Medical devices: action needed to address the lack of patient protection

● **The Implant Files scandal is yet another warning of the urgency of the situation and of the weaknesses of the existing legislation, at the expense of patients' safety.**

Whether it is a breast implant or a cardiac pacemaker, marketing of a medical device is not subject to marketing authorisation (MA). Only a CE marking (European compliance) is required, which is often conferred by private organisations, on the basis of technical documentation (1). This situation is conducive to abuse and to disasters.

Medical device vigilance: a lack of human resources and responsiveness. The Implant Files, a global investigation by journalists, brought to light numerous failings in the medical device sector worldwide, which are detrimental to patients (2). In the absence of an MA, the authorities mainly react after a malfunction has been reported, or has been identified by active medical device monitoring. Such surveillance is weak in France, as shown by a report from the "Inspection Générale des Affaires Sociales (IGAS)" (the French government audit office for health and social security) (3). "*In 2017 alone, the 19 assessors* [from the French Health Products Agency] *(…) handled the processing of 17 142 reports, of which 13 467 required investigation (major and critical safety alerts). Such a high workload forces them to work on a "just-in-time" basis (…) and to take a light-touch approach to some major cases (around 60%) (…). Overall, this leads to highly variable time frames for implementing corrective measures following an incident, which are relatively long (ranging from 21 to 215 days, with an average of 95 days) and are unrelated to the severity of the incident*" (3).

Protect patients before and after marketing. In response, the French government has announced actions primarily aimed at *"reinforcing the assessment and supervision of practices for medical device implantation, in particular for those carrying the greatest risk"* and *"guaranteeing the traceability of implantable medical devices in healthcare establishments"* (4).

Medical device vigilance needs to be reinforced considerably, as does the assessment of practices and traceability. However, the need to control entry onto the European medical device market must not be overlooked, so that dangers are detected before patients are exposed to them. The pharmaceutical sector shows that an MA is not in itself sufficient for safeguarding the interests of patients, especially when the requirements for obtaining an MA are not rigorous. However, establishing a European MA for medical devices would represent significant progress, and would indicate that public authorities recognise their core responsibility in this area.

The new European regulation which will come into effect in 2020 still does not provide for controlling market access for the highest risk medical devices (5). It is to be hoped that the authorities, in France and other countries, will demand that this measure will be implemented in order to protect patients, as was also proposed by a report of the French National Assembly in March 2019 (6).

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3- Aballea P et al. "Audit de la maîtrise des risques sanitaires par l'Agence nationale de sécurité du médicament. Tome 1: rapport définitif de synthèse" IGAS 2018: 124 pages.
4- Ministère des Solidarités et de la Santé "Dispositifs médicaux: garantir leur sécurité et leur efficacité". https://solidarites-sante.gouv.fr accessed 22 January 2019: 3 pages.
5- "Nouveaux règlements européens relatifs aux dispositifs médicaux - Point d'information" 29 August 2017: 2 pages.
6- Borowczyk J and Dharréville P "Rapport d'information (…) en conclusion des travaux de la mission d'information relative aux dispositifs médicaux" French National Assembly 6 March 2019: 107 pages.