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Empowering regulatory science for medical devices in Europe

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Summary

From clinical and ethical perspectives, the need for scientific evidence establishing safety and efficacy of high-risk therapeutic medical devices, and for transparency of that evidence, is similar to new drugs—but requirements for devices and drugs have developed quite differently. The first European system for evaluating new devices applied a framework that had been developed for industrial products. Despite reforms the same flawed structure persists, as a fundamental obstacle to the uniform application of clinical standards, adherence to the principles of open science, and flexibility to respond to innovations. In this Viewpoint, we summarise how the regulatory system evolved and review how it needs to change, for the assessment and approval both of implantable devices and of laboratory diagnostic tests. There are too few clinically-qualified regulators within the EU governing institutions, so substantial investment is needed to boost scientific expertise within a central coordinating unit. Clinicians and scientists must support these changes by developing shared principles with regulators. Some colleagues within each medical specialty should develop expertise in 'regulatory science'.

Origins of regulations

Regulations for medicines and medical devices were developed mainly in response to crises.[1] The first legislation to control the safety of pharmaceutical products, in the United States of America (US), was precipitated by deaths from sulfanilamide syrup in 1937. The first European Economic Community directive was triggered by deaths and malformations caused by thalidomide between 1957 and 1962. Concerning medical devices, US legislation followed recommendations in 1970 from an expert group chaired by Theodore Cooper, intended to supplant an "unquestioning acceptance of claims for medical device safety and performance unsubstantiated or inadequately supported by scientific fact".

The exception is the European Union (EU) system for medical devices, which was neither

precipitated by a scandal nor designed after objective analysis; its development was prompted by requests to the European Commission from manufacturers' trade associations.[1] When the first medical device directive (MDD) was drafted in the late 1980s, a political decision was taken to apply the "New Approach" adopted by the Council of Ministers in 1985[2]; its purpose was unrelated to healthcare, but rather to deliver an effective internal common market by harmonizing standards for industrial products in different manufacturing sectors. Evaluation of evidence to demonstrate that products conformed with requirements was outsourced to independent inspection companies called notified bodies (NB). They still have a key role (Table 1).

With hindsight, insisting on the New Approach was a poor decision for high-risk medical devices, since unforeseen consequences persist as major limitations of the EU regulatory system. Notified bodies function as 'quasi-regulators'—they decide if devices should be approved, but as private organisations operating in a competitive marketplace they are not bound by EU requirements for public access to documents.[3] They can provide only limited advice to companies whose devices they assess, due to conflicts of interest inherent in their dual roles. Oversight of NB by national authorities was often inadequate. The fragmentary nature of the EU regulatory system and the absence of a scientific framework have created a gap in the evidence for high-risk medical devices between the US, which favoured experimental study designs, and the EU which has relied more on observational study designs.

Evolution of the EU regulatory system

The MDD rules were written deliberately in "rather abstract terms"[4], and manufacturers were left to decide what clinical studies were needed. Substantial concerns accumulated due to varying standards across NB, problems from some devices approved with insufficient evidence[5], and reports of serious complications or deaths from some high-risk implantable devices approved on claims of equivalence to existing devices but without new clinical investigations.[6] In 2008 the

European Commission initiated a public consultation to establish if there was a need to recast the MDD, which led after a protracted legislative process to their replacement in 2017 by the Medical Device Regulation (MDR)[7] and the In Vitro Diagnostic Medical Devices Regulation (IVDR).[8]

The MDR came into effect in 2021 with the laudable aim to promote higher standards of evidence for high-risk medical devices, but again there was only a nebulous requirement for 'clinical data providing sufficient clinical evidence' (MDR Article 61.1).[7] It was intended that scientific standards would be set by common specifications, but that provision has not been realised, possibly due to a lack of prioritisation and probably to limited regulatory capacity.[13] Compliance with common specifications for particular device types would be mandatory. Instead, many guidance documents on procedures have been issued by the MDCG (see Table 1), but adherence with their recommendations is voluntary, and variable interpretation between EU member states is a real possibility. Guidance on clinical methodologies for evaluating devices under the MDR is awaited. New high-risk devices (implantable and Class III) require 'clinical investigations' but the type of clinical evidence (e.g. whether from observational or experimental studies) is not defined.

The MDR was implemented after insufficient consideration also of its impact on the availability of devices. A large number of devices had to be recertified, and increased requirements for clinical evidence led to unpredictable and protracted conformity assessments.[10] Prolonged authorisation processes increased the costs of certification and resulted in manufacturers withdrawing some essential products from the market, including certain well-established technologies and devices for children.[11,12] The perception became widespread that the EU was no longer a favourable environment for innovation.[13] The Austrian National Public Health Institute (Gesundheit Österreich GmbH) is now monitoring the availability of medical devices, for the European Commission (https://health.ec.europa.eu/study-supporting-

monitoring-availability-medical-devices-eu-market_en).

The MDR and IVDR required the European Commission to report to the European Parliament within 5 years after full implementation of the legislation, but that scheduled review was brought forward after strong lobbying from industry and other stakeholders. A new draft Regulation was tabled by the European Commission in December 2025 (Proposal 2025/0404)[14], and it is now being considered by the European Parliament and Council, with impetus coming from political imperatives to deliver 'simplification' and support 'competitiveness'.[15] In his keynote speech to the High-Level Conference on "Medical Devices: Innovation and Patient Safety" that was organised by the Directorate-General for Health and Food Safety (DG SANTE) of the European Commission in Brussels on 16th March 2026, the Commissioner for Health Olivér Várhelyi stated that a major overhaul was absolutely necessary "without compromising on patient safety". How could that be achieved?

Priorities for medical devices

A regulatory science project, CORE–MD (Coordinating Research and Evidence for Medical Devices; www.core-md.eu) was funded by the EU Horizon Europe program from 2021 to 2024. Led by the European Society of Cardiology with the European Federation of National Associations of Orthopaedics and Traumatology, and supported by the Biomedical Alliance in Europe (www.biomedeurope.org), all stakeholders (including some national regulatory agencies and NB) contributed to an extensive review of the EU system. CORE–MD confirmed deficiencies in the availability of evidence for high-risk medical devices, a dearth of randomized trials, and a high risk of bias in many published studies.[16-18] It proposed a logical and progressive framework for observational clinical studies and controlled trials of medical devices, appropriate to each stage in their life-cycle.[19] In a separate publication it described alternative methodologies under the banner of "large simple trials", which encompasses variants such as registry trials and pragmatic

studies.[20]

The US Food & Drug Administration (FDA) and the European Medicines Agency (EMA) implement scientific approaches to support regulatory decision-making, whereas for medical devices the EU has emphasised interpretation of legal rules applied by a variety of organisations operating independently. Further reform should set standards for demonstrating clinical efficacy, when needed for high-risk therapeutic implants, while retaining the requirement for simpler devices that manufacturers should establish their safety and performance. Principles that should underpin reconsideration of the regulatory framework[21] are summarised in Figure 1. Clinical evidence for high-risk medical devices should be representative of women as well as men, and there should be equitable access to safe and effective technologies for all patients, including children[22] and patients with orphan indications.

Priorities for in vitro diagnostic medical devices

The IVDR largely copied the format and provisions of the MDR; this was recognised by the Director General of DG SANTE, Sandra Gallina, in closing remarks at the High-Level Conference. It suggests that there was insufficient expertise in medical laboratory science within the European Commission, and too little engagement with external advisors, when the legislation was drafted. The IVDR introduced a general classification of *in vitro* diagnostic medical devices **(**IVDs), from class A (low-risk) to class D (implying high public and individual risk), within a more logical and consistent framework. Genetic tests are largely in Class C, whereas previously many could be placed on the market through self-certification.

Article 5.5 of the IVDR introduced regulation of IVDs developed within health institutions [In-House IVDs; called laboratory-developed tests (LDTs) by the FDA]. They are needed for precision medicine[23]; >90% of all results transmitted to patients are from approved (CE-marked) IVDs, but >50% of all available IVD tests are IH-IVDs.[24] In-House IVDs are controlled by national

competent authorities, rather than NB; and differently from medical devices, national regulators allow evaluation and publication of their results before any transfer to the manufacturing sector.

When the IVDR was introduced, insufficient attention was paid to the need for special arrangements for laboratory tests used for rare or orphan indications, which discouraged innovation by the academic sector in favour of manufacturing monopolies.[25] There was little recognition that within laboratories the performance of diagnostic tests is already monitored effectively through external quality assessment (EQA). To exploit this monitoring of quality assurance through post-market surveillance of IVDs, there should be greater collaboration between EQA providers, industry, laboratories, and regulators.

A key priority for the latest revision of the IVDR should be to develop specific policies that are not derived from the MDR. In particular, relaxing restrictions to facilitate the sharing of IH-IVDs between healthcare institutions is essential to foster collaborative innovation and improve patients' access to advanced, personalised care. Equally essential is the abolition of IVDR Article 5.5d which forbids use of an IH-IVD if an 'equivalent' CE-IVD exists, because that prevents diagnostic innovation in favour of market monopolies.

Expanded roles for the European Medicines Agency

The impact assessment that was made by the European Commission in 2012 during preparation of the MDR and IVDR acknowledged that many medical respondents to their public consultation had argued in favour of a central agency for medical devices.[26] A clear majority of the larger number of respondents from industry did not support that policy, however, and it was not adopted. Nonetheless, the MDR established a mechanism for clinicians to be appointed to Expert Panels (EP) managed and supported by the EMA, for them to provide independent, non-binding opinions on selected decisions by NB. The Screening Panel has judged that ~10% of submissions for high-risk devices require a full scientific opinion from a Thematic EP; 16 have

been published, the majority identifying deficiencies in clinical evidence.[27] Despite this, all reviewed devices were granted market access, so there is a pressing need for clarity and transparency on how NBs act on EP recommendations. A recent analysis of 34 opinions (including some that have not yet been published) again reported that the challenges most frequently identified by the experts (in 48% of their comments) concerned the sufficiency of clinical evidence supporting benefit–risk determinations.[28]

The IVD EP needs to be reinforced, with the appointment of optimally selected diagnostic experts, and with its remit expanded beyond category D tests. The majority of innovative precision diagnostic tests are genetic, so they belong to category C, but currently those IVDs do not qualify for evaluation by the EP.

The new draft regulation does not envision the EMA becoming a single European regulator of devices, but it has been proposed that it should acquire a coordinating function among national authorities for classification, derogations, multinational clinical investigations, vigilance, and market surveillance.[14] The roles of EP will expand to provide scientific advice to the European Commission, member states, NB, and manufacturers. The EP will contribute to the development of guidance, common specifications, and standards, at EU or international level. They will designate breakthrough status for certain new devices, and orphan status for devices intended for rare indications or paediatric use, and they will give tailored advice on clinical investigations. Members of the EP should therefore have experience of clinical research and be provided with training in regulatory science.[29]

We welcome these proposals for the EMA to take on new roles, but delivery of significant reform will be impossible without major investment. There is an urgent need for more scientific and engineering expertise and regulatory capacity within the European Commission and its agencies. The unit in the European Commission that is responsible for coordinating delivery of

the MDR and IVDR is too small, with only one medically qualified officer. In contrast, in 2025 the NB had 3,358 full-time equivalent employees engaged in conformity assessment procedures[30] including an estimated 1000 with clinical experience, but these assessors in the NB do not collaborate with the MDCG to prepare guidance on clinical evidence requirements.

Regulatory science as an academic and clinical subspecialty

Definitions of 'regulatory science' fall into two main categories—the view (often propounded by regulators) that it is the application of sound scientific methodologies to evaluate drugs and devices and diagnostic tests (which just means good-quality research), and the alternative concept (which we endorse) that it is the use of scientific approaches to determine which regulatory policies and standards best assure safety and efficacy and can lead to technologies being approved that will improve both individual clinical outcomes and public health, without disproportionate over-regulation.

Regulatory frameworks are increasing in complexity, and EU regulators need active support from clinicians, laboratory scientists, epidemiologists, statisticians, and engineers—at the EMA, where membership of the EP is being renewed (https://health.ec.europa.eu/medical-devices-expert-panels_en), and in NB. Expertise in regulatory science should be a subspecialty interest for some colleagues in each medical field. Members of European medical associations should assist regulators with the development of evidence standards and common specifications, and they should provide high-quality evidence from comprehensive medical device registries.

How can fundamental change be delivered?

Insights from the CORE–MD project influenced consensus recommendations submitted to the European Commission by the Biomedical Alliance in Europe on behalf of 35 medical professional associations.[21] The draft EU regulation will establish special regulatory pathways for

orphan medical devices and breakthrough products, and new revisions relating to In-House IVDs, but some other proposals cause concern—such as easing conditions to establish equivalence of devices as a means to obtain CE-marking. CORE-MD advised that a new high-risk implantable device should not be permitted to enter an existing class without a randomised trial against an active comparator, or evidence from objective performance criteria[19]; otherwise the new device may perform worse than existing alternatives. Under the MDD, major problems occurred with some high-risk devices that had been approved on the basis of equivalence[6], so that lesson should not be unlearned. The draft regulation also seeks to delete the standard of "clinical data providing sufficient clinical evidence", which raises the uncomfortable prospect of more subjectivity rather than consistency.

The EU system needs to shift its orientation to creating policies based on scientific evidence, to give it the best chance to break free from recurrent revisions to the legislation. Research in regulatory science, and engagement by professional associations whether independently or in a concerted fashion with the Biomedical Alliance, should be supported by public funding. At the EMA, the functions and operation of its Healthcare Professionals Working Party (HCPWP) should be reviewed, so that stakeholders can contribute fully to its new roles.

Equivalent standards should be applied by national authorities around the world, so we support initiatives to promote mutual reliance and regulatory convergence that are being developed by the International Medical Device Regulators Forum and the Global Harmonization Working Party.

Contributors

AGF wrote the first draft. All the authors contributed to preparatory discussions and revised and edited the text.

Data sharing statement

No new data were created for this manuscript.

Declaration of interests:

AGF was Scientific Coordinator of the CORE–MD project, and he is a past-chair of the Regulatory Affairs Committee of the Biomedical Alliance in Europe.

RAB does not accept direct or personal payments from medical device or pharmaceutical industry, He reports research/educational funding to the institutions of employment from Abbott Vascular, Boston Scientific, Teleflex and Terumo without impact on personal remuneration.

EMCD chairs the In Vitro Diagnostic Devices Task Force at the Biomedical Alliance in Europe, from the European Society of Human Genetics.

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TM reports institutional payment from EU Horizon 2020 to his previous employer HPRA, the Irish regulatory authority, for the CORE–MD project. He declares past institutional funding from the EU4health programme for the DeCODe (Developing Child and Orphan Device) Project, and from the EU Horizon Europe / Innovative Health Initiative for HEU-EFS (Harmonised European Union Early Feasibility Study) and for GREG (Guidelines for Real World Evidence Generation). He chaired the Regulatory Affairs Committee, Biomedical Alliance in Europe.

PKA, RGHHN, and TM are members of Expert Panels for medical devices at the EMA.

PS is chair of the Regulatory Affairs Committee of the European Society of Cardiology, and co-chair of the Healthcare Professionals Working Party of the EMA.

EM has received honoraria for regulatory science education from Thermofisher, donated to the Biomedical Alliance. She chairs the Regulatory Affairs Committee and is past-President of the Biomedical Alliance in Europe.

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Legend to Figure

Figure 1: **Principles for an ideal regulatory system**.

Adapted with permission from recommendations of the Biomedical Alliance in Europe, submitted to the European Commission in 2025.[21]

Table 1: Roles of regulatory actors for medical devices in the European Union

Body	**Responsibilities**
European Commission	Unit D3 in the Directorate-General for Health and Food Safety (DG SANTE) proposes and oversees the legislative framework for medical devices and in vitro diagnostics (IVDs) in the EU. It adopts implementing acts, manages transition periods, and coordinates central infrastructure such as EUDAMED (the European database on medical devices).
Medical Device Coordination Group (MDCG)	Statutory committee co-chaired by the European Commission and a member state, composed of representatives from all Member States. It prepares and endorses guidance documents to ensure the harmonised interpretation and implementation across the EU of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR), with support from 13 working groups. Approved stakeholders including the Biomedical Alliance in Europe attend open sessions.
National Competent Authorities (NCA)	Governmental regulatory agencies within individual Member States, responsible for designating and auditing Notified Bodies, authorising clinical investigations, and conducting post-market surveillance and vigilance. They collaborate at the European level via the MDCG and the Competent Authorities for Medical Devices (CAMD) network.
Notified Bodies (NB)	Independent, private third-party organisations designated by a Member State's NCA. Manufacturers must submit applications for certain low-risk (Class I devices with a sterile, measuring or reusable component), and all medium-risk (Class II), and high-risk (Class III) devices to these bodies, and for all IVDs except for those in category A (non-sterile). NB review technical documentation, quality management systems, and clinical evaluation reports, and grant the certificates of conformity required for CE-marking and market access.
European Medicines Agency (EMA)	The mandate of the EMA was expanded by the MDR. The Expert Panels and Groups Office (based in the Committees and Quality Assurance Department of the Human Medicines Division) provides administrative, technical, and scientific support to the medical device Expert Panels.
Expert Panels (EP)	Composed of independent clinical, scientific, and technical experts appointed by the EMA to conduct CECPs (Clinical Evaluation Consultation Procedures), providing scientific opinions to Notified Bodies regarding their clinical evaluation of certain high-risk medical devices. A similar scheme for class D IVDs is called the PECP (Performance Evaluation Consultation Procedure). Expert panels also provide tailored scientific advice, upon request, to manufacturers and the European Commission.
Competent Authorities for Medical Devices (CAMD)	This umbrella group of EU competent authorities functions as an informal network to facilitate collaborative projects, communication, and surveillance of medical devices, between the national regulatory agencies across Europe.