The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

Statement on medical devices and in-vitro diagnostics regulations

The Standing Committee of European Doctors (CPME) welcomes the opportunity to provide input to the ongoing targeted evaluation of the EU rules on medical devices and vitro diagnostics.

CPME believes that having high quality standards for medical devices is essential to ensure patient safety. All necessary efforts should be made to ensure that access to medical devices is guaranteed in all member states, leaving no one behind.

European doctors remain supportive of the objectives of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR) to ensure rigorous pre-market assessment and market surveillance to increase patient safety. We note that there has been some progress on traceability of devices, however, it can still be developed further. In this regard, any future revision of the current regulatory framework needs to ensure that EUDAMED is fully operational. We also reiterate the need to prevent future disruptions in the availability of medical devices to safeguard patient care. This applies, for example, to the small but particularly vulnerable patient group of infants and young children, for whom there have repeatedly been dramatic shortages in the supply of sometimes vital medical devices.

Certification of medical devices reassures doctors that these devices are safe for use, therefore standards must not be downgraded. EU legislation and regulations (e.g. for AI, Per- and polyfluoroalkyl substances – PFAS, etc.) which also affect medical devices should be kept in mind when the MDR and IVDR are evaluated and considerations are made as to whether further regulation is indicated.

We stress that it could be worth simplifying requirements for all low-risk devices, but that must be done without compromising patient safety.

Regarding key areas for certification for doctors for AI products, the certification of AI-driven software solutions is essential and should, at least, address cybersecurity, data privacy, efficiency and workflow integration, interoperability, explainability, model robustness, bias mitigation, and legal liability. This is even more important in the context of emerging technological (including digital) and scientific progress in the medical devices field and the growing interplay between medical devices and artificial intelligence legislations[1].

[1] For further details please refer to the CPME policy on Deployment of artificial intelligence in healthcare

In a broader perspective, centralisation of the system management functions to the European Medicines Agency (EMA) would ensure greater coordination[2]. The agency should go beyond medicines and take a more active role on medical devices to offer scientific, technical and administrative support. EMA medical devices expert panels should contribute to stronger post-market surveillance activities on medical devices, especially for high-risk medical devices A future revision of the regulatory framework on medical devices and in-vitro diagnostics should provide EMA with the necessary responsibilities and resources to ensure an appropriate implementation of the legislation, to streamline processes and avoid duplication of work.

It is important that data submitted during the registration of medical devices is formulated in a consistent manner and is openly accessible. This enables doctors and guideline developers to effectively utilise this information. In particular, we emphasise that post-marketing research on high-risk medical devices is essential for continuously monitoring the safety and effectiveness of these devices.

Safety is not just about indicating that a medical device complies with law. Manufacturers should not only disclose to the national competent authorities the data submitted for the conformity assessment, but also need to submit data on clinical effectiveness of devices[3]. We call on the European Commission to put in place strong obligations for manufacturers to submit all necessary data/evidence when requesting certification of a new medical device or in-vitro diagnosticsWe also acknowledge the threats to the future availability of orphan medical devices and note industry's call for specific incentives; however, when considering incentives for orphan devices, the Commission should keep in mind the risk of artificial "orphanisation" of conditions which has been a strategy by the pharmaceutical industry to benefit from the incentives for orphan drugs. To prevent this, any incentives to certain types of medical devices should not be of financial nature, or involve regulatory data protection. Procedural facilitations could be considered provided that they do not compromise patient safety.

When considering which categories of medical devices should be incentivised, their categorisation should be based, to the greatest possible extent, on objectively verifiable criteria. How "innovative" a medical device is perceived to be during its development stage is largely influenced by subjective expectations.

If binding timelines for conformity assessments are introduced, any failure by notified bodies to comply with such timelines should not result in tacit authorization. Such outcome would be unacceptable as it would be detrimental to patient safety.

[2] A joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on necessary reforms in MDR and IVDR: priorities / main point calls for promotion of EMA involvement, presented at the EPSCO (Health) of 3 December 2024, available at: https://data.consilium.europa.eu/doc/document/ST-15380-2024-INIT/en/pdf, last accessed on 14 February 2025.

[3] Hulstaert, F., Pouppez, C., Primus-de Jong, C., Harkin, K., & Neyt, M. (2023). Gaps in the evidence underpinning high-risk medical devices in Europe at market entry, and potential solutions. *Orphanet Journal of Rare Diseases*, *18*(1), 212., available at: https://link.springer.com/article/10.1186/s13023-023-02801-7, last accessed on 30 January 2025.

We stress the need for long-term solutions that address the inadequate implementation of the new medical device and in-vitro diagnostics regulations and notified bodies capacity, to ensure that patient safety is preserved. In this context, notified bodies should invest in digitalisation and use AI for their benefit when assessing requests from manufacturers for certification of new medical or in vitro diagnostics. EMA could support the development of guidelines to harmonise these processes that could be applied by all notified bodies.

However, while digitalisation offers opportunities to enhance information delivered to patients or healthcare professionals, we strongly believe that the electronic product information should never replace the paper version to medical devices intended for patients, but remain complementary.

Finally, sustainability in the medical devices sector should be better integrated into the MDR and IVDR[4]. Given the growing attention to sustainability among doctors in Europe, we underline that incorporating sustainability into the design and use of medical devices is not only relevant from an environmental perspective but also offers opportunities to stimulate cost-effectiveness and innovation in a sustainable manner, without compromising patient safety.

[4] *Towards sustainable devices in healthcare*, Health Council of The Netherlands, 2022, available at: https://www.healthcouncil.nl/binaries/healthcouncil/documenten/advisory-reports/2022/09/13/towards-sustainable-devices-in-healthcare/Towards-sustainable-devices-in-healthcare.pdf, last accessed on 19 March 2025.