



Prescrire



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## **“Implant Files” Campaign for an effective marketing authorisation for high-risk medical devices**

Journalists recently launched the "Implant Files", an investigation into the medical device industry which was published in a number of countries, mainly in Europe. The Implant Files raise the alarm over medical devices, over which there are few controls, from their arrival on the market through to postmarket surveillance (materiovigilance). The above associations have joined forces to condemn the health authorities' failure to adequately oversee the trade in high-risk medical devices.

Everything suggests that some authorities in France and Europe consider medical devices as consumer goods like any other. Likewise, the European Commission has seen fit to place medical devices under the aegis of its Directorate-General for Enterprise, while medicines come under the responsibility of the Directorate-General for Health. In France, the Administrative Documents Commission – *Commission d'accès aux documents administratifs* (CADA) is opposed to publishing the list of medical devices that have received the CE mark and those that have not, on the grounds of trade secrecy.<sup>1</sup>

Simple compresses or toothbrushes are clearly not expected to be subjected to extensive controls. But it is incomprehensible why implants, which remain in the body for years, are not subject to a marketing authorisation (MA), whereas drugs, even though treatment can be halted immediately in the event of a problem, do need a MA.

Many stakeholders, including signatories to this document, called in 2012 for high-risk medical devices (including implants) to be subject to a marketing authorisation. The MEP rapporteur of the Draft Regulation, who was personally in favour of such prior authorisation, described the methods used by the implant industry lobby to defeat the draft regulation as “repugnant”.<sup>2,3</sup>

<sup>1</sup> [https://www.lemonde.fr/implant-files/article/2018/11/27/implants-la-commission-d-acces-aux-documents-administratifs-invoque-le-secret-des-affaires-contre-la-transparence\\_5389017\\_5385406.html](https://www.lemonde.fr/implant-files/article/2018/11/27/implants-la-commission-d-acces-aux-documents-administratifs-invoque-le-secret-des-affaires-contre-la-transparence_5389017_5385406.html)

<sup>2</sup> How lobbying blocked European safety checks for dangerous medical implants”, *The BMJ*, 26 November 2018 <https://www.bmj.com/content/363/bmj.k4999.full>

<sup>3</sup> [https://www.lemonde.fr/implant-files/article/2018/11/27/comment-les-legislateurs-europeens-ont-cede-au-lobby-des-implants-medicaux\\_5389262\\_5385406.html](https://www.lemonde.fr/implant-files/article/2018/11/27/comment-les-legislateurs-europeens-ont-cede-au-lobby-des-implants-medicaux_5389262_5385406.html)

This lobbying was successful since the EU Regulation that will come into force in 2020 does not include a marketing authorisation requirement for medical devices.

French health officials claim that the situation as described by the Implant Files will be significantly improved with the new Regulation. However, not only does this Regulation not make marketing authorisations mandatory, even for the most dangerous medical devices, but it continues to give a key role to the Notified Bodies, which will be responsible for issuing or refusing the CE mark, despite their past failures.

In France, there is a single Notified Body responsible for the control of medical devices: LNE/G-MED (and SGS-ICS for prescription support software) – a public establishment of an industrial and commercial nature. Further to the release of the Implant Files, the newspaper *Le Monde* asked the LNE/G-MED for the lists of medical devices for which it has issued or refused the CE mark. LNE/G-MED declined to provide these lists. And CADA, contacted by *Le Monde*, endorsed this stance on the grounds of trade secrecy.<sup>1</sup>

In practice, the situation described by the Implant Files is the culmination of several decades of laxity and “passive market control”, as the French General Inspectorate of Social Affairs (IGAS) calls it.<sup>4</sup> There is no reason to believe that the situation will improve sufficiently with the new Regulation, particularly in view of LNE/G-MED’s lack of transparency.

We therefore demand with the utmost urgency that the French health authorities do everything within their power to further protect patients and enable them to make informed choices with regard to medical devices. This includes demonstrating maximum transparency with regard to the criteria and results of CE certification, significantly strengthening postmarket surveillance, and guaranteeing public access to incidents and accidents involving medical devices.

We ask that France bring the implementation of an effective marketing authorisation for high-risk medical devices to EU level. We also demand that the government organise another National conference on medicines and medical devices. Despite the first conference in 2011 following the Mediator scandal, many of the actors are still under the influence of the powerful industry lobby. The health-product evaluation and control system is very lax, too lax. These combined factors are likely to result in recurrent major health disasters.

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<sup>4</sup> [https://www.lemonde.fr/implant-files/article/2018/11/30/implant-files-un-rapport-de-l-igas-souligne-les-incroyables-lacunes-de-la-surveillance-de-l-autorite-sanitaire\\_5391112\\_5385406.html](https://www.lemonde.fr/implant-files/article/2018/11/30/implant-files-un-rapport-de-l-igas-souligne-les-incroyables-lacunes-de-la-surveillance-de-l-autorite-sanitaire_5391112_5385406.html)