The Label2Enable perspective on the EDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space

Background

In July 2012 the EDPB-EDPS adopted a joint opinion on the EHDS which addresses, *inter alia,* the use of apps in the healthcare setting. Based in the principles of data protection as enshrined in the GDPR, the EDPB-EDPS argue that the data collected in wellness apps and other digital applications should not be included in the EHDS unless such data are collected and shared based on the prior consent of the data subject. They argue furthermore that wellness app generated data should not be available for secondary use because such data do not have to meet high data quality requirements. The Opinion also sets forth the argument that because wellness apps can be wide ranging, inferences could be drawn which may expose a data subject to harm. Accordingly wellness app data should not be included in the EHDS.

The Label2Enable project welcomes the insightful work of the EDPB-EDPS but would argue that rather than concluding that wellness app generated data should be excluded from the EHDS, the concerns should be robustly addressed within the EHDS to ensure that these valuable data are not lost from the realm of data that can be used directly for patient care, nor from that which may be re-used in the context of research and innovation for better care. This document further details how the Label2Enable project envisages this can be achieved.

Data Quality

In paragraphs 34-36 the EDPB-EDPS note that wellness apps are not subject to the same quality requirements as devices falling under the MDR and that accordingly the data they generate cannot be treated as equal to data generated by medical devices and should be excluded from the EHDS.

The robust CEN-ISO/TS 82304-2 framework and label proposed by Label2Enable and the European Commission in the related Horizon Europe call text, are a core step to using standards of data quality that the EDPB-EDPS rightly argue is lacking in Europe at present. Requiring compliance to key requirements in the CEN-ISO/TS 82304-2 framework would be a good measure to address the quality concerns raised by EDPB-EDPS without resorting to the exclusion of these data, which will add important insights and which patients may often want their healthcare professionals to take into account when providing care.

Transparency and Trust

In paragraphs 78-79 the EDPB-EDPS begin by addressing the value of labelling of wellness apps as a key tool in ensuring transparency regarding key features of an app to support app users in their choice of reliable applications. They note however that the EHDS proposal does not realise the full potential of such labelling because the label called for in the Proposal is limited to the interoperability of the wellness app with EHR systems.

The Label2Enable project fully agrees that wellness app' interoperability with EHR systems is only one of many elements that should be certified and alone will do little to support users in their

choice of reliable applications. Accordingly, we argue that rather than excluding wellness app data from the EHDS because the proposed label addresses only interoperability with EHRs, the EHDS Proposal should be strengthened to ensure that app labels address issues of quality of the data they generate so that such data can be useful when integrated by EHRs, rather than simply assert that they can be integrated. This would align with the essential requirements in Annex II and with TFEU Article 114(3) which requires a high level of protection of human health in achieving harmonisation. The CEN-ISO/TS 82304-2 label addresses the requirements in Annex II and those in Article 31(2) of the proposed EHDS Regulation, as visualized in Figure 1.

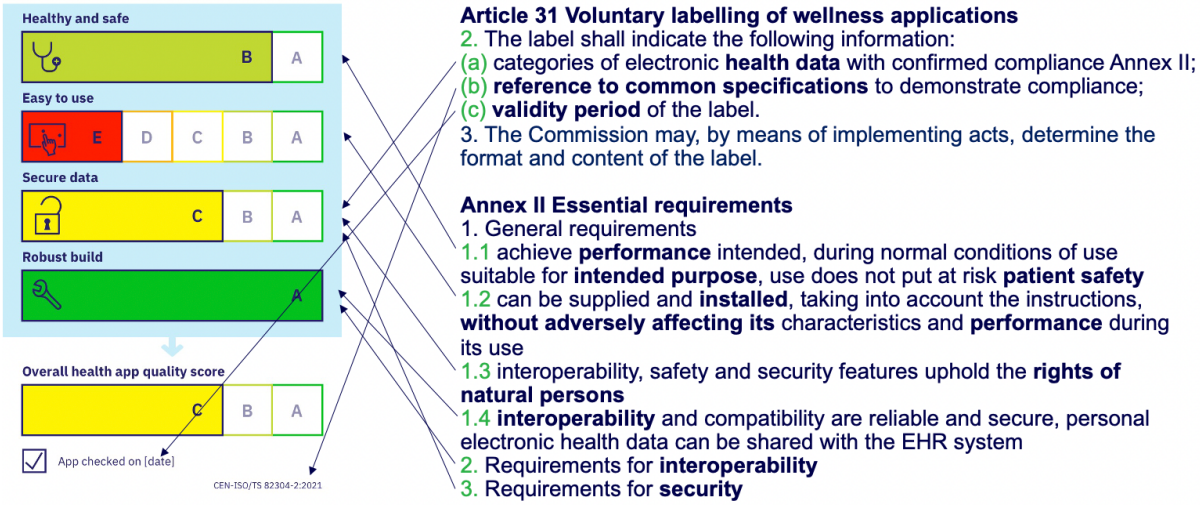

Figure 1: Alignment of the CEN-ISO/TS 82304-2 label with EHDS Article 31(2) and Annex II

Capacity for misuse

In paragraphs 80-81 the EDPB-EDPS argue that the data generated by wellness apps may be very widely and could allow third parties to combine these data with other data sets to draw inferences that could be used to the detriment of the data subject.

The Label2Enable project welcomes the observations of the EDPB-EDPS about the potential threat of wide ranging data collection by wellness apps. The CEN-ISO/TS 82304-2 labelling scheme includes at its core the principle of data minimization applied in the (individual) health app. Furthermore, to ensure that data subjects can protect themselves against potential misuse, the assessment framework includes if sharing Personally Identifiable Information with third parties needs to be actively selected by the app user (thus requiring informed consent for such data sharing). The certification scheme that the Label2Enable project co-creates for CEN-ISO/TS 82304-2 will be aligned with EU level legislation and as such could address an opt-out for secondary use of data.

Conclusion

Many health and wellness apps are placed on the EU market following self-certification as a Class I medical device. Some are in a higher class and as such are subject to certification through a Notified Body. Notified body topics addressed have previously been estimated to cover some 40% of the requirements in CEN-ISO/TS 82304-2. The exact overlap is investigated in the Label2Enable project to ensure that app assessment organisations will not duplicate the legal requirements imposed by

Notified Bodies for Class IIa, IIb or III apps. Most wellness apps, however, fall entirely outside the scope of the Medical Devices Regulation. In the context of highly stretched healthcare systems across Europe and allowing patients (and citizens) to be more actively engaged in promoting their own health and wellness, the CEN-ISO/TS 82304-2 labelling scheme and the Label2Enable project, focus on addressing the information needs of patients and people with low health literacy. This will play a significant and useful role in improving confidence in apps as important tools in supporting selfcare for all users, including more vulnerable users. The EDPB-EDPS raise important issues about the need for greater trust in the data such tools generate and the way in which such data can be used. However, to conclude that because of these issues wellness apps should be excluded from the remit of the EHDS is to miss an ideal opportunity to address these challenges and to ensure that the apps, which are increasingly used by European patients and citizens every day, are safe and trustworthy and deliver on their promise. Rather than excluding wellness apps, the concept of their labelling should be expanded beyond interoperability with EHRs to address the challenges raised by the EDPB-EDPS along the lines advocated by the Label2Enable project in its **feedback on the proposed EHDS Regulation. URL: https://label2enable.eu/assets/downloads/label2enable_feedback-on-the-proposed-ehds-regulation.pdf**

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 into the following suggested amendments:

Section 5
Other provisions on interoperability *[given the wider scope of Annex II, in particular Annex II(1) another title seems more appropriate]*

Article 31 *"~~Voluntary l~~* ***Labelling of wellness applications****, medical devices and other digital health applications [aligning with wording Article 33(1)(f) and mindful of the feedback of the Standing Committee of European Doctors, page 11: https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-065.FINAL.CPME.position.EHDS.pdf]*
1. ~~Where a manufacturer of a~~ A wellness application, medical device or other digital health application that is placed on the market or put into service [aligning with wording in Article 31(8)] ~~claims interoperability with an EHR system and therefore compliance with the essential 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 th~~s~~e essential requirements laid down in Annex II*** *and common specifications in Article 23. The label shall be issued by the manufacturer of the wellness application.*[1]

[1] In the certification scheme the Label2Enable project develops, the certification scheme owner issues the label and the related more detailed health app quality report. The report will provide the information healthcare professionals need to confidently recommend a health or wellness app. CEN-ISO/TS 82304-2 intentionally entails third-party assessment, mindful of the remarks from both healthcare professionals and insurers that they "need more than the blue eyes of the app manufacturers" to acquire the needed trust. The requirements for accredited app assessors will differ considerably from those for the MDR notified bodies and as such are expected to not add to the existing capacity issues of MDR notified bodies.

2. The label or related list of required data to be registered as referred to in Article 32(4) 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 specifications** 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 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 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 ~~wellness~~ applications with the essential requirements laid down in Annex II.
8. Each supplier of an ~~wellness~~ application, for which a label has been issued, shall ensure that the ~~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 an ~~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 ~~wellness~~ applications which are high-risk AI systems as defined under Regulation […] [AI Act COM/2021/206 final].”

ANNEX II

Essential requirements for EHR systems and products claiming interoperability with EHR SYSTEMS
*The essential requirements laid down in this Annex **shall apply mutatis mutandis to health and wellness applications products claiming interoperability with EHR systems**.*
1.General requirements
*1.1. An electronic health record system (EHR system) shall **achieve the performance intended** by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, it is **suitable for its intended purpose** and its use **does not put at risk patient safety nor lead to decisions detrimental to a natural person** [aligning with Article 35(a)].*
*1.2.An EHR system shall be designed and developed in such a way that it can be **supplied and installed also by natural persons with disabilities** [aligning with Article 10(2)(k)], **in compliance with Directive (EU) 2019/882 on accessibility requirements for products and services, taking into account the instructions** and information provided by the manufacturer, **without adversely affecting its** characteristics and **performance during its intended use**.*
*1.3.An EHR system shall be designed and developed in such a way that its interoperability, safety and security features **uphold the rights of natural persons**, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.*
*1.4.An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that **interoperability and compatibility are reliable and secure**, and personal electronic **health data can be shared** between the device and the EHR system.*