Future governance of medical technologies in Europe

Joint discussion paper of

MedTech Europe
from diagnosis to cure

AESGP

COCIR
Advancing Healthcare

eurom

EAAR European Association of Authorised Representatives

FIDE
European Dental Industry

DISCUSSION PAPER

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Executive summary

In this joint discussion paper, the European medical technology industry, represented by MedTech Europe, AESGP, COCIR, EEAR, EUROM and FIDE, makes the case for a reform of the European regulatory system for medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs).

The paper highlights shortcomings in the current multilayered governance system, which affect the efficiency of the CE marking process, leading to delays in device availability for patients and healthcare systems as well as challenges to the competitiveness of the medical technology sector in Europe. To address these issues, the paper proposes centralising key tasks and describes specific roles and responsibilities for a future centralised governance structure aimed at improving efficiency and effectiveness.

The document emphasizes the importance of first establishing the key guiding principles, determining the appropriate level of empowerment, and defining the roles and responsibilities that a central structure should assume. Once these foundational elements are in place, a detailed impact assessment can be carried out to define the optimal setup and functioning of the central structure.

This discussion paper is meant to facilitate and stimulate exchanges with all involved stakeholders.

Why is a reform of the governance system needed?

Eight years into the EU Regulations for medical devices and *in vitro* diagnostics (MDR/IVDR), structural challenges regarding the governance system have become apparent. These challenges relate to a lack of clear accountability, transparency, and involvement of stakeholders. Moreover, the governance system misses a 'captain of the ship' who has the explicit responsibility and accountability for ensuring the timely availability of legacy and innovative MDs and IVDs to patients and health systems. Without the leadership of an empowered central structure, there is no mechanism to course-correct shortcomings or to promote the EU regulatory system globally.
This structural weakness has a concrete impact on the practical implementation of the legal frameworks. It creates diverging and unpredictable practices and fragmentation and thus leads to inefficiencies, high costs and delays in bringing medical technologies on the market in Europe. This situation needs to be addressed urgently in order to restore Europe's attractiveness and competitiveness for medical technologies.

The primary and ultimate goal of the European regulatory systems should be to make a broad range of safe and performing existing and innovative MDs and IVDs promptly available to patients, health care professionals and health systems, taking into account the medical needs of today and the future. The governance system should be designed to fully support this objective in the most efficient, predictable and transparent way possible and with a mind-set that promotes innovation and innovation ecosystems for developers of medical technology solutions in Europe.

In order to deliver on the goals of the MDR and IVDR - i.e., ensure predictability, transparency, efficiency, patient safety and foster innovation - Europe needs an accountable, dedicated central governance structure that has the mandate to take system-level decisions, manage the decentralised network of Notified Bodies and represent the EU globally at international fora, among other roles.

The medical technology industry proposes that the governance of the MDR and IVDR should evolve based on the following principles:

1. Key tasks and responsibilities should be centralised under a new single structure. This new central governance structure should be patient-centric. Its core priority should be to ensure the timely availability of safe and performing devices for patients, healthcare professionals and health systems as well as to strengthen the innovation capacity and the competitiveness of the medical technology sector.

2. The central governance structure should be accountable for the smooth functioning of the MDR and IVDR regulatory systems. In this respect, it should ensure transparent and predictable procedures and the alignment and coherence with other horizontal EU legislation applicable to the medical technology sector.

3. The decentralised Notified Body system is still needed and should remain a core pillar of the future regulatory system. The new central structure should improve time, costs and predictability of Notified Body services.

4. An empowered mandate, mission and vision, well defined roles and responsibilities, and an appropriate expertise for the broad range of MDs and IVDs are indispensable for a well-functioning new future central governance structure. As long as the governance structure is adequately resourced and can deliver on its mandate and responsibilities and, it is secondary, where exactly that central structure is institutionally set up.

5. An impact assessment regarding the main organizational options should be conducted with the aim of selecting one in which a new central structure can:
   a) *deliver on its mandate and responsibilities, ensuring the fulfilment of the objectives of the IVDR and MDR including a sustainable, robust regulatory system which promotes innovation while ensuring a high level of patient safety;*
   b) ***has sufficient budget and empowerment to carry out its mission;***
   c) *be sufficiently staffed to carry out its mission with expertise and experience specific to each MDs and IVDs;*
   d) *ensure predictable and transparent processes, and reduce complexity, administrative burden and ultimately costs for innovative devices, as well as for devices and Quality Management Systems already certified under the medical devices and IVD legislation;*
   e) *provide for early and continuous dialogue, collaboration and feedback between economic operators, regulators and Notified Bodies;*
   f) *be time and cost effective and overall decreasing time and costs of managing the regulatory system and certifying of devices.*

1. Challenges in current governance

1.1. Multiple layers

Today, the regulatory system for MDs and IVDs is overseen and implemented by a number of different actors with overlapping or unclear roles and responsibilities. There is a lack of distinct accountability for the smooth functioning of the regulatory system, for ensuring the timely availability of safe and performing new and existing devices for patients and healthcare systems, and for promoting the competitiveness of the European medical technology sector globally:

- European Commission D3 unit for Medical Devices – Unit D3 chairs the Medical Devices Coordination Group (MDCG) and acts as its secretariat. It facilitates the Committee on Medical Devices and liaises with other units within the European Commission including those responsible for pharmaceuticals, environmental matters, artificial intelligence and so on. The unit also initiates and coordinates projects to support the smooth implementation of the regulatory system, for example through HORIZON and other EU project funding streams. Finally, it represents the EU jointly with MDCG International at external fora such as the International Medical Device Regulators Forum (IMDRF). It is fair to say, that today the D3 unit is significantly understaffed for these extensive roles and responsibilities.

- Medical Devices Coordination Group[1] – the MDCG's role is to harmonise MDR/IVDR implementation and administrative practices via guidance documents and contribute to development of standards and Common Specifications. It should also assist the national Competent Authorities (CAs) with coordination activities and to provide general MDR/IVDR implementation advice to the actors of the system. The MDCG is comprised of national experts of all EU Member States and works via a number of working groups and task forces in which the Member States experts participate.

- National Competent Authorities (CAs) – the role of CAs is to ensure that medical devices placed on the European market are safe and performing. Their main responsibilities encompass market surveillance, enforcement, vigilance and Notified Body oversight and in some cases designation. National Competent authorities also gather as CAMD (Competent Authorities for Medical Devices), to facilitate cooperation and coordination on MDR/IVDR topics. It should be noted that in some Member States the CA might be separate from the authority that carries out oversight/market surveillance – e.g. in Germany.

  Designating Authorities – some Member States have designating authorities separate to CAs which are responsible for the designation of Notified Bodies at national level, while some do not. The key role of designating authorities is to ensure that Notified Bodies have the adequate expertise and meet the necessary standards to assess the conformity of medical devices before those can be placed on the EU market. Designating authorities gather as NBO (Notified Body Oversight).

[1] MDCG role is detailed in MDR Art.105/IVDR Art.99

- Notified Body Coordination Group (NBCG-Med) – the NBCG-Med is composed of representatives from Notified Bodies and its work is overseen by the European Commission. The NBCG Med's role is to promote consistent and harmonized practices among Notified Bodies (NBs) across the EU. Its activities also include monitoring the performance of NBs.

- Expert panels – they have a role in the 'Clinical evaluation consultation procedure' (CECP) and the 'Performance evaluation consultation procedure' (PECP) for certain high-risk MDs and IVDs and offer voluntary scientific advice to manufacturers for specific device categories. Furthermore, they provide scientific, technical and clinical assistance to the Commission and the MDCG, contribute to the development and maintenance of guidance and CS and contribute to the development of standards at international level. Expert panels provide opinions, which are not legally binding, but need to be taken into consideration by Notified Bodies. Expert panels are comprised by experts from EU Member States and are hosted and coordinated by the European Medicines Agency.

- Joint Research Centre (JRC) – the JRC is the European Commission's science and knowledge service, which supports the implementation of the MDR/IVDR by providing scientific and technical support. They coordinate the selection procedure for EU reference laboratories.

- EU reference laboratories – these laboratories provide scientific and technical expertise to support IVDR implementation by e.g. performing specialized tests, verifying methodologies and evaluation of class D IVDs.

- European Medicines Agency (EMA) & national medicines authorities – these actors are involved in the medical technologies regulatory system through certain consultation procedures, such as under MDR per Annex VIII Rule 14 (devices incorporating medicinal substances) or Rule 21 (substances or combinations of substances). EMA also hosts and coordinates the expert panels amongst other responsibilities.

1.2. Inconsistent and fragmented action

Today's multilayered governance system comes with a lack of clarity regarding roles and responsibilities, for example for regulatory decisions, and for bringing innovative devices which address unmet needs on to the EU market. The fragmentation within the governance system and the lack of one single player responsible and accountable for ensuring that safe and performing products reach patients in a timely manner, demonstrates the need for a single, accountable structure that takes ownership of the regulatory system.

For example, some Member States did or did not allow derogation under MDCG 2022-18 on application of Article 97 to legacy devices – this created an unlevel playing field across the EU. In another case, during the COVID-19 emergency, national Competent Authorities took different approaches as to whether the Notified Bodies could audit devices remotely or not. That situation led to delays in patients' access to devices as in some Member States the certification was blocked, while in others the process could continue remotely.

2. Which aspects of governance should be centralised?

The regulatory system for medical technologies should be designed in a way that is patient-centric, efficient, fosters innovation and meets the MDR and IVDR objectives as laid down in their preambles 1 and 2. In order to realise these goals, it is needed that certain roles and responsibilities of the governance of the system become **centralised under a single structure at EU level that ends the splitting of tasks across different players**.

All roles and responsibilities of a new central governance structure outlined below need to be laid down by law and adequately resourced.

1. **Accountability & Empowerment**

The central governance structure needs to be designed:

- **as an empowered authority with a mandate, mission and vision to set a strategy and take decisions for the entire medical technology sector in the EU;**
- as being responsible **for the functioning of the European market for all medical technologies** and accountable to the European institutions. The European institutions should regularly evaluate the performance of the central structure, based on Key Performance Indicators (KPIs) outlined in an agreed and transparent plan;
- as being responsible for **ensuring the timely availability of safe and performing medical technologies and for strengthening the innovation capacity and global competitiveness of the medical technology sector. The central structure would be the external 'face' of the EU medical technology sector in international fora.** It needs to have an overview of significant market factors at EU and global level and to take a pro-active approach in fostering the competitiveness of the sector and whilst mitigating arising challenges caused by global developments. For instance, it would help to solve disruptions in supply chains or a temporary unavailability of certain materials, similarly to recent FDA initiatives to streamline regulatory pathways for changes in sterilisation methodologies[2];
- to include a **Management Board consisting of political representatives of Member States and Stakeholders** that oversee the work;
- **industry representatives, including SMEs, and Notified Bodies should be part of the Management Board** in parity with patient and healthcare professional groups. The Board will identify needs for possible adaptation and improvements of the regulatory systems. It will also establish the work plan for the central structure together with KPIs and an adequate budget;
- with a clear framework for **a structured dialogue between manufacturers and Notified Bodies**. It should be codified that the dialogue can start long before the submission of an application for a conformity assessment to allow for discussion on clinical strategy and can continue throughout the whole conformity assessment process, without compromising Notified Body's independence.

[2] https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

2. International alignment and coherence within EU legislation

The central governance structure needs to be designed:

- to promote and ensure coherence between the MDR/IVDR and other horizontal EU legislation applicable to devices, such as digital, product, sustainability, or chemicals EU legislation. This should be achieved through
    - sufficient, dedicated expertise and resources to monitor, identify and resolve inconsistencies or overlaps between horizontal EU legislation and the vertical MDR/IVDR;
    - a dedicated department and determined processes for alignment with legislators of horizontal rules impacting medical technologies;
    - the provision of opinions on any new EU legislation to ensure that requirements are fit for medical technologies (i.e. avoid contradictions and overlaps). Those opinions need to be taken into account and to be justified if rejected (regulatory scrutiny board, recommending body);
- to promote reliance on regulatory decisions in other major jurisdictions compatible with CE marking;
- to take a leading and proactive role at international organisations (e.g. IMDRF, ISO) and drive initiatives, such as international standards development or digitalization.

3. Notified Body system oversight & harmonization

The central governance structure needs to be responsible for:

- **designating Notified Bodies (NBs)** in order to enhance consistency and time efficiency of the process;
- establishing and maintaining a **plan for the continuous monitoring and assessment of NBs** to ensure the efficient and effective functioning of the NB system. This plan should include KPIs for NB performance, costs, and timelines of the end-to-end certification process. It will help identify and address inefficiencies. The KPIs as well as data collected from this exercise should be **fully transparent and publicly available;**
- establishing a **clock-stop mechanism** for the product certification process with clearly defined timelines;
- driving efficiency by eliminating bureaucracy and duplication in the regulatory system; in particular digitizing the data exchange between stakeholders;
- establishing clear and transparent provisions for NBs to ensure alignment across the EU, in particular on procedures, timelines and fee structures, including maximum time and fee levels (those should be based on a 'fee per procedure/code' principle rather than on a 'fee per hour/report/question' principle); all of those should be made publicly available.

4. Appeal possibility & resolution of disputes

The central governance structure needs to be designed:

- to have the final say regarding the interpretation of guidance documents and any related disputes; the guidance interpretation has to be transparent and be made publicly available;
- to provide a formal appeal system for NB and Member State decisions (e.g. classification decisions); decisions have to be made publicly available;

- to set up exchange groups discussions for informal dispute resolution options between involved actors, as needed;
- to take on other related tasks, e.g. grant exceptions regarding the application of the UDI-system and EUDAMED.

5. Dedicated pathways

The central governance structure needs to be responsible for:

- establishing dedicated pathways for EU-wide (rather than national) derogations, reliance on regulatory decisions of other countries, course corrections and emergencies, innovation, unmet medical needs and orphan devices, etc;
- **it needs to be highlighted that the actual provision of conformity assessments and certifications of medical technologies shall stay with NBs, as they have the needed specific expertise.**

6. Guidance development & harmonized application

The central governance structure needs to be responsible for:

- drafting and ensuring the timely adoption of documents for regulatory implementation; these documents should be user- and in particular SME-friendly;
- establishing a priority list regarding needed guidance documents. Stakeholders should give input on this list;
- prioritising the use of existing international standards or international guidance over the development of new EU standards or guidance. Where the international standard or guidance already exists, EU guidance should only cover additional (European) aspects;
- pursuing a compliance check for any new EU guidance to ensure alignment with other existing EU legislation
- issuing guidance with a risk based approach as inherent in the MDR/IVDR;
- ensuring alignment and consistency with already published guidance documents;
- ensuring a **harmonized** application of guidance, standards or common specifications that support the implementation of the IVDR and MDR;
- defining clear responsibilities and timelines for the implementation of new legal requirements and guidance;
- taking decisions by **qualified majority**; **which are binding** and need to be implemented by all parties, also those who abstained or voted negatively.

7. Stakeholder engagement

The central governance structure needs to be responsible for:

- **establishing and ensuring a mandatory early and meaningful involvement of stakeholders as a standard practice for every guidance development.** It will help to assess potential impacts on the market and for patients and make the guidance fit for purpose;
- ensuring a **harmonized, and consistent stakeholder involvement in all working groups and sub-bodies of the future central structure**. For example, all official stakeholders should be

provided with the comments, responses and related conclusions from all stakeholder consultations;
- defining a formalized **review process for stakeholder consultations**, for instance such as at ISO level[3], **with reasonable timelines** that allow for sufficient and realistic time for internal information gathering within companies.

8. Innovation capacity and competitiveness of the medical technologies sector

The central governance structure needs to be designed:
- for **leading and actively promoting the competitiveness of the medical technology sector and the attractiveness of the European market for medical technologies** whilst ensuring the safety and performance of the devices; it should put in place dedicated initiatives and projects that support innovation, foster investment in Europe and increase the competitiveness of the EU. This will benefit patients, health professionals and health systems in Europe and beyond;
- to **operate an early warning mechanism** that identifies potential challenges impacting the competitiveness and innovation in the EU and to take mitigating actions;
- to continuously assess the regulatory system for MDs and IVDs to ensure the availability of devices and the proportionality of requirements whilst technologies evolve; e.g. it should adapt the rules for technologies that have become well-established.

Conclusion

Governance is a fundamental pillar of the MDR and IVDR. It must be designed in a way that ensures an efficient, patient-centric and innovation-friendly functioning of the two Regulations.

In recent years critical weaknesses have emerged due to the lack of clear leadership and accountability, insufficient transparency and limited stakeholder involvement. These shortcomings have led to inefficiencies, high costs and delays, making it harder to bring or keep medical devices available for patients and healthcare systems in Europe. As a result, Europe's medical technology sector faces growing challenges in competitiveness and attractiveness.
To address these issues, a swift governance reform is essential, where key tasks are centralised under a single structure. This would translate into full clarity and strong leadership, as well as increased efficiency and predictability for the benefit of patients, and all actors involved in the MDR/IVDR regulatory system.

The key principles, roles and responsibilities for such a new central structure outlined in this paper are meant to contribute to the ongoing 'Targeted Evaluation' of the MDR/IVDR performed by the European Commission. Further discussions and assessments are still needed to determine where and how this structure should be implemented.

The medical technology industry stands ready and is committed to engaging with all stakeholders to ensure the effective implementation of these proposals and to support a regulatory system that serves patients and fosters innovation.

[3] https://www.iso.org/stages-and-resources-for-standards-development.html

About us

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions. www.MedTecheurope.org

The Association of the European Self-Care Industry (AESGP) is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices* in Europe, an area also referred to as consumer healthcare products. https://aesgp.eu/
**Self-care medical devices are generally available without medical prescription and are self-administered.*

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. We provide a wide range of services on regulatory, technical, market intelligence, sustainability, standardisation, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association. https://www.cocir.org/

EEAR is the alliance of European Authorised Representatives who have joined forces to promote professional conduct and competence. The EAAR members provide European Authorised Representative services to non-European manufacturers of medical devices and in-vitro diagnostics

EUROM, founded in 1958 as an umbrella organization, eurom represents the interests of high-tech industry manufacturers across Europe. The current membership reflects a tradition of small and medium-sized enterprises with precision engineering expertise and a strong scientific background. eurom is especially active in the fields of medical and laboratory technology, as well as photonics.

Federation of the European Dental Industry (FIDE), FIDE is the recognized voice of the European dental manufacturing industry.

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