Digital Health Uptake

Towards the labelling of health apps in the EU

Building on lessons learnt from the European energy, food and medicine labelling schemes

Authors: Petra Wilson and Anett Molnar, Legal experts, Label2Eable project (representing HIMSS, the Healthcare Information and Management Systems Society, as consortium partner)

For the empirica DHU team
October 2024

*There is a growing recognition that health apps need to play a much stronger role in health systems. The app stores available to European citizens show that a wealth of health and wellness apps exist, but a slow and fragmented approach to verifying the trustworthiness of such apps and regulatory approaches for incorporating them into health systems is limiting their integration into healthcare provision. Central to uptake and integration of apps is a well-recognised labelling system that can **show the trustworthiness of an app** for citizens who will use them and healthcare professionals who may want to prescribe or recommend them. The value of such **user-friendly labelling systems** which include of a visual representation of key information of product (a label) supported by a transparent governance structure and clear rules on conformity assessment has been proven on other domains, such as energy, food and medication. The EU energy label, for example, is reported to be recognised by 93% of consumers and taken into account by 79% when buying related appliances in 2019.* [1]

A recently concluded EU project, Label2Enable, looked into existing consumer labels in search for valuable insights into the legal and practical solutions that could be adapted to health apps, regardless whether these apps qualify as medical devices or not, and concluded that this is a vital next step for the EU to embrace as it seeks to drive more resilience and sustainability in health systems by supporting patients and citizens in taking a more proactive role in their health and wellness management.

An **EU level health app quality label is urgently needed to build trust in health and wellness apps for citizens and healthcare providers and to help build a more stable market environment for app manufacturers**. Citizens' need to better understand which apps they can rely on when using apps as part of their health and wellness management, whether that is directed by a health professional or taken on their initiative. Healthcare providers and insurers should have unbiased and reliable information when making decisions on incorporating the use of health apps into their care services. App manufacturers could also benefit from a system whereby their certified and labelled health or wellness app (hereinafter health app) could access the internal market across the EU while demonstrating the safety, security and usability of their device.


Between 2022-2024, the Label2Enable project developed a certification scheme to be used in Europe for the adoption of the international health app labelling standard *CEN-ISO/TS 82304-2: Health software — Part 2: Health and wellness apps — Quality and reliability*. Experts working on the international standard took inspiration from well-known labels, namely the **EU energy label**, the **Nutri-Score** front-of-pack nutrition label and the United States' Food and Drug Administration over-the-counter medicine label. Given the context of the EU-wide adoption of such a certification scheme, the project team analysed the key EU laws regulating the labelling of energy, food, and

---
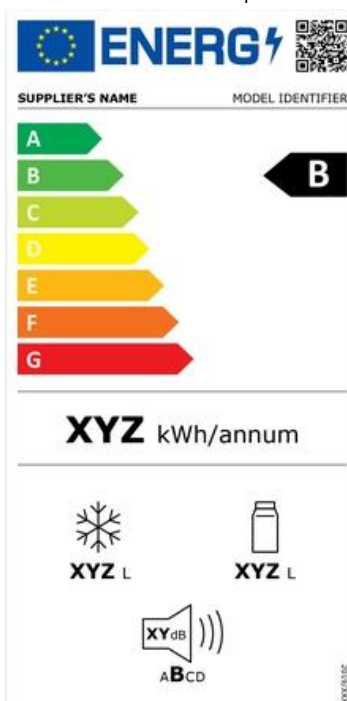
[1] EC website: About the energy label and ecodesign, https://commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/energy-label-and-ecodesign/about_en

medicine products so that in addition to the look of the actual labels, we can learn from the legal framework that established them.


NUTRI-SCORE A B C D E
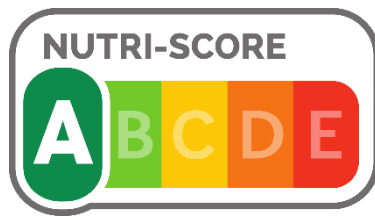
Research was carried out focusing on [Regulation (EU) 2017/1369](#) setting a framework for energy labelling, [Regulation (EU) 1169/2011](#) on the provision of food information to consumers, and [Directive 2001/83/EC](#) on the Community code relating to medicinal products for human use as well as the legal and practical solutions related to their implementation. In order to draw conclusions on lessons learnt that could be adapted for the benefit of health apps, especially within the dynamic and evolving context of European legislation relevant for digital health technologies, stakeholders were consulted from different interest groups across the EU.

Key findings include:

► **Earning and maintaining the trust** of consumers and industry is a long process. For a label to be effective, it needs to be in plain sight, attract attention and then be accepted and understood by the consumers before it can potentially influence their choices.

► **Familiarity with the label is key to its acceptance** and should be fostered through education and engagement actions that target both users and potential prescribers of health apps.

► **Certification by expert third party organisations is central to building trust**. Energy and front-of-pack nutrition labelling are based on self-assessment/certification, while medication labelling is third party certification, reflecting the risk of medication misuse on health.

Flag or logo — **Health app quality label**

App icon — **App name**

Platform icons

Name app manufacturer

Benefit of the app

With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

⚠ Check [here] when app requires approval from a health professional before use

Healthy and safe — B | A

Easy to use — E | D | C | B | A

Secure data — C | B | A

Robust build — A

Overall health app quality score — C | B | A

☑ App checked on [date]

CEN-ISO/TS 82304-2:2021

► As labels provide a highly visual representation of key information, it is important that in addition to the labels, **health apps are equipped with accompanying adequate documentation** that helps healthcare professionals to recommend apps and insurers to decide on reimbursement, as well as there is a need for a depository to locate details of certified apps.

► Stakeholders participating at the Label2Enable workshops shared support for **a gradual approach to make quality labelling of health apps mandatory.** They would welcome the **rigour and certainty of a label underpinned by EU legislation**, similar to medicines labelling, and the EU flag on the label, similar to the EU energy label as a trust-adding factor.
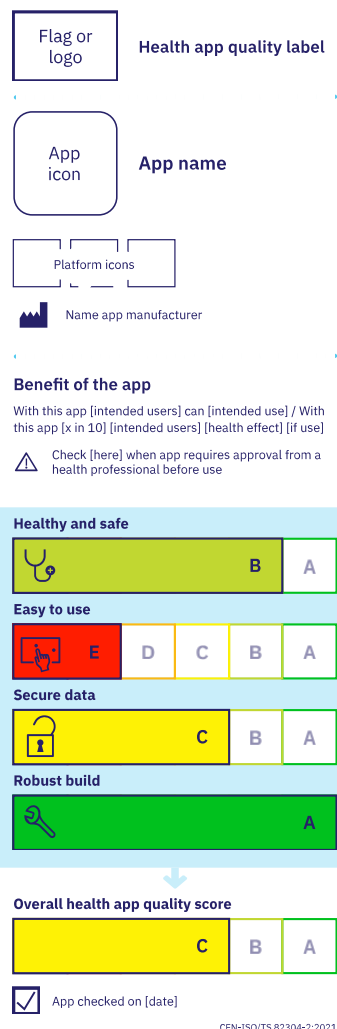
The project concluded that it is possible and necessary to implement the CEN ISO/TS 82304-2 certification scheme, including its colour coded label with the EU flag embedded, in order to better serve its citizens with trusted and secure health apps and to support informed decision-making. It could provide valuable input into developing the labels provided for in the European Health Data Space (EHDS) Regulation, and other future EU labels.

Recommendations:

▶ **Align requirements**

Relevant European institutions and bodies, as well as Member State authorities should assess if the CEN ISO/TS 82304-2 labelling scheme could be adopted as a harmonised standard and / or incorporated into other compliance assessment schemes relevant for health apps in order to better align the requirements and ease the administrative burden of all that are involved.

▶ **Create test beds**

Until EU level support in the form of legislation is secured, national or regional initiatives could provide test beds for locally adapted CEN-ISO/TS 82304-2 labelling projects to showcase how trustworthy, accurate, easy to use, secure and effective mobile apps are.

▶ **Involve stakeholders**

Citizens, healthcare providers, healthcare professional, manufacturers and payors should be involved, not just as users but as co-creators of labels. Certification bodies that involve stakeholders through design and maintenance of the scheme are considered by Label2Enable stakeholders as vital factors to build trust.