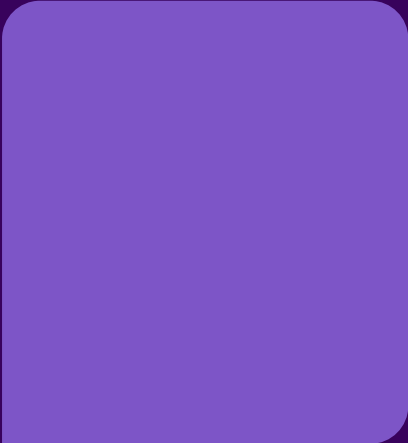




DI'S RECOMMENDATIONS FOR A REVIEW OF REGULATIONS FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES



Simplify regulation, enhance innovation, and improve patient safety

Introduction

The regulation of medical devices (MDR), and the regulation of in vitro diagnostic medical devices (IVDR) brought significant regulatory changes for manufacturers of medical devices and combination products in Europe. MDR and IVDR replaced the previous directives on medical devices and in vitro diagnostic and aim to enhance patient safety and harmonize requirements for medical devices in the EU.

Unfortunately, the MDR has become an example of European legislation that, despite its positive and well-intentioned goal of improving patient safety, has resulted in significant bureaucratic challenges. This is particularly true for SMEs, who experience obstacles to growth and development in a strategically important sector for the EU.

Increased bureaucracy and longer approval processes ultimately mean poorer access to innovative health technology solutions for European patients. It is therefore crucial that the EU Commission, European Parliament, and the Council show urgency and act now to reverse the trends for the life sciences industry and ensure future health technology solutions in Europe.

Danish Industry (DI) thus welcomed the European Parliament's resolution of 23 October 2024, which presses for urgent actions regarding regulatory frameworks in the area.

Significant Challenges

- Lack of resources in the “*Notified Bodies*”, including uncertainties regarding practical interpretation of regulation, resulting in bottlenecks and delays in the approval process.
- Difficulty for manufacturers in navigating the new rules, especially since *Notified Bodies* are not allowed to advise them directly. SMEs are particularly hard hit by complex requirements and high costs.
- Lack of harmonization and inconsistent interpretation and application of regulation make it harder to ensure efficient and competitive production of goods.
- Lack of predictability and transparency in the processing of applications for new products and high costs associated with the application process.
- Needs to establish fast-track procedures for 'breakthrough' technologies and devices for health crises.
- Absence of clear definitions and specific procedures hampers the development of rare and pediatric medical devices.
- Requirement for re-certification of medical devices every 5 years creates unnecessarily large administrative burdens on an already challenged system.
- Slow rollout of the EUDAMED database limits transparency and coordination.
- Combination products ("integral drug-device combination") face particular challenges in terms of regulatory responsibility for the approval process.
- The impact of horizontal EU regulation on medical devices, including inconsistencies between sector-specific and horizontal regulation.
- Shortage of certain types of medical devices can create inequality in access to health services across the EU.

Based on experience and input from our member companies, we present the following positions and solutions.

1. Capacity building at the Notified Bodies

Challenge

The Medical Device Regulation (MDR), which came into effect in May 2021, has introduced significant regulatory changes for manufacturers. These changes have resulted in a more complex approval pathway and split responsibilities between EMA and Notified Bodies (NB), causing delays in market entry for new products.

Solution

Simplifying and streamlining the approval process for medical devices.

DI suggests establishing a single, responsible governance structure that can provide clear guidance so that the Notified Bodies can administer regulation uniformly across the EU.

When it comes to integral drug-device combination products (IDDC's) EMA should assume full responsibility for all regulatory tasks. This would reduce complexity and delays.

Furthermore, increasing regulatory capacity at both European and national level for assessing medical devices and ensuring manufacturers receive scientific advice on device changes are also essential steps.

Proposal

DI calls for establishing a single, responsible governance structure that can provide clear guidance so that the Notified Bodies can administer regulation uniformly across the EU.

2. Lack of advice and clarity

Challenge

Under the current system, manufacturers cannot receive advice from the EU's Notified Bodies, as is the case with the U.S. Federal Food and Drug Administration, FDA.

This is a challenge for both large and small manufacturers of medical devices, including manufacturers of integral drug-device combination products (IDDCs), where the expertise primarily lies with the European Medicines Agency (EMA) and national authorities.

Manufacturers of devices face challenges in interpreting legislation and understanding exactly what is expected of them. They are left in a situation without a clear way to get the necessary advice and guidance, which can complicate and delay the approval process.

Proposal

DI calls for Notified Bodies to offer advice and scientific guidance for manufacturers, thereby aligning this with the possibilities offered in the proposal for revision of the EU pharmaceutical legislation.

3. A single, responsible governance system for combination products

Challenge

Manufacturers face a regulatory vacuum for scientific advice on the device component of combination products, complicating their development and approval processes.

Solution

DI proposes to establish a mechanism where manufacturers can get scientific advice from competent authorities both in relation to the drug and device parts of IDDCs.

Inspiration can be found in the setup of EMA. DI proposes establishing a "one-door-entry" system where a single authority is responsible for both the medicine and device part of combination products. This would create a more streamlined and efficient approval pathway.

Proposal

DI calls for a "one-door-entry" solution where EMA has full responsibility for both the medicine and device parts of IDDC products, including advice, assessment, and approval.

4. Fast-track for breakthrough technologies addressing unmet medical needs

Challenge

We are poor at converting innovation into commercialization in Europe. When a European company has the muscles, solutions, and ambitions to scale up, it often gets hampered by inconsistent and restrictive regulation at multiple levels, which hampers future health solutions.

At the same time, innovative medical products that address unmet medical needs particularly need to be able to rush to market. Red tape, expensive and slow approval processes reduce the incentive to research and develop health solutions that address unmet medical needs.

Solution

Therefore, DI propose a dedicated fast-track pathway for innovative products, with due consideration for patient safety, to ensure faster market access.

Inspiration can be found in European pharmaceutical legislation, which sets a fixed number of days for a given approval process.

Proposal

DI calls for implementing a fast-track approval process for innovative medical products that address unmet medical needs.

5. Reduce administrative burdens - adjust the requirement for re-certification

Challenge

There is a need to reduce the overall administrative burdens resulting from both MDR and IVDR. Legislation places significantly increased monitoring requirements on manufacturers of medical devices.

Despite this, MDR continues to require that all certificates be renewed every five years, even though both manufacturers and Notified Bodies continuously monitor the medical devices on the market.

This requirement creates a significant administrative burden for both manufacturers and Notified Bodies, whose capacity is already stretched, without contributing to increased patient safety.

Hence, there is a need for aligning certification with the lifetime of medical technologies.

Proposal

DI calls to adapt the certification of a medical device to follow a life-cycle approach.

6. Predictability and transparency at Notified Bodies

Challenge

A significant challenge for manufacturers of medical devices, particularly SMEs, is the lack of predictability and transparency in processing applications for new products and costs associated with the process.

In other words, there is great uncertainty when it comes to predicting what achieving approval will eventually cost the individual company.

Therefore, efforts should be made for Notified Bodies to work with transparent and fixed fees, which will provide greater predictability in product launch planning.

It is also problematic that Notified Bodies in the EU have no economic incentive to keep fees low for manufacturers, which could potentially lead to "the most expensive solution" for companies.

Furthermore, it is difficult to predict how long an approval process will take, as no timelines are set for the process, as is the case with pharmaceutical legislation. Notified Bodies also lack economic incentives to advance the process.

Overall, the above hampers the incentive to place new medical products on the market in the EU.

There is a need to reduce the costs for obtaining approval, as well as to set maximum timelines for assessment processes. This is especially true for SMEs.

Proposal

DI calls for introducing a payment model for Notified Bodies based on results and adherence to predetermined timelines.

7. Horizontal EU regulation's impact on medical devices including potential inconsistencies between sector-specific and horizontal legislation

Challenge

Manufacturers of medical devices must not only comply with sector-specific legislation but also to a significant extent with horizontal legislation, especially from the EU. Examples include GDPR, sustainability reporting, PFAS, Battery Regulation, REACH, AI Regulation, etc.

Naturally, this increases complexity, and not only SMEs but also larger manufacturers face challenges in finding their way in and complying with legislation that is not designed in a sector-specific context. There are even companies that experience potentially conflicting requirements in sector-specific and horizontal regulation.

Technological development also means that more and more medical devices have a built-in digital component, e.g., hardware that also includes software, either integrated into the device or as an accessory. Such components are significant, especially when it comes to supporting the transformation of the healthcare sector to bring healthcare closer to the individual patient.

Additionally, the software in medical devices increasingly uses AI. With the requirements set in the AI Regulation, it is uncertain whether medical devices with an AI component can be certified without significantly more administrative burdens. When implementing the AI Regulation, it is therefore crucial to consider the existing sector-specific legislation to avoid creating additional administrative burdens for manufacturers.

Moreover, digital and electronic solutions should be generally promoted, e.g., electronic user instructions.

Proposal

DI calls for initiating measures to facilitate the implementation of horizontal EU legislation, with the purpose of reducing the overall administrative burden on medical device manufacturers.

8. Additional national regulation on medical devices

Challenge

The MDR is legally binding and directly applicable in every EU Member State. However, the MDR provides for such opening clauses for specific national law leading to numerous special national regulations in practice. This extra layer of numerous regulatory requirements of the MDR creates excessive regulatory hurdles for the companies.

Proposal

DI calls for a review of the opening clauses for the Member States for their necessity and effectiveness. National supplementary rules must be reduced to a minimum and the MDR should be a priority over conflicting national regulations.

9. Harmonization and global standardization

Challenge

Efforts should be made towards increased harmonization of regulatory requirements within the EU and across global markets. This also applies to the use of international standards.

This aims to facilitate companies' access to multiple markets while reducing burdens.

Proposal

DI calls for a long-term objective for IDDC products to be developed and adapted to industry standards, to harmonize the regulatory approach to these products.

First by harmonizing within the EU and recognizing IDDCs as one product with a single application.

Secondly, efforts should be made towards a general and globally aligned framework, terminology, and approval method for IDDC products.

10. Balanced focus

Challenge

The challenges posed by MDR/IVDR highlight the need for more balanced legislation with focus on both patient safety, innovation, and market access. In themselves, innovation and market access are conditions and means of improving patient safety.

Proposal

A balanced approach and prioritization of innovation are necessary to ensure that European patients are not overlooked due to complex legislations when new innovative medical devices are launched in the market.

Concluding remarks

It is generally acknowledged that the MDR and IVDR create excessive regulatory hurdles, particularly challenging for the small and medium-sized companies with limited financial and human resources.

We are facing a critical situation where the current regulation is not delivering on its objectives as originally intended by the EU legislator. The unpredictability, complexity, and burden of the regulations mean that many devices on the market today as well as new, innovative medical technologies are not reaching patients in Europe as they should.

The competitiveness of the whole medical device industry and even the viability of many small businesses (SMEs) are at risk. These trends must be addressed immediately and before European healthcare is further impacted.

Cost and administrative burdens will render production uneconomical and thus hinder health care provision and the development of innovative devices. Not least in relation to low-risk devices in class I the increased effort required for regulatory compliance would not contribute towards achieving increased patient safety.

DI therefore expressly welcomes the EU Commission's decision to bring forward the evaluation of the MDR and IVDR and calls for an appropriate revision of the regulation to reduce hurdles, simplify processes, and resolve ambiguities.