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VOGEL COMMUNICATIONS GROUP

Concept of human guarantee in the use of artificial intelligence: what are the challenges for manufacturers of medical devices?

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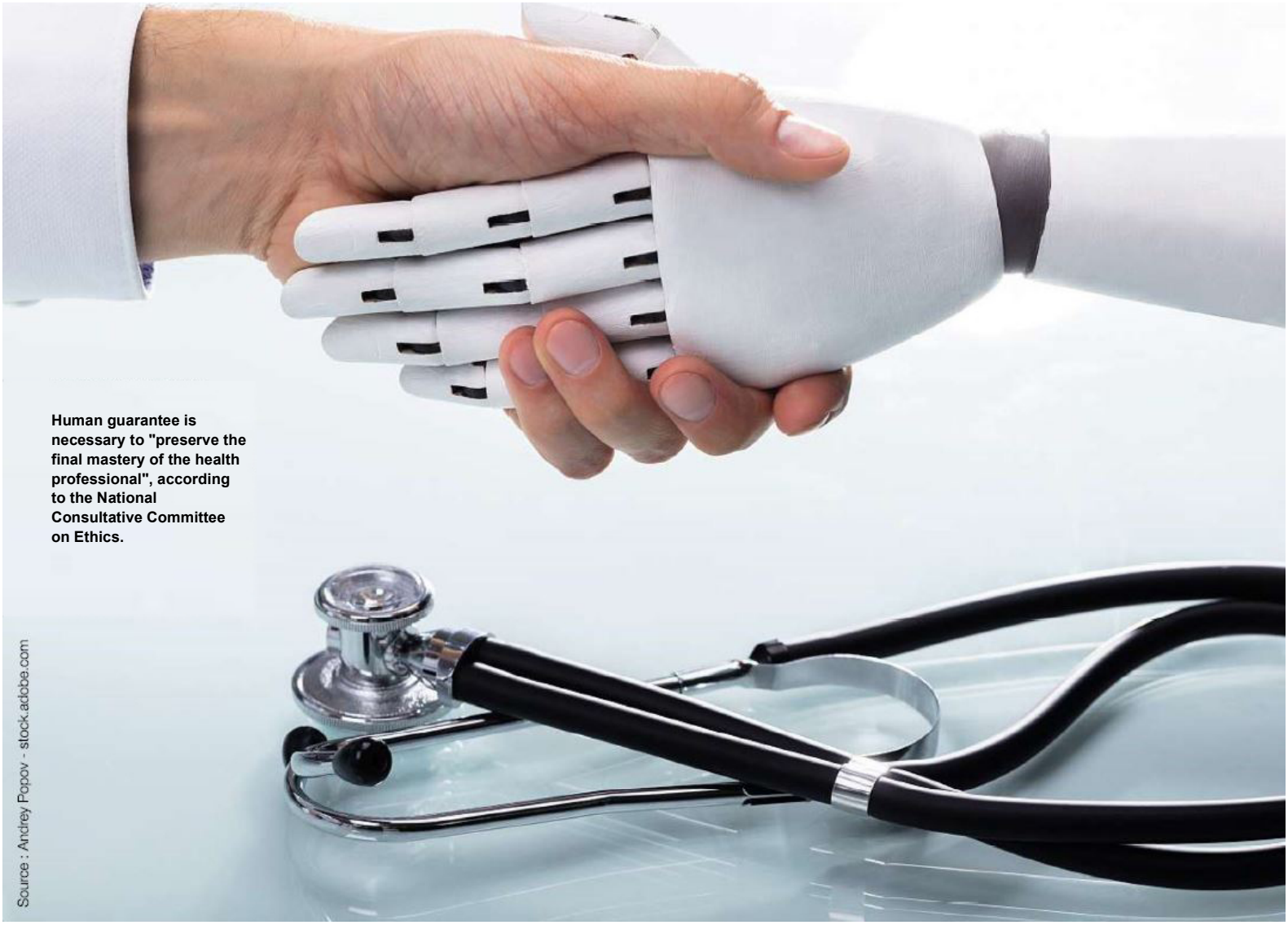
Although AI's assets in terms of healthcare are considerable, the risks they entail are no less real. This is why it is interesting to understand the notion of human guarantee that Maitre Cécile Théard-Jallu presented in last September at the MD's meeting *La Rentrée du DM* in Besançon and that she explores in this publication.

Ethics occupies a major place among the issues related to artificial intelligence. Indeed, many players share the desire to preserve man's autonomy and his control over the machine, which must remain a tool enabling him to take more enlightened decisions for legitimate purposes. This Human Guarantee concept is one of the pillars of the European AI development policy among 6 other key principles: (i) technical robustness & safety, (ii) privacy & data governance, (iii) transparency, (iv) diversity, non-discrimination & fairness, (v) societal & environmental well-being, (vi) accountability.[i] It also lies at the heart of the Global Partnership on Artificial Intelligence (GPAI) launched in June 2020 by France and Canada, aiming at a long-term international competitiveness.



Human guarantee is necessary to "preserve the final mastery of the health professional", according to the National Consultative Committee on Ethics.

Source : Andrey Popov - stock.adobe.com

This partnership has already led to the involvement of almost fifteen countries, including the United States, the United Kingdom and South Korea.[ii]

Human guarantee is particularly important in the health sector, where the use of AI is spreading all along the patient's journey. The benefits of AI are considerable (customized medicine in prevention, diagnosis and care, greater reliability of medical acts thanks to massive reference data, optimization of flows in facilities etc.). However, risks are also real, notably a loss of autonomy in decision-making by healthcare professionals, a questioning of their link with the patients or the presence of "black boxes".

France is a frontrunner on the field driven by actors such as Frenchmen David Gruson and Judith Mehl. The National Consultative Committee on Ethics took up the issue by publishing on May 29, 2019, Opinion No. 130 laying the foundations of this concept. They revolve around 12 recommendations calling in particular for the empowerment of all actors, independent control and the training of professionals. The concept is now being promoted before the WHO within the framework of a taskforce dedicated to the regulation of AI.[iii]

A likely introduction of this principle into French law

Having almost completed its parliamentary journey after being adopted on second reading by the National Assembly in July 2020,[iv] Article 11 of the new bioethics Bill recommends that human guarantee be integrated into a new Article L. 4001-3 of the French Public Health Code. According to this article:

"« I. *I. When an algorithmic processing learning from massive data, is used for preventive, diagnose or therapeutic acts, the health professional who decides of such use must make sure that the person concerned has been informed beforehand and as the case may be, that he or she is informed of the resulting interpretation.*

II. Traceability of any action taken in connection with the processing referred to in I above and of any data used by it, shall be ensured and the resulting information shall be made accessible to the health professionals concerned.

III. An Order of the Minister of Health sets out, following the opinion delivered by the High Authority for Health [HAS]*, the list of different types of algorithmic processing activities that are the subject of the information mentioned in I above. It specifies, upon the opinion of the National Commission for Data Processing and Liberties* [i.e. the French Data Protection Authority of CNIL]*, for each type of processing, the nature of actions and storage duration of data whose traceability is provided for in II above".*

- Therefore, the concept is currently based on:
  - patient information before use of AI and once the results have been generated, under health professional supervision;
  - the capacity of AI tools and players in tracing treatments and data and in ensuring transparency for the professional user;
  - the whole system being governed by a regulatory framework adopted under the control of the authorities entrusted with overseeing either care activities (as well as the financial coverage of tools by the health insurance) or the protection of personal data.

The previous wording, which required that data entry should be carried out under the supervision of the health professional or that the medical decision should not be based solely on the AI tool, disappeared in the course of the parliamentary debates. It is true that it presented notably a risk of slowing down adherence to certain AI tools used autonomously by patients, thus discouraging innovation. For its part, the obligation of transparency, imposed on developers, was mentioned in a general way.

A principle to be taken into account from the early design phase of MD

Medical devices are increasingly integrating AI. The manufacturer is thus concerned by this new principle since the requirement for traceability and information sharing related to AI will have to be taken into account from the initial design phase and throughout the life cycle of the product. This concerns all the players involved as manufacturers, suppliers, services providers, distributors, users and insurers, whose policies will have to be drawn up accordingly.

An inspection will also need to be carried out, either with targeted, planned or random, internal or external procedures. It should be noted that a pioneering project in the oral health field has already established the first Human Guarantee Board.[v]

The principle is also being developed in the first self-assessment grid for MDs incorporating AI, adopted on October 14, 2020 by HAS.[vi] In a way, it is a question of establishing a "human guarantee by design", following the example of the "privacy by design" instilled by the GDPR, and of monitoring its respect throughout the medical device's life, based on the 3 levels of supervision recommended by the EU:

- *Human-In-the-Loop* (HITL): human intervention in each decision cycle related to the AI tool,
- *Human-On-the-Loop* (HOTL): human intervention - in the design of the AI tool and its operation,
- *Human-In-Command* (HIC): Supervision capability for the general activity of the AI system.

Human guarantee still needs to be specified in its outlines, both in terms of the information to be shared by health professionals with their patients and of the processing and data sets to be traced and controlled. Sharing reference data for consultation by health professionals also raises the question of the compatibility of the new system with the protection of intellectual property.

In any case, the first field experiences I have observed show that some organizations have already taken up the subject and included it in their legal and operational documentation. As is often the case on the market, it is better to be a leader than a follower.

www.degaullefleurance.com

Source : De Gaulle Fleurance & Associes

Cécile Théard-Jallu

[ii] *httpsf/bitly/SOULNuJ*

[ii] *https://bit.ly/3iPuqkT*

[iii] *https://bit. ly/3jUhVWE*

[iv] *https://bit.ly/36V8F0Y*

[v] *https://bit. ly/34PyvAR*

[vi] *https://www.has-sante.fr/jcms/p_3212876/fr/un-nouvel-outil-pour-l-evaluation-des-dispositifs-medicaux-embarquant-de-l-intelligence-artificielle*
- this reference has been updated since the final version of HAS' guide was released after the first publication of this article in French.