Press release of the national Academies of Medicine, Pharmacy and Surgery

A real risk of medical device shortage

A press release expresses an official position of the National Academy of Medicine. The Academy in its) session of Tuesday, May 31, 2022, adopted the text of this report by 69 votes for, 3 votes against and 5 abstentions.

PREAMBLE

The National Academies of Medicine, Pharmacy and Surgery warn of a risk of shortage of MD and IMD due to implementation difficulties of the new European Regulation (EU) 2017/745 relating to medical devices (MDNR). If only implantable medical devices (IMD), numbering 25,000, are affected initially and acutely, all MDs are eventually affected (400,000). However, the three Academies emphasize the merits of this MDNR, whose objective is twofold. It's on the one hand, to improve health and safety by considerably strengthening certain essential aspects of the current regulatory approach: supervision of notified bodies (NB), conformity assessment procedure, clinical investigations and clinical assessment, vigilance and market surveillance, new obligations imposed on economic operators. It is, on the other hand, to introduce provisions guaranteeing the transparency and traceability of MDs and IMDs. All these elements should contribute to strengthen the confidence of the health system users.

DEVELOPMENT

The upcoming implementation of MDNR leads to a bottleneck that is currently blocking the process:

1. The basic requirements of this validation (new certification for CE marking) do not not take into account the known nature and the established usefulness, often for several years, of numerous medical devices, in particular implantable ones.
2. Notified bodies are too few. Their number was over 50, while today only 28 have obtained their approval, with a strong geographical disparity (only one for France, GMED, and probably a second at the end of the year, AFNOR). In addition, these NBs must not only assess IMDs for CE marking, but also ensure the prior assessment of the manufacturers who produce them and be themselves recertified every three years.
3. The number of files is increasing sharply: their importance and cost being sometimes increased tenfold.

What are the foreseeable consequences?

1. The blocking of the entire evaluation system by the NBs and the risk of product shortages essential for the interventional and surgical care of patients, due to the double fact of the impossibility of their certification and marketing stop (as of May 26, 2024);
2. A mobilization in favor of the validation of existing MDs and IMDs and, this, to the detriment of innovation and the development of new MDs, a necessary factor of progress;
3. The removal of some niche product lines deemed unprofitable and yet essential for some patients;
4. Finally, the possible disappearance of some companies that will not be able to cope with the new requirements.

The current system is therefore, as the last parliamentary report pointed out, "between two regulatory waters".

RECOMMENDATIONS

The problem is not to dispute the basis and usefulness of the MDNR but to discuss its modalities and application deadlines.
Consequently, the National Academies of Medicine, Pharmacy and Surgery recommend:
1. An increase in the means made available to notified bodies, in particular the French ones, regarding the number of experts.
2. An extension of the transition period for the new regulation implementation by at least two years in order to avoid a collapse of the whole system of MDs and IMDs in Europe (notification bodies and companies), and the resulting loss of opportunity for patients.
3. A real assessment of the risk, for some patients, of being deprived of essential medical MDs and/or IMDs.

N.-B. For the most acute situations, accentuated recourse, but limited in time, to derogatory possibilities provided for by the MDNR (article 59) have already been implemented by the ANSM.

Glossary
IMD: Implantable medical device means to be implanted in whole or in part in the human body in particular to compensate for a faulty act or function.
CE marking: Any medical device to be used and placed on the market have had since 1990 and 1993 to be validated by a conformity indicator (Directives 90/385 /EEC and 93/42/EEC). These guidelines were superseded by a single regulation in 2017 (EU) 2017/745 which applies to all European States.
NBs (Notified Bodies): bodies responsible for the evaluation and compliance of these MDs (issue of CE marking). These NBs must themselves be certified (a procedure that requires more than 900 days) and must also certify the companies that manufacture medical devices