 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

MDR (Medical Device Regulation)

The characterisation of a software app as a 'medical device' or 'non-medical device' is determined as per the 'intended purpose' of the app as defined by the developer / manufacturer.

To be a Medical Device, an app would usually need to meet one of the functions below:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation or compensation of injuries or handicaps,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception.

Classification and Certification of mobile apps as Medical Devices

- MDR classifications reflect a medical device's potential risk of harm. 4 classes of risk: I, IIa, IIb, III
- The higher the class, the greater the involvement of a notified body in conformity assessment.
- Devices that are considered to be in conformity with the MDR are certified and bear the CE marking.

➢ Labelling within MDR means: written, printed or graphic information appearing on the device/packaging inc: name, address of registered place of business, UID, warnings, indication of medical device, etc…

Health in the AI Act proposal

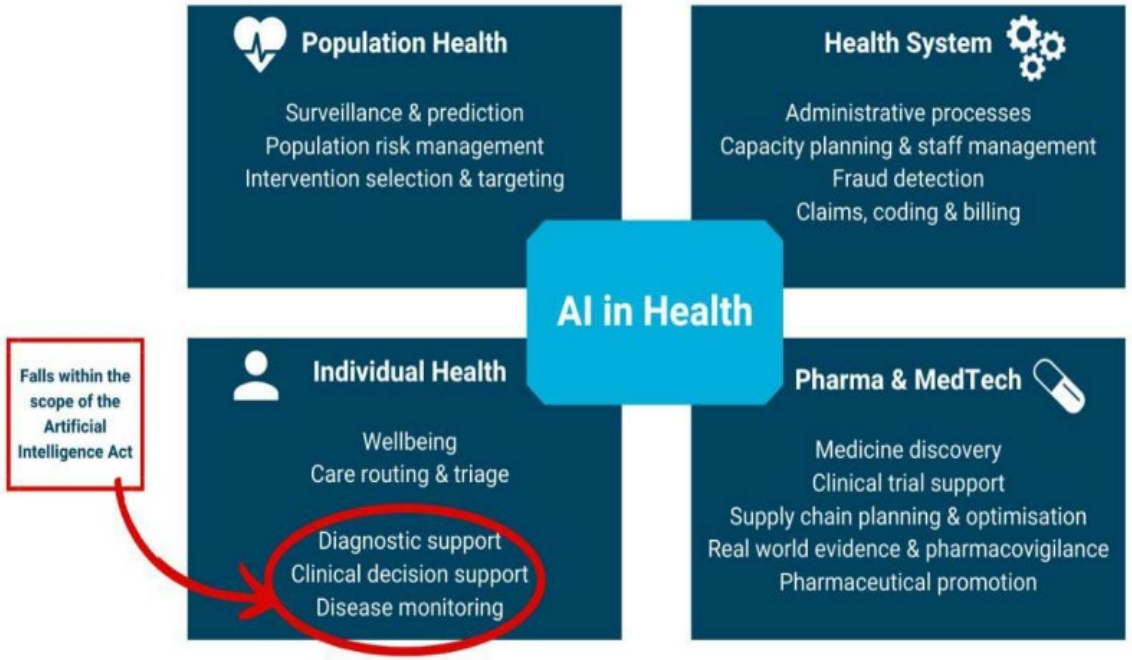
Relevance for healthcare :

- **Unacceptable risk** - no AI systems for health are singled out
- **High risk**

- All medical devices using AI, which require third party certification under EU Medical Device Regulation and EU In vitro Diagnostics Regulation (MDR Class IIa, IIb, III).
  - ➢ Not for the more simple apps which do not directly interact with a drug or give a reading on which a patient makes a health relevant decision.

- AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services.

Generally limited applicability to AI in healthcare sector



Based on USAID & the Rockefeller Foundation (2019), IDB (2020)

EU Pharma legislation

- The Commission adopted a proposal for a new Directive and a new Regulation in April 2023, which revise and replace the existing general pharmaceutical legislation.
  - Incentives for the development of medicines for areas of **(high) unmet medical need** - which could be further explored for **potential application is the health apps sector** to support the development of apps in areas of (high) unmet medical need.

- **Reimbursement of apps within the healthcare sector is NOT regulated at EU level.**

  - Transparency Directive (89/105/EEC) of pricing and reimbursement (P&R) of medicines is currently not being reviewed.
  - Reimbursement of health apps is **within the competence of the Member States.**
  - **Example: DiGA legislation in Germany** which allows digital healthcare apps to be prescribed by doctors under statutory health insurance. Includes MDR class I + IIa. Apps go through application process to prove safety, functional capacity, quality, data protection compliancy + demonstrate positive effects in patient care.

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
- **Medical Devices Regulation** establishes that apps intended to have a medical purpose are medical devices, and must be certified as compliant (the legal requirements and whether done by a third party or self-certified depend on class of device in which the app is classified)
- **Reimbursement of apps** within healthcare is a Member State competence, allowing for national certification schemes to be developed including quality labelling, reimbursement and payment structures.

THANK YOU FOR YOUR ATTENTION

please do get in touch if you have questions:
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