Clinical evaluation of medical devices: as of 2025, progress is difficult to ascertain and weaknesses persist

● The reforms culminating in the 2017 Medical Devices Regulation did not take into account the calls from Prescrire, among others, for the creation of a European Medical Devices Agency.

The early European directives on medical devices, which were drawn up in the 1990s within the framework of "CE marking", enabled the development of a market for health products which, unlike drugs, had not been previously tested or authorised by a public health product regulatory agency (1).

In 2019, in its response to a public consultation held by the European Medicines Agency (EMA), Prescrire highlighted the danger of the lack of a marketing authorisation procedure regulated by a public agency for the highest risk medical devices, in line with the one introduced by the Food and Drug Administration (FDA) in the US (5-7).

A 2017 European Regulation, progressively applied since 2021, was brought in to strengthen the clinical evaluation of medical devices before and after their market introduction. It requires manufacturers to conduct clinical trials ("clinical investigations") for the highest risk medical devices; gives the authorities increased supervisory powers over the certification bodies ("notified bodies") that issue medical device manufacturers with the certificates needed to market their products and to apply the CE marking; obliges these notified bodies to consult European Commission expert panels prior to certifying certain high-risk medical devices; and has created a central portal for certain clinical data for the authorities responsible for market surveillance (Eudamed) (1).

A number of measures designed to improve transparency have also been announced or implemented by the 2017 Medical Devices Regulation: it has introduced a Summary of Safety and Clinical Performance (SSCP), for use by health professionals and patients, for the highest risk medical devices; and set out plans for the public to be given access to certain data, mainly through Eudamed, in particular on serious incidents that occur in the post-market period and surveillance activities by the authorities (1).

However, there are still a number of issues. Under this regulation, medical devices remain under the CE marking system, which is primarily limited by the lack of systematic evaluation of products by a public authority, including the highest risk medical devices (Class IIb or III). Medical devices that are considered by their manufacturers to be low risk (Class I) may be marketed without any involvement from a notified body. Medical devices over which major uncertainties remain due to the use of new technologies are not necessarily covered by the most stringent obligations (1).

The 2017 Regulation still does not require a detailed, comprehensive clinical evaluation report produced by the notified body, or otherwise the manufacturer, to be made public once a device has been granted CE marking. It has, however, created Eudamed: an ambitious, centralised European database designed for use by various stakeholders, including manufacturers, notified bodies, health authorities and the general public. Eudamed is ultimately set to provide both administrative data (on products, manufacturers, and issued or rejected certificates) and clinical data (on adverse effects and clinical investigations) (2,3). The information available to the general public should include the SSCP and some clinical data, in particular on adverse effects (4).

As of mid-2025, the roll-out of Eudamed is several years behind schedule, with the clinical investigation and adverse effects modules still in development as of the start of this year. The general public can only access very limited administrative data via this database. The website states that if the SSCP is not available in Eudamed, it must be provided by the manufacturer upon request. The opinions issued by expert panels on a few high-risk Class III medical devices have been published by the European Commission on its website (2,4).

New requirements concerning the clinical evaluation of medical devices demonstrate that the 2017 Regulation has the potential to be a source of progress and greater transparency. But as of mid-2025, concrete progress is still partial and difficult to ascertain, firstly because of the large number of medical devices that remain on the market through compliance with the old regulatory requirements, and secondly due to the delayed introduction of the public-facing component of Eudamed. Certain provisions also give manufacturers numerous ways to circumvent the most stringent requirements that provide patients with the highest level of protection.

In practice, to check the strength of evidence produced by the evaluation of a medical device, healthcare professionals need to consult various sources, for example by searching online for an SSCP and submitting requests to manufacturers or distributors.

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Minimal clinically important difference: a useful concept, but critical analysis required

- When comparing scores or results based on a numerical rating scale, a statistically significant difference in favour of the intervention under investigation is not necessarily clinically meaningful for patients.
- The "minimal clinically important difference" is the smallest difference that patients consider to be tangible for a clinical endpoint quantified using a score. Two methods are used to determine the minimal clinically important difference: expert consensus and anchoring.
- The consensus method is based on the opinion of experts. It is not always reliable for determining what is important or tangible for patients, and especially for a given patient.
- Anchoring is the method most frequently used. It is based on the opinion of patients. But its results depend on the patient population chosen and the questions they are posed.
- There are several limitations on the scope of the concept of minimal clinically important difference, related to how this threshold was determined and how it is used.
- If the detailed results of a trial or meta-analysis mention a threshold above which the effect observed is considered clinically important, this information is useful, but not sufficient. It is also necessary to critically analyse how the threshold was chosen and interpreted.

To what extent will this treatment reduce the pain, disability or other problems caused by my condition? These are the questions explicitly or implicitly posed by patients (1). When designing a clinical trial to answer questions of this type, investigators frequently use scores or numerical rating scales to quantify severity of symptoms, functional consequences, or other aspects of quality of life. When reading an article reporting the results of such a trial, it is useful to ask oneself how meaningful a change measured using these scores would be for patients (2-4).

For example, the International Prostate Symptom Score (IPSS), which ranges from 0 to 35, evaluates the severity of the symptoms experienced by patients with benign prostatic hyperplasia. In randomised trials, this score was on average 1 to 2 points lower with *finasteride* or *dutasteride* than with placebo (5). It is useful to think about whether such a difference is meaningful for the patients concerned, which is why readers of *Prescrire* and *Prescrire International* often encounter statements such as "*this difference is statistically significant, but of uncertain clinical relevance*".

The concept of minimal clinically important difference was defined in the late 1980s as "*the smallest difference in score in the domain of interest which patients perceive as beneficial*" (6). More generally, it is the smallest difference in score that patients consider to be tangible, whether in terms of clinical benefits or adverse effects (2,7-9). Minimal clinically important difference is a patient-centric concept, intended to reflect the importance patients attach to the change in a clinical endpoint quantified by a score (2,9).

How does one determine the threshold above which a difference is considered clinically important for patients? This article provides a simplified summary of the methods used to determine the minimal clinically important difference.