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Update on the support provided to professionals by the French Health Authority for the deployment of e-health in France

In a series of articles published this month, the *Haute Autorité de Santé* (French Health Authority) recalled the materials it has produced in connection with the deployment of e-health in France.

The French Health Authority has indeed developed tools, guides and guidelines to support developers of apps and smart devices, practitioners wishing to set up teleconsultation activities or healthcare professionals approved industry-specific software solutions and approved databases.

As part of its missions, the French Health Authority contributes to the development of e-health, an area that covers many applications of information and telecommunications technologies in the field of health.

In particular, this concerns mobile health (i.e. smart devices and software applications related to health or well-being), software for health professionals (including prescription support software or electronic medical records), telemedicine (including teleconsultation and tele-expertise activities), or user information.

Regarding mobile health (or "m-health"), the French Health Authority has produced a set of good practice guidelines for manufacturers and evaluators (evaluating bodies, consumer associations or medical professional organizations)[1]. These recommendations cover apps and smart devices that have no stated medical purpose. In other words, they apply specifically to apps and smart devices dedicated to well-being and prevention that are not medical devices.

In these guidelines, the French Health Authority lays down criteria for the delivery of reliable and quality health content as well as the guarantee of confidentiality and security of personal data by a health app. or smart device. These guidelines include 101 good practices divided into five categories: "informing users" (description and consent), "health content" (design of initial content, standardization, generated content,

interpreted content), “technical content” (technical design, data flow), “security/reliability” (cybersecurity and confidentiality) and “usability/use” (usability/design, acceptability, integration/import).

In addition to these good practices, the guidelines prepared by the French Health Authority include a risk matrix that makes it possible to tailor the level of applicability of these good practices according to the relevant app and/or smart device. This modulation depends on the main target user (healthcare professionals, patients, the general public, etc.) and the main intended use axis (information, prevention, data analysis, etc.).

Regarding the exercise of remote medical practice based on a device that uses information and communication technologies (telemedicine), the French Health Authority has, in particular, published guidelines to facilitate the implementation of teleconsultation, tele-expertise and tele-imaging by healthcare professionals[2].

As detailed in a previous article[3], the French Health Authority insists *inter alia* on the need to use specific IT tools for the exchange, sharing and storage of data, including a secure health messaging system and a sharing platform guaranteeing the confidentiality and security conditions required for the processing of health data. With regard to the conduct of the activities, the French Health Authority also recommends identifying the patient and knowing his/her geolocation. The healthcare professional must authenticate himself/herself via a strong authentication system.

Regarding industry-specific software used by healthcare professionals, the French Health Authority’s mission is to develop procedures for the certification of software to support the processes of prescription and dispensation. This optional certification certifies that the software meets the quality and safety criteria set out in the guidelines published the French Health Authority (i.e. patient information, drug information, health product display, prescription, data security and confidentiality)[4].

Through these work products, the French Health Authority provides tools for improving professional practices as part of the deployment of e-health in France. All professionals operating in this industry will also have to ensure compliance with applicable legal and regulatory provisions, in particular as regards medical devices, the exchange of information and the processing of personal health data.

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[1] Good practice guidelines on health apps and smart devices, French Health Authority (October 2016)

[2] Best practice guide for “*the quality and safety of teleconsultation and tele-expertise activities*”, French Health Authority (May 2019); best practice guide for “*the quality and safety of tele-imaging activities*”, French Health Authority (May 2019)

[3] Cf. article entitled Practical recommendations of the French Health Authority for the implementation of teleconsultation and tele-expertise activities published on our Blog in September 2019

[4] Pursuant to Decree No. 2019-856 of August 20, 2019 on the certification of software to assist in the processes of prescription and dispensation, and the daily allowance in the event of part-time work for

therapeutic reasons, the certification standards are being updated to take into account the new expected minimum functionalities