

A centralised European Medical Devices Agency, and soon!

In July 2025, the national authorities for health products of 17 EU countries called for the creation of a centralised European agency for medical devices. They argued that it would strengthen cooperation between countries, by coordinating their vigilance and risk-assessment activities in an increasingly complex market. This would make it possible to better protect patients, while being more cost-effective for member states, and reducing the administrative burden on medical device companies (1). The hopes raised by their remarkable position statement were immediately dashed by the European Commission's announcement of a reform with quite different aims.

No medical devices are evaluated or granted authorisation by a health authority before their market introduction, not even those that pose the highest risk to patients. This stems from a political choice in Europe, back in the 1990s, to make do with CE marking, a system that gives manufacturers a great deal of autonomy. Many medical devices can be brought to the market under the sole responsibility of the manufacturer. The other medical devices, even those that pose the greatest risk to patients, are first simply examined by a certification organisation called a "notified body", often a private-sector organisation. The successive reforms of Europe's medical device regulations reflect the realisation that CE marking is inappropriate for health products, yet there have been no moves to replace it (2). The 2017 reform introduced stricter requirements for manufacturers and notified bodies, bolstering rather than challenging their roles. Whether these reforms have improved the information available about medical devices or the evaluation of their harm-benefit balance remains uncertain (3).

Despite the staggered introduction of the 2017 regulations, and the fact that full implementation had already been postponed from 2024 to 2028 on the grounds that "*overly onerous requirements*" would increase the risk of medical device shortages, their implementation proved difficult for manufacturers and notified bodies. In a kneejerk reaction, the Commission launched a project to simplify the regulations. Yet again, the health of the market took precedence over transparency.

In contrast, since the 2010s, Prescrire has been calling for the introduction of marketing authorisations for the highest-risk medical devices, and for the creation of a centralised European agency (4). Although the European Medicines Agency's (EMA) new responsibilities for medical devices remain limited, they make it the best placed organisation to take on this role. As of 2026, it is beyond debate that the EMA should be given the necessary means, and in particular the legislative and budgetary support, to evaluate and monitor the highest-risk medical devices. Indeed, according to the national health authorities themselves, there is now an urgent need to address this issue. The Commission cannot claim to be ensuring "*a high level of (...) patient safety*" while outsourcing the safety of medical devices to the companies that manufacture and sell them, and those paid to certify them (5).

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References 1- CAMD, HMA "European medical device competent authorities statement on reform of the EU regulatory framework for medical devices" July 2025: 3 pages. 2- "Mise sur le marché des dispositifs médicaux: l'Union européenne est consciente des faiblesses du marquage CE, mais n'y renonce pas" *Rev Prescrire* 2023; 43 (481): 859-867. 3- "Clinical evaluation of medical devices: as of 2025, progress is difficult to ascertain and weaknesses persist" *Prescrire Int* 2025; 34 (275): 277-278. 4- "Medical devices: marketing authorisations are needed" *Prescrire Int* 2012; 21 (130): 223. 5- European Commission "Targeted revision of the EU rules for medical devices and in vitro diagnostics" 8 September 2025: 4 pages.
