feedback on the proposed EHDS Regulation

Label2Enable (L2E) is a Horizon Europe Coordination and Support Action (Jun22-May24).[1,2] Its objective is to support the Europe-wide adoptions of the CEN-ISO/TS 82304-2 certification scheme and its trusted health and wellness app quality label. The label makes the scores of an app in *Healthy and safe*, *Easy to use*, *Secure data* and *Robust build* (which includes interoperability) transparent, see Figure 1. The project has 3 pillars: **Trust, Use** and **Adoption** of a quality certification scheme**.** The main deliverable of the **Trust** pillar is a robustly tested, efficient, self-explanatory certification scheme for the CEN-ISO 82304-2 health app assessment framework, that (a) complies with the ISO 17000 certification series and all applicable EU level legislation and core values, (b) is easy to use for (accredited) app assessors and app developers, (c) is trusted by citizens, health care professionals (HCPs) and insurers, and (d) delivers consistent results. The main deliverable of the **Use** pillar is the communication to support citizens - including the many with low health literacy - in choosing an app (82304-2 label) and HCPs in recommending an app (82304-2 report). The main aim of the **Adoption** pillar is cross-country recognition of the 82304-2 certification scheme for a competitive digital single market. The L2E consortium partners[1] mirror the mHealth stakeholders. Leiden University Medical Center coordinates L2E. See Annex 1 for more on CEN-ISO/TS 82304-2:2021 and the L2E project.

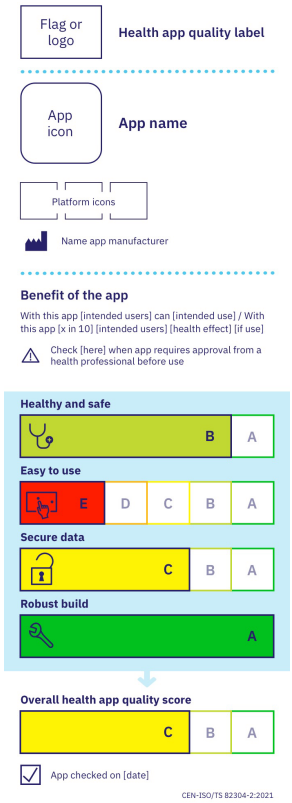

Figure 1: CEN-ISO/TS 82304-2's quality label

L2E warmly welcomes the proposed legislative framework for the EHDS and the support for the **labelling and certification of apps** that it embraces. We believe however that three key amendments to the current draft should be considered for the proposed Regulation to meet its objective of primary and secondary use of data, the empowerment of patients and the growth of a digital single market:

1. **Extend the definition of wellness apps to include all apps marketed as health and wellness apps**

The stated objective to the EHDS legislative proposal is to achieve a cascading effect in medical devices that aim to be interoperable with EHR systems. To be fit for the digital age and build a future-proof economy that works for all people, the EHDS should embrace all apps used in healthcare and wellness maintenance, including apps that are not marketed as interoperable with EHR systems, but which play a key role in supporting citizens' health and wellness. This would also help avoid fragmentation of legislation and complexity of compliance assessment and take into account different maturity of informatisation level of the countries, making quality information on health and wellness apps still available to all citizens.

2. **Go beyond interoperability and label quality**

In order to ensure that high quality apps can be safely used by citizens for self-care and for patient care, and that the data they generate can

be trusted, the labelling of health and wellness apps should be one of all round quality, including reliability, usability, and other characteristics of quality, on top of interoperability with EHRs. Extending the scope of assessment, will have a major impact on the volume, quality and trustworthiness of health data collected through apps which can be used for both care and research purposes. Also, labelling of the apps should be mandatory and should be certified by designated third-party assessment mechanisms to ensure inclusive and equitable access to related health (data) services and increase overall trust among the stakeholders.

3. **Reference a suitable quality labelling scheme**

Quality labelling should be standardised across Europe, by reference to technical specifications and certification schemes. Article 10(2) and 13(1) aims include access to safe and high-quality data for healthcare, also for those with limited access or disabilities, as per Recital (58) up-to-date quality and utility information, inclusiveness, ease of use, non-discrimination, and a choice between in person and digital services. *Healthy and safe* in the 82304-2 label addresses health risks, ethics, and health benefit. *Easy to use* includes accessibility and usability. *Secure data* covers privacy and security. *Robust build* includes technical robustness and interoperability. CEN-ISO/TS 82304-2 should be directly referenced within the preamble to the EHDS Regulation to ensure that a harmonised approach to inclusive quality labelling is adopted throughout the EU. Such standardisation should be foreseen within the relevant EU budgets and implementing legislation.

Further detail on extending quality labelling of apps beyond EHR interoperability and referencing CEN-ISO/TS 82304-2

The compromise text put forward by the Czech presidency amends Article 31 to make the interoperability labelling of apps required rather than voluntary. L2E warmly welcomes this proposal and urges the co-legislators to go further so that the labelling of apps also includes trustworthiness, safety, ethics, usefulness, usability, accessibility, privacy, and security as well as EHR interoperability. Several Member States are looking at new models to certify health and wellness apps to support integration of apps in their health systems, in some cases for the reimbursement of such apps, in others simply to build trust and confidence in their use among HCPs and patients.[3] CEN-ISO/TS 82304-2 provides the ideal basis for such wider harmonised certification to achieve global competitiveness with EU values.[4]

Experiences with the EU Energy label, and more recently front-of-pack nutrition labelling, show that if assessment is not mandatory, assessments are likely limited and geared towards a subset.[5-7] For instance, in Belgium a year after introduction of the Nutri-Score the vast majority (89%) of Nutri-Score labelled products found in the five largest retailers were own-brand products from two retailers. Also, 56% of the products displayed Nutri-Score A or B, while 26% displayed D or E. Fruit and vegetable products most frequently carried a Nutri-Score (18.8%), meat and meat products significantly less (8.4%).[7]

Certification could in due course be undertaken by third-party organisations, harmonised at EU level. HCPs and insurers have repeatedly told us they need ‘more than the blue eyes of the app manufacturers’ and thus favour third-party assessment over self-assessment. Several studies prove them right: the majority of apps are not evidence based or are discordant with public health guidelines, lack empirical evidence for effectiveness or validation of measurement tools, are not theoretically grounded, lack expert and user involvement and fail to provide assurances around privacy, security, or health risks.[8] In many respects, Apple Inc. and Google Inc. are currently the de facto regulators, and they’re not known for their scrutiny.[8-11]

We are well aware of the considerable number of health apps, ditto shortages of MDR notified bodies and the extensive requirements to become a notified body. In the L2E project 6 health app assessment organisations from 6 countries have joined in the effort to test the 82304-2 EU certification scheme with 24 health apps. Among them are 2 MDR notified bodies, to ensure an 82304-2 assessment of a class IIa/IIb/III app does not duplicate a legal task. Part of the 82304-2 certification scheme is how to qualify as an app assessor. These qualifications are expected to be of a quite different magnitude than those for MDR notified bodies, making the barrier to market entry as an accredited 82304-2 health app assessment organisation significantly more attainable.

Certification costs for (health and) wellness applications are in the current proposal largely directed towards manufacturers, see impact assessment. Yet a business model that enables paying for certification (and quality of an app) largely lacks with the exception of the few successful wellness apps which target consumers direct (110 apps are responsible for 50% of the downloads).[12] Frontrunner Germany currently reimburses 33 (MDR class I/IIa) health apps.[13] In the first year some 45.000 prescriptions for apps were written in a population of 73 million people with statutory health insurance.[14] One (medical device) app is reimbursed as part of a care pathway in Belgium.[15]

Patients are now missing out on effective apps that can improve their health and lives. An example is the monitoring app with follow up of a nurse cancer patients used in a large randomized controlled trial. They lived five months longer with more quality of life and less hospitalisations. Those with less tech skills benefitted more.[16,17] Yet, despite the clinical benefit these types of apps are not usual care. To quote a medical professional: *"If this were a drug that had a survival advantage of this magnitude, it would be priced at USD 100,000 and we would ask how we get this into our practice".*[18] Also, some citizens are currently missing out more than others, as health app users are generally younger, higher educated, have higher eHealth literacy, higher incomes, and more often excellent health than non-users.[19,20] The 82304-2 label design is grounded in testing with people with limited health literacy. Nearly one in two European have limited (insufficient or problematic) health literacy. People with low social status, low education, old age, and financial problems more often have limited health literacy.[21]

Suggested amendments

Apps intended to have a medical purpose require certification under the MDR. To avoid a double burden of certifying under MDR and certifying under EHDS the two certification requirements should be brought together and the definition of medical device software provided through the application of MDCG 2019-11 should be built into EHDS and its implementing legislation.

Our recommendations could for example translate in the following editorial changes:

Recital (35) *"Users of health and wellness applications, such as mobile applications, should be provided with consistent, standardised information ~~informed~~ about the quality of these applications including their usefulness for health and healthcare and their capacity ~~of such applications~~ to be connected and to supply data to EHR systems or to national electronic health solutions~~, in cases where data produced by wellness applications is useful for healthcare purposes~~. The capability of those applications to export data in an interoperable format is also relevant for data portability purposes. ~~Where applicable, users should be informed about the compliance of such applications with interoperability and security requirements. However, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them, a~~ A certification scheme ~~would not be proportionate. A voluntary~~ and labelling scheme, in line with well-established international guidance in this field, such as the technical specification CEN-ISO 82304-2:2021 should therefore be established as an appropriate mechanism for enabling the transparency*

for the users of health and wellness applications regarding compliance with the requirements, thereby supporting users in their choice of appropriate health and wellness applications with high standards of quality, including interoperability and security. The Commission may set out in implementing acts the details regarding the format and content of such label."

Recital (36) *"The distribution of information on certified EHR systems and labelled health and wellness applications is necessary to enable procurers and users of such products to find quality and interoperable solutions for their specific needs. … The objectives of the EU database of interoperable EHR systems and health and wellness applications should be to enhance overall transparency, to avoid multiple reporting requirements and to streamline and facilitate the flow of information."*

Article 2(2)(o) *'health and wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for ~~other purposes than~~ healthcare, ~~such as~~ or health self-management including well-being and pursuing healthy life-styles;*

Article 10(2) *"Each digital health authority shall be entrusted with the following tasks: (h) contribute, at Union level, to the development of the European electronic health record exchange format and to the elaboration of common specifications addressing quality, including interoperability, security, safety, ease of use, accessibility, non-discrimination or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and health and wellness applications referred to in Article 32.*

CHAPTER III
EHR systems and health and wellness applications

Article 14
"Interplay with legislation governing medical devices and AI systems
3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 ~~that claim interoperability of those medical devices with EHR systems~~ shall prove compliance with the essential requirements on quality and interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.
4. Providers of high-risk AI systems as defined in Article 6 of Regulation […] [AI act COM/2021/206 final], which do~~es~~ not fall within the scope of Regulation (EU) 2017/745, ~~that claim interoperability of those AI systems with EHR systems~~ will need to prove compliance with the essential requirements on quality and interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems."

Article 25(3)
"The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by allowing manufacturers to enter the information referred to in paragraph 2 into the EU database of EHR systems and health and wellness applications referred to in Article 32, as an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system."

Section 5
Other provisions on quality and interoperability

Article 31 ***"~~Voluntary l~~Labelling of health and wellness applications***
1. Where a manufacturer of a health and wellness application claims ~~interoperability with an EHR system and therefore~~ compliance with the essential quality and interoperability requirements laid down in Annex II and common specifications in Article 23, such health or wellness application ~~may~~

shall be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by ~~the manufacturer of the wellness application~~ an accredited app assessor.
2. The label or associated documentation shall indicate the following information:
(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;
(b) reference to common specification to demonstrate compliance;
(c) validity period of the label.
3. The Commission, may, by means of implementing acts, determine the format and content of the quality and interoperability label
4. The label shall be drawn-up in one or more official languages of the Union or languages determined by the Member State(s) in which the ~~in which the~~ health or wellness application is placed on the market.
5. The validity of the label shall not exceed 5 years.
6. If the wellness application is embedded in a device, the accompanying label shall be placed on the device. 2D barcodes may also be used to display the label.
7. The market surveillance authorities shall check the compliance of health and wellness applications with the essential requirements laid down in Annex II.
8. Each supplier of a health or wellness application, for which a label has been issued, shall ensure that the health or wellness application that is placed on the market or put into services is accompanied with the label for each individual unit, free of charge.
9. Each distributor of a health or wellness application for which a label has been issued shall make the label available to customers at the point of sale in electronic form ~~or, upon request, in physical form~~.
10. The requirements of this Article shall not apply to health and wellness applications which are high-risk AI systems as defined under Regulation […] [AI Act COM/2021/206 final]."

Article 32 ***"Registration of EHR systems and health and wellness applications***
1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 and health and wellness applications for which a label has been issued pursuant to Article 31.
2. Before placing on the market or putting into service an EHR system referred to in Article 14 or a health or wellness application referred to in Article 31, the manufacturer of such EHR system or health or wellness application or, where applicable, its authorised representative shall register the required data into the EU database referred to in paragraph 1.
4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and health and wellness applications pursuant to paragraph 2."

Article 33 ***"Minimum categories of electronic data for secondary use***
1. Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:
(n) electronic data related to insurance status, professional status, education, lifestyle, and health and wellness ~~and~~, including behaviour data relevant to health;"

ANNEX II

"Essential requirements for EHR systems and products / health and wellness apps ~~claiming interoperability with EHR SYSTEMS~~
~~The essential requirements laid down in this Annex shall apply mutatis mutandis to products claiming interoperability with EHR systems.~~

Essential requirements for health and wellness apps
[To be expanded to reflect quality beyond interoperability and security]

Annex 1: CEN-ISO/TS 82304-2:2021 and the Label2Enable project

CEN-ISO/TS 82304-2:2021 health and wellness apps – quality and reliability[22] was an assignment from the European Commission. As part of the Digital Single Market transformation of health and care it aimed to facilitate supply of innovative digital-based solutions for health, also by Small and Medium-sized enterprises, with common principles and certifications. This Technical Specification – which spans wellness apps and health apps including medical device apps – was already referenced in the EU Toolbox for COVID-19 tracing apps.

CEN-ISO/TS 82304-2's main content is a health app quality assessment and a health app quality score, label, and report. The framework was founded in 26 existing frameworks and a Delphi study with 83 experts from 8 stakeholder groups residing in 6 continents, predominantly Europe, and references 28 existing standards.[23] The L2E project develops an ISO 17000 series EU certification scheme for the CEN-ISO/TS 82304-2 assessment framework. The scheme is tested with 24 intentionally diverse apps and in particular small and micro companies. Each app is tested by a differing subset of 2 health app assessment organisations. Outcome measures include inter-rater reliability, that is the consistency in assessment results that promotes cross-country recognition, and if the process is efficient and self-explanatory for both app assessment organisations and app developers.

The score, label and report communicate in increasing detail the results of the health app quality assessment. The label's main inspirator was the both in uptake and quality improvement very effective EU Energy label, which is similar to CEN-ISO/TS 82304-2 in providing a score, label, and report ('product information sheet') and being maintained by CEN/CENELEC, in collaboration with ISO and IEC. The label was already tested in the Netherlands with people with limited health literacy. Further testing with people with limited health literacy in four corners of Europe (Denmark, Hungary, Italy, and likely France) is part of the L2E project, as is translating the label in 25 commonly used EU languages, aligning with the aims of EHDS Article 31(4). The project will also co-create communication to adequately introduce the label to end-users, test how to display the label in app stores, app libraries and trusted health sources and provide guidance as to the level of detail in the health app quality report.

Health authorities of Italy and Catalonia are part of the L2E consortium. The Netherlands Ministry of Health is about to pilot its proposed national health app assessment framework based on CEN-ISO/TS 82304-2 with 10-15 apps.[24] Norway has already tested 5 apps with 82304-2 and provides citizens access to two of them via its national portal.[25] Sweden is also reported to already work with CEN-ISO/TS 82304-2.[26] An overview for the French Health Authority aimed at referencing apps in the digital healthcare space highlights the potential of CEN-ISO/TS 82304-2 to harmonise app quality requirements.[3]

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