

**Template for comments**

Xt-EHR D8.3 Wellness application 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	4.1.6 Article 48(2)	54-55	1312-1322 and 1346		major	general	Data from wellness apps might easily saturate the EHR file, in particular the section on patient-provided data. As rightly indicated in the deliverable, the patient-provided data section in the patient summary has been conceived as a section where data is reported by the health professional in relation to additional information provided by the patient (e.g. travel history or state of will directives). For doctors, it is important that data from wellness apps do not increase documentation burden and cause alert fatigue. In addition, the quality of health data generated by wellness applications is not the same as data generated by medical devices, and there is a risk that data generated by wellness apps lead the EHR file to become less suitable as a clinical tool. Data from wellness apps can indeed be useless for the healthcare professional provider due to poor data quality, no standardised protocol, no transparency on algorithms, and lack of scientific documentation, etc. For more information see CPME position on the European Health Data Space, Section 11 Digital Applications, page 11: <a href="https://www.cpme.eu/api/documents/adopted/2022/11/cpme_2022-065_FINAL_CPME_position_EHDS.pdf">https://www.cpme.eu/api/documents/adopted/2022/11/cpme_2022-065_FINAL_CPME_position_EHDS.pdf</a>	Add as recommended best practices the following: "(v) Consider the interface of healthcare professionals, to be able to easily select relevant information in the EHR. (vi) Consider to reduce documentation burden and alert fatigue for health professionals, meaning that data from consumer wellness apps shall not be sent to/seen in the patient summary unless requested by a qualified registered health professional. (vii) Medically certified apps that are documented cost-beneficial, if requested by the doctor, and in agreement with the patient, might be granted access to export data directly to the EHR.	