

Template for comments

Xt-EHR D8.3 working document wellness apps and labelling guidelines											
1	2	3	4	5	6	7	8	9	10	11	12
Deliverable: Version:	Organisation name	Xt-EHR target stakeholder group	Section/ Subsection number	Page number	Line number	Figure/ Table / Paragraph number	Category of comment (major or minor)	Type of comment (general, technical or editorial)	Comment (justification for change)	Proposal how to resolve comment, proposed change	Observation/ response to comment by WP, information if and how comment was addressed
EU Member State (MS) ISO 3166 two-letter country code or "EU" for European stakeholder organisations e.g. DE	e.g. Federal Ministry of Health	e.g. Health authorities and legislators	e.g. 2.1.1	e.g. 14	e.g. 323	e.g. Figure 2	e.g. minor	e.g. editorial	e.g. Figure caption lacks introduction of acronyms	e.g. Introduce acronyms used in Figure 2 for reference and to avoid misinterpretation	e.g. agreed, acronyms introduced in D9.1_v1.0
EU	CPME - Standing Committee of European Doctors	Health care experts and providers	4.1.7 Interoperability elements	71	1278		major	general	The deliverable is proposing to explore a two-way communication with the EHR for wellness apps without taking into account its function. A two-way communication could only refer to 'wellness apps' that are to be used by natural persons as 'personal health environment' [see for example [persoonlijke gezondheidsomgeving, https://www.pgo.nl/". Please note that in the Netherlands a number of hospitals already meet the conditions for two-way communication. These conditions follow from a Dutch standard, called 'Medijn', which is a 'set of agreements' for safe, interoperable, and reliable communication between the EHR and the personal health environment (PGO), which can be a wellness app or a website, used and managed by the patient.]. However, fitness apps or counting steps apps, which also fit into the definition of a wellness app, should not have the same privileges. These latter apps should only have a one-way exchange, where the app does not retrieve and access to information covered by professional secrecy. This is important to ensure that vulnerabilities are not introduced into the EHR, that only necessary data is accessed and retrieved, and that medical confidentiality is safeguarded.	A two-way system introduces vulnerabilities into the EHR and is a major technical risk. Limit the two-way exchange to wellness apps that function as 'personal health environment'.	
EU	CPME - Standing Committee of European Doctors	Health care experts and providers	4.1.7 Interoperability elements	71	1278		minor	technical	The deliverable mentions in the discussion column that "For instance, Art 3(2) (right to access) mandates that individuals should be able to download the priority categories of data at least. Once downloaded, they may want to make use of it within a wellness app." It is unclear what uses can be made within the wellness app.	Clarify and give examples of what it means "using the data in the wellness app.". This is important to understand the impact it could have in the patient-doctor relationship and in the amount of information that could then reach the EHR (doctor's working tool) and its consequence on data quality.	
EU	CPME - Standing Committee of European Doctors	Health care experts and providers	4.1.7 Interoperability elements	71	1278		minor	technical	The EHR should only integrate wellness apps data (from fitness apps or step counting apps for example), if medically provided or in agreement with the treating physician, otherwise they risk of saturating the file with data, rendering it difficult to find relevant and useful information. Health data generated by wellness applications and other digital health applications do not have the same data quality requirements and characteristics of those generated by medical devices. This data can pose a significant medico-legal challenge for doctors.	The EHR should only integrate wellness apps data, such as fitness apps or step counting apps, if medically provided or in agreement of the treating physician. Such apps must comply with ISO standards (e.g., ISO/TS 82304-2 on Health and wellness apps – Quality and reliability) and be CE approved.	