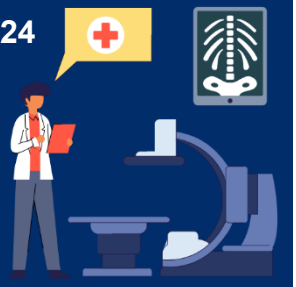
Biomedical Alliance in Europe

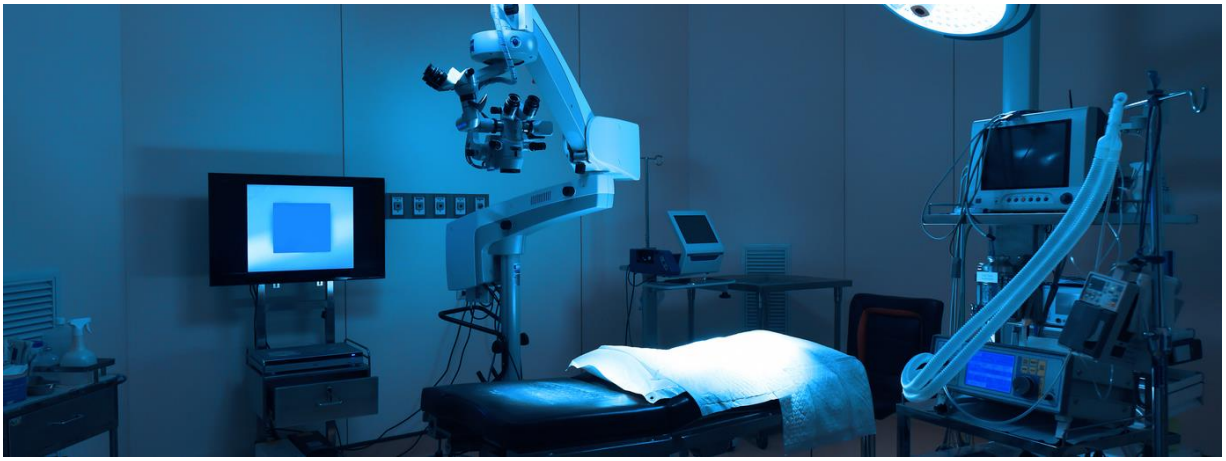
BioMed Alliance position on the MDR review

January 2024



Implementing regulatory science to protect Public Health

Introduction



Clinicians and healthcare professionals welcomed the general objectives of the Medical Device Regulations, but they now highlight *concerns and recommendations* that need to be addressed urgently to ensure significantly better availability of safe medical devices for patients in Europe. The review of the Medical Device Regulation and the In Vitro Diagnostic Devices Regulation provides a chance to address pressing issues and prevent essential medical devices from disappearing, while improving access to innovative devices and increasing investment in science, research and development within the European market.

About us

The Biomedical Alliance in Europe (BioMed Alliance) is a unique initiative of 35 leading European medical societies that together include hundreds of thousands of researchers and health professionals. It provides expert advice to policy makers and regulators on the implementation of the Medical Device Regulation and In Vitro Diagnostic Device Regulation, through the work of its dedicated Task Forces and its stakeholder membership of a number of working groups of the Medical Device Coordination Group. It was also a partner in the 2021-2024 H2020 CORE-MD Project, which aimed to review methods for evaluating high-risk medical devices, in order to translate expert evidence into advice for EU regulators and to recommend an appropriate balance between innovation, safety, and clinical effectiveness.

Essential principles of a patient-centred regulatory system

Evidence based & transparent

Regulatory requirements for the safety, performance, and effectiveness of devices should be based on scientific principles, and their impact should be evaluated to determine if they are fit for purpose. All clinical evidence should be publicly shared and easily accessible.

Proportionate to risk & fair

High standards of safety and effectiveness are key, but the level of evaluation should be proportional to the potential risk for individual patients balanced by the potential clinical benefit while maintaining high standards of safety and effectiveness. Regulations should ensure that particular groups of patients are not disadvantaged, such as people with rare diseases, and children or adults requiring highly individualised treatment.

Consistent

There should be consistency between reviews of different devices within the same type or used for the same clinical indication – so that similar clinical evidence is expected, and similar criteria are applied, leading to predictable outcomes of conformity assessments performed by different notified bodies.

Flexible & interactive

Review and approval processes must be responsive to unmet needs, new technological developments, and changing healthcare needs. Procedures should be available to allow innovators, developers, manufacturers, and clinical trialists to obtain advice on requirements for clinical studies, in face-to-face discussions with regulators / evaluators.

Efficient

A regulatory system needs to be supported by adequate human resources, coordinated structures, and organisational capacity, to ensure that medically appropriate decisions (proportionate regulation) and cost-effective outcomes are delivered in good time (“minimum resources for maximal results”).

The Medical Device Regulation

The Medical Device Regulation (MDR) that was adopted in 2017 was intended to revise the EU regulatory framework for medical devices in order to enhance their safety. Clinicians welcomed its objectives and the intention to increase safety and transparency. Nonetheless, implementation of the MDR has been accompanied by numerous issues and transition periods have had to be extended. Now, the planned evaluation of MDR is brought forward.

The clinical community represented within the BioMed Alliance has in the past raised awareness of problems including delays in implementation, limited capacity of Notified Bodies, and the slow roll-out of EUDAMED. In addition, they focused on unintended consequences of the reform, including high costs of certification, issues with the evaluation of paediatric and orphan devices, perception of research and development leaving Europe and limited transparency and predictability. BioMed Alliance has presented its concerns at meetings of the Medical Device Coordination Group, in discussions with Commission officials and policy makers, in workshops and in statements available on the website.

Key issues

Insufficient level of clinical evidence & transparency

While the MDR includes increased requirements for clinical evidence, a methodological framework for the clinical evaluation of high-risk medical devices is lacking. At the same time, there is still insufficient transparency of the clinical evidence for medical devices.

Recommendations:

- Develop a methodological framework for the clinical evaluation of high-risk devices proportional to the potential risk for individual patients and balanced by potential clinical benefit to ensure fast access to effective and safe medical technologies.
- Revise the current definition of ‘state-of-the-art’ so that it can be used as a valid comparator for clinical investigations.
- Develop a methodological framework for the clinical evaluation of lower-risk medical devices, where a greater reliance on observational studies and post-market monitoring would be appropriate based upon clinical outcomes and patient safety.
- A mechanism must be established to identify necessary guidance and common specifications, and ensure they are prepared with scientific experts, in a timely manner.

- Healthcare professionals should have access to the EUDAMED database of reported concerns about high-risk devices (i.e. anonymised incident reports, which are available in other regulatory jurisdictions e.g. the MAUDE database maintained by the FDA); as well as the alerts, recalls, and field safety notices that are already public.

Recommendations:

- The full costs of certification should be more transparent. A single web source should give the standard fees per notified body, and compare examples of indicative costs for the different stages of review.
- Notified bodies should be encouraged to reduce their charges by avoiding any duplication of their procedures (such as repeated assessment of a sterilisation protocol separately for each size in a range of a product, when it is common to them all).
- Pathways to regulatory approval with reduced costs should be available for devices that are needed rarely, since they can provide only a small return on investment, and for devices that have been developed by SMEs which demonstrate that they would otherwise need financial support to remain viable.

High costs of certification

The costs of conformity assessment form an important barrier, particularly for orphan and paediatric devices, some legacy medical devices, and some applications by SMEs. Surveys of manufacturers imply that costs have contributed significantly to devices being withdrawn from the EU market, while remaining on the market in other jurisdictions like the USA or Canada where the costs of certification can be sometimes 10 times lower than in the EU.

Limited availability of orphan/paediatric devices

Orphan and paediatric devices are a particular group of devices that cater to small patient groups, including paediatric patients or patients with rare diseases. Due to their specificities,

Recommendations:

- For review by the EU of devices used rarely or for innovative medical devices, the principle of pooling of resources and specialisation of regulatory bodies should be accepted, established, and advertised. Specialist regulatory expertise can be matched with the specific needs of manufacturers.
- We welcome the proposed implementing decision to establish an Expert Panel for Orphan and Paediatric Medical Devices.
- The EU should develop special pathways that will enable orphan and paediatric medical

manufacturers face important hurdles in the system that hinder their recertification under the MDR. Particularly the costs of certification form an important barrier for these devices since they generally cater to small numbers of patients which offers less return on investment.

devices to be approved if necessary, with less pre-market clinical evaluation, as long as that is followed by adequate post-market studies.

- There should be public funding for registries of high-risk medical devices (including orphan devices), undertaken by specialist medical professional associations.
- Implementation of national and EU-wide derogations should be facilitated for devices that are essential for clinical care, but which are about to disappear from the market (see article 59 of the MDR).
- The option of providing certificates with conditions should be explored for essential legacy devices that have been on the market without issues for many years, and for certain orphan and innovative devices.

Recommendations:

- A mechanism must be established to ensure that when a manufacturer reports to its national regulator that it is going to withdraw a device, the information is shared not only with other regulators across EU member states but also with the clinical community (also via European medical associations), with patients, and with purchasers.
- Guidance should be prepared on steps to take after withdrawal of a device is announced, including options that could mitigate shortages and measures to reduce any clinical impact.
- Healthcare professionals and providers should have access to a single mechanism and point of contact where they can report shortages or non-availability of devices that are needed for patient care, and where they can raise key concerns about safety or notify regulators about adverse incidents that have occurred with the devices that they use.

Growing risk of devices disappearing from the EU market

Some manufacturers have decided not to apply for (re)certification under MDR and to withdraw their devices from the European market, partially due to the high costs of conformity assessment. A survey among manufacturers conducted by Gesundheid Osterreich on behalf of HaDEA, indicated that 46 percent of respondents have stopped or will stop the production/marketing/supply of some of their devices on the EU market since 2021.

Innovation is impeded

In addition to issues with legacy devices, the characteristics of the regulatory system make it costly and complicated to put new products on the market, including for breakthrough devices and SMEs. There are already signals that innovation is moving to other jurisdictions.

Recommendations

- It needs to be much easier for innovators, developers, manufacturers and clinical trialists to consult a notified body for early advice about what clinical evidence will be needed for their device to be approved. The pilot with the Expert Panels for Medical Devices should be expanded.
- The EU should establish a special pathway that will enable manufacturers of independently confirmed breakthrough technologies to undergo an accelerated conformity assessment, with mandatory clinical follow-up in the post market phase.

Recommendations:

- Travel costs for healthcare professionals, patients, and civil society representatives who attend the MDCG should be reimbursed by the European Commission.
- Dates for face-to-face meetings, and selection of the times for open sessions with stakeholders, should be set well in advance (> 2 – 3 months) and not changed.
- Consultations and requests for input from stakeholders need to have sufficiently flexible deadlines, that take into account the busy schedules of clinicians, patients, and other volunteers.
- Draft guidance documents and consultations with stakeholders should be conducted in an open and transparent manner, similar to the EMA and US FDA approaches to guidance development.

Need to strengthen stakeholder involvement

As recognised stakeholders to the Medical Device Coordination Group, the BioMed Alliance and other healthcare professional and patient organisations contribute to the MDR implementation.

Increasing regulatory complexity

The European regulatory framework for health technologies is becoming increasingly complex. The MDR interlinks with several key new regulations including the Artificial Intelligence Act, the In Vitro Diagnostics Regulation, the European Health Data Space, the Regulation on Health Technology Assessment, and the Clinical Trials Regulation. There is an important need for legal clarity on the overlap between these regulations.

Recommendations

- If implementation of the AI Act, and of the EU Health Data Space Regulation, includes drafting of tertiary legislation and/or the development of guidance relevant to diagnostic and therapeutic technologies, then it will be important for healthcare professionals to be involved in each process. The opportunity could be taken to address any persisting doubts about conflicting recommendations.
- EU requirements for the management of clinical studies of medical devices should be simple and clear, as proposed by the Coalition for Reducing Bureaucracy in Clinical Trials.

Recommendations

- There is a need to make the system more efficient, and different options should be considered including an overview of the specialisations of each notified body, to match specialised expertise with the specific needs of manufacturers.
- There is a critical need for more regulatory staff and expertise within the European Commission's Directorate General for Health and Food Safety (DG SANTE) and particularly for staff with clinical expertise.
- Many of the persisting issues could be addressed if an adequate support structure for the MDR and IVDR is created.

Need to streamline governance

There is limited capacity within DG SANTE Unit D3 and a lack of a coordinated regulatory support system.

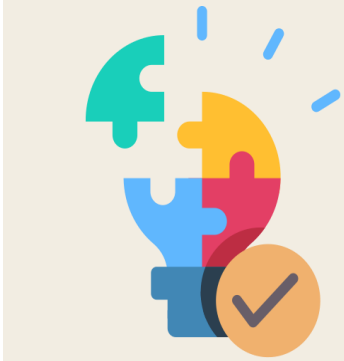
Need for a new coordinating mechanism to address pressing issues in the system

There is a need for a new body that can coordinate the EU regulatory system and serve as a point of contact particularly for small and medium-sized enterprises and manufacturers of orphan and paediatric devices. There are different options to create such a mechanism, and their disadvantages and benefits must be carefully evaluated to identify the most effective way forward.

Notified Bodies have gained responsibilities, functions and workload under the Medical Device Regulation and In Vitro Diagnostic Medical Devices Regulation. They are private organisations that are designated by Competent Authorities which are responsible for overseeing their performance. Cooperation and coordination are foreseen through the Notified Body coordination group, but this coordination does not go far enough to address excessive costs, lengthy procedures and issues in communication. BioMed Alliance believes that the role of the European Medicines Agency in the field of medical devices could be expanded, so it can take on a broader management role to coordinate the scientific aspects of the regulatory system for devices.

Functions of the new coordinating mechanism

- Enhance coordination in the system and ensure synergies and complementarities within and between the different actors including notified bodies, manufacturers, the Commission, healthcare professionals and other jurisdictions at the global level.



- Early dialogues and advice, particularly for orphan devices, breakthrough innovation and SMEs.
- Designate orphan devices.
- Manage an affordable pathway to conformity assessment for orphan devices, breakthrough devices and SMEs.

- Maintenance of register of approved device registries.
- Coordination of market surveillance.
- Mechanism to ensure that conditions on certificates, for post-market clinical follow-up, are met by manufacturers or their certificates are withdrawn.
- Joint reviews with HTA, joint horizon scanning.
- EU participation in the international program for single audits, the IMDRF's Medical Devices Single Auditing Programme (MDSAP).