Ref. Ares(2024)8905137 - 12/12/2024

European Commission

CALL FOR EVIDENCE
FOR AN EVALUATION

This document aims to inform the public and stakeholders about the Commission's work, so they can provide feedback and participate effectively in consultation activities.

We ask these groups to provide views on the Commission's understanding of the problem and possible solutions and to share any relevant information that they may have.

TITLE OF THE EVALUATION	EU rules on medical devices and in vitro diagnostics – targeted evaluation
LEAD DG – RESPONSIBLE UNIT	DG SANTE – Unit.D3 (medical devices)
INDICATIVE TIMETABLE (PLANNED START DATE AND COMPLETION DATE)	Q1 2024 – Q4 2025
ADDITIONAL INFORMATION	https://health.ec.europa.eu/medical-devices-sector_en

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the document, including its timing, are subject to change.

A. Political context, purpose and scope of the evaluation

Political context

Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) were adopted in 2017. The Regulations aim to ensure that only safe and effective devices are on the EU market, to protect patient safety and public health while supporting innovation. The Regulations aim to create a robust, transparent and sustainable legal framework, further aligned with international practices, which improves clinical safety and fair market access for manufacturers.

Considering the extent of the changes introduced by the Regulations, transition periods were envisaged to ensure a smooth transition to the new rules. These transition periods continue to apply and due to some challenges, have been extended.

In view of the significant challenges encountered in transitioning to the new rules, while Articles 121 MDR and 111 IVDR require the Commission to conduct an evaluation by May 2027, the Commission has decided to launch a targeted evaluation of the Regulations in 2024.

Purpose and scope

In line with the evaluation criteria set out in the Commission's Better Regulation guidelines, the evaluation will assess the effectiveness, efficiency, relevance, coherence and EU added value of the Regulations. The evaluation will also set out the areas where the Regulations have not yet been fully implemented and will cover the extent to which the provisions have been implemented.

The evaluation aims to assess the performance of the legislation. Focus will be put on the impact of the legislation on the availability of devices, including 'orphan devices' and devices for small populations, as well as the development of innovative devices in the EU. Due consideration will be given to costs and administrative burdens, especially for SMEs, as well as the benefits arising from the implementation of the legislation. The evaluation will also explore the potential for simplification and will assess the coherence of the Regulations with other EU legislation, in particular legislation on environmental and digital policy.

In terms of geographical scope, the evaluation will cover the implementation of the Regulations in all EU Member States and other relevant European Economic Area (EEA) and non-EEA countries, the latter concerning primarily relevant activities within the International Medical Device Regulators Forum (IMDRF) and activities carried out based on bilateral agreements and their impacts on safety, availability and trade. The evaluation will cover the period between the adoption of the legislation (5 April 2017) and 31 December 2024, for the areas that are already being implemented. The evaluation will also assess whether the objectives of the Regulations can be achieved by the end of the extended transition periods taking into account the current regulatory framework and the ways of implementing it.

B. Better regulation

Consultation strategy

Through various consultation activities, the Commission aims to map the phases of the implementation of the Regulations that have already occurred. It also aims to assess the extent to which the objectives of the Regulations have been met in an effective and efficient way, whether it can address current and future needs and whether it is coherent with the objectives of EU health policy and other policies.

The consultation strategy aims to ensure that all stakeholders concerned will have an opportunity to express their views and share evidence on the implementation of the Regulations.

The consultation process will include the following actions.

- A call for evidence for interested parties to provide feedback in any of the 24 official EU languages.
- A 12-week questionnaire-based public consultation giving interested parties the possibility to contribute to the evaluation in any of the 24 official EU languages (available on the Commission's 'Have your say portal).
- A set of targeted consultation activities tailored to particular stakeholder's groups, including workshops.
- Consultations of the Medical Device Coordination Group in order to complement the consultation process.
- A stakeholder conference will take place during the evaluation to further complement the process.
- Particular focus will be put on SMEs involvement and specific ways to further reach out to them are being explored.

In line with the Commission's better regulation policy to evaluate policies, we invite scientific researchers as well as academic organisations, learned societies, and scientific associations with expertise in medical devices to submit relevant published and pre-print scientific research, analyses and data. We also invite EU Member States and relevant stakeholders to submit position papers.

All input received from stakeholders will be taken into account during the evaluation exercise. A synopsis report covering all consultation activities will accompany the evaluation report (Commission staff working document). A factual summary report on the replies to the public consultation will be published on the Commission's consultation page once the public consultation has been closed.

Why we are consulting?

The objective of the public consultation is to gather feedback on the effectiveness, efficiency, relevance, coherence and EU added value of the Regulations on medical devices from 2017 to 2024. For that purpose, the consultation will seek to collect evidence and data from relevant stakeholders.

Target audience

The main stakeholder groups identified include:

- EU Member States/EEA' competent authorities responsible for medical devices;
- independent third-party bodies that assess the conformity of medical devices with relevant safety requirements ('notified bodies');
- economic operators and associations representing them having activities in medical devices in the EU;
- healthcare professionals and associations representing them having activities in the EU;
- the general public , as well as patients and consumers, and associations representing them having activities in the EU;
- civil society organisations active in medical devices;
- independent experts from academic and research institutes active in medical devices;
- regulatory affairs experts, associations and companies active in medical devices;
- European bodies, including the European Medicines Agency;
- international intergovernmental organisations and other international associations active in medical devices;
- Non-EU/EEA countries.

Data collection and methodology

The evaluation will use evidence obtained through stakeholder's consultation, literature review, annual reports of national competent authorities and relevant studies. It will analyse the:

- impact assessment on the revision of the regulatory framework for medical devices;
- outcomes of and raw data collected within several ongoing studies such as the study on 'regulatory governance and innovation in the field of medical devices' or the study supporting the monitoring of availability of medical devices on the EU market[1];
- Member States annual reports, notably on the monitoring of notified bodies and on market surveillance activities;
- data gathered and shared in the Medical Device Coordination Group;
- academic reports, scientific opinions and recommendations;
- position papers, surveys and workshops performed and evidence provided by various stakeholders, including business associations, healthcare professional organisations and patient associations;
- case law of the Court of Justice of the European Union, complaints, NGO reports and Eurobarometer surveys;
- outcome of discussions in conferences and events organised by various stakeholders.

Additional sources of information may be identified during the evaluation, particularly any evidence on the availability of devices (including orphan and innovative devices) and on the costs and benefits of the Regulations, including the potential for simplification and burden reduction, will be sought.

The analysis will use a combination of quantitative and qualitative methods.

[1] Both listed studies are funded by the EU4Health programme in its 2022 Work programme (reference to activities: (HS-p-22-19.04, 06, 07, 08, 09, 10 and 11)).