

A More Innovation-Friendly Regulatory Framework for the European Medical Technology Sector: Six Measures to Strengthen Competitiveness

The European medical technology sector is a key strength for Europe. By developing, producing, and marketing innovative and patient-safe medical devices – including digital health solutions and the use of artificial intelligence – the sector helps reinforce and future-proof healthcare systems both within Europe and globally.

Unfortunately, the sector-specific regulation in the EU, in the form of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), have become examples of how excessive bureaucracy and lengthy assessment and certification processes can undermine European competitiveness, often without delivering added value for patients, clinicians, or society.

In this position paper, MedTech Denmark (Medicoindustrien) outlines six recommendations for how an innovation-focused revision of the MDR and IVDR can boost the sector's competitiveness and ensure that patients have access to the latest and most advanced health technology solutions.

A More Innovation-Friendly Regulatory Framework for the European Medical Technology Sector: Six Measures to Strengthen Competitiveness

Overview of the Medical Technology Sector

The European medical technology sector is a cornerstone of Europe's economic and healthcare strength. Through the development, production, and marketing of innovative and patient-safe medical devices – including digital health solutions and the use of artificial intelligence – the sector supports and future-proofs healthcare systems both locally and globally. In addition, the sector is vital to EU by employing 930,000 people and generating 15,700 patent applications annually.¹

Medical devices are regulated in the European Union by the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), both adopted in 2017. These regulations have tightened requirements for manufacturers and the notified bodies that certify manufacturers and assess medical equipment. While the industry supports the intentions behind these regulations, their implementation has faced significant challenges, particularly a lack of capacity among notified bodies. As a result, extended transition rules now apply until the end of 2028 for certain products, depending on their risk classification.

Unfortunately, MDR and IVDR have become examples of how excessive bureaucracy and lengthy regulatory clearance processes can undermine European competitiveness, often without delivering added value for patients, clinicians, or society. The regulations have fostered processes that are frequently unpredictable, costly, and administratively burdensome.

Currently, the European medtech sector is under such pressure that new and innovative solutions are often launched in the United States and China before reaching European patients—a reversal from the past, when Europe was the primary launch market for most health tech innovations. According to a 2022 report by the University of California and Boston Consulting Group, 89% of major medtech companies now prefer to launch new innovative medical devices in the United States first rather than the EU.² A survey among

¹ MedTech Europe, Facts & Figures, 2025: <https://www.medtecheurope.org/wp-content/uploads/2025/09/medtech-europe-facts-and-figures-2025-digital.pdf>

² Boston Consulting Group & University of California, Interstates and Autobahns Global Medtech Innovation and Regulation in the Digital Age, 2022: <https://web-assets.bcg.com/8c/f0/06744e8848ea9654bbd0765bf285/bcg-interstates-and-autobahns-mar-2022.pdf>

MedTech Europe members found that around half of companies plan to deprioritize the European market.³

Recognizing these challenges, the European Parliament, in its October 2024 resolution “Urgent need to revise the medical devices regulation,” called for a revision of MDR and IVDR to restore Europe’s attractiveness for developing, producing, and marketing of innovative medical devices. The European Commission’s life sciences strategy, published in June 2025, also highlights medical devices as an area where Europe risks losing competitiveness, especially due to regulatory hurdles. The Commission intends to present a draft revision of MDR and IVDR in December 2025, aiming to create a more competitive regulatory framework while ensuring patient access to the latest and most advanced health technologies.

Health Commissioner Olivér Várhelyi and several member states, such as Denmark, have called for innovation-focused revisions to the MDR and IVDR. The next step is to implement these changes and establish a more innovation-friendly regulatory framework for Europe's medical technology sector.

Purpose of Revising the MDR and IVDR

European patients must have timely access to the latest, safest, and most innovative health technologies. Achieving this requires that Europe remains an attractive location for manufacturers and suppliers. Revising MDR and IVDR is therefore essential to strengthen the sector’s competitiveness. The current slow, costly, and unpredictable regulatory clearance process has contributed to shifting innovation away from Europe, particularly affecting small and medium-sized enterprises (SMEs), which make up over 90% of the sector. A revision will benefit the entire industry and make Europe more attractive for SMEs.

Six Concrete Measures to Strengthen European Competitiveness in Medtech

³ MedTech Europe, MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 2022:
<https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf>

A revision of MDR and IVDR should focus on making the regulatory clearance and oversight more agile, less costly, and, above all, faster. In particular, the following six measures are recommended:

- **Make the regulatory clearance process faster, more efficient and predictable, and less costly.**

Currently, before companies can place medical devices or in vitro diagnostic products on the European market, they must undergo a regulatory clearance process that includes conformity assessment of the product and certification of their quality management systems by a notified body.

This process ensures products placed on the EU market comply with applicable regulations and meet high patient safety standards. The degree of control depends on the risk classification of the products: the higher the risk class, the stricter the control.

The EU regulations for medical devices were intended to foster a well-functioning internal market in the EU while ensuring a high level of protection for patients and users. Unfortunately, the current regulatory framework has led to significantly increased regulatory clearance costs and substantially longer time-to-market. Additionally, there are considerable variations in both costs and timeframes among the different notified bodies responsible for conformity assessment of these devices.

Therefore, the process should be faster, more efficient, predictable, and less costly, especially for small and medium-sized companies heavily burdened by administrative demands. Specifically, there should be clear, consistent, and enforceable deadlines for notified body reviews, and mandatory transparency from notified bodies regarding their fee structure and timelines for both product conformity and quality management system assessments.

Specifically, enhancing opportunities for early engagement and dialogue are essential to clarify expectations regarding evidence requirements and appropriate device classification. This should encompass the option to seek scientific advice both independently of and within the regulatory clearance process. Such early engagement can raise the quality of conformity assessment submissions and foster a more efficient system, ultimately streamlining procedures also within notified bodies.

A specific example of classification difficulties in the current regulatory framework concerns software for medical devices. Under MDR Rule 11, low-risk medical device software (MDSW) is often classified as at least class IIa, requiring involvement from

a notified body – even when the actual risk to users or patients by utilising the software is minimal. To address this, enhanced early dialogue about classification, improved guidance on the application of MDR Rule 11, and a more clearly defined risk-based approach would help create a more efficient and agile process.

- **Introduce a dedicated fast-track path for breakthrough innovation**

At present, Europe lacks a dedicated regulatory pathway for breakthrough innovations. As a result, entirely new and innovative health technology solutions designed to address unmet clinical needs are subject to the same lengthy regulatory clearance procedures as any other medical device. In other words, there is no accelerated regulatory review process in Europe, even for products of substantial health significance.

This situation contrasts with the fast-track pathways available in the EU for pharmaceuticals and advanced therapies, and places the EU at a clear disadvantage compared to other regions – such as the United States, Japan, and Australia – which have established dedicated fast-track procedures for breakthrough innovations in medical technologies.

The absence of an accelerated regulatory pathway results in delayed market entry for cutting-edge medical technology innovations in Europe compared to other regions, ultimately postponing European patients' access to the latest advancements. From an industry standpoint, this makes Europe a less favourable destination for the introduction of novel health technologies.

To address this, a dedicated regulatory framework should be developed under the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) that facilitates the development, assessment, and adoption of innovative medical technology solutions within the EU, thereby benefiting patients and healthcare professionals alike. Implementing a fast-track regulatory procedure for breakthrough medical devices is a critical component of this strategy.

Such a fast-track pathway should be structured to allow for earlier engagement with subject matter experts, provide more explicit regulatory guidance throughout the conformity assessment process, and incorporate robust post-market surveillance following clearance. This approach would maintain high standards of patient safety while increasing regulatory efficiency, which is essential for enhancing the global competitiveness of the European medical technology sector.

In this context, innovation encompasses both transformative technologies and incremental modifications that address previously unmet clinical needs by

enhancing the functionality and performance of existing devices. This includes software updates, reduced maintenance times, and improved interoperability of medical technologies. Innovation may also extend to solutions that were originally intended exclusively for clinical environments but are now adapted and validated for safe and effective use in home or community settings.

- **Streamline the Process regarding Product Changes**

In the European Union, manufacturers of medical devices and in vitro diagnostic (IVD) devices are required to obtain prior assessment and acceptance from the appropriate notified body before implementing significant changes to a device or diagnostic test. The notified body is responsible for evaluating whether the proposed change impacts the validity of the original conformity assessment.

Although the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) specify that only substantial changes – those affecting safety, performance, usability, or the overall risk-benefit profile – require assessment by a notified body, current practices often diverge from this principle. In practice, notified bodies frequently demand notification and clearance for all device modifications, regardless of their significance, despite the fact that such oversight is not explicitly required by the regulations. This results in an unnecessarily complex and costly product change process, discouraging manufacturers from providing timely updates and improvements to medical devices available within the European market.

Mandating notification and assessment for every modification, including minor updates, introduces avoidable bottlenecks that undermine the efficiency of the regulatory system. Consequently, patients and healthcare professionals in Europe may be left with outdated medical devices, while other regions benefit from more up-to-date solutions. This lack of risk-based proportionality fails to reflect the continuous improvement cycle inherent in the medical technology sector and ultimately delays the delivery of improved products to patients. In some cases, manufacturers may opt to withdraw products or halt updates due to the burdensome, costly, and unpredictable nature of the current update process.

To resolve these challenges, regulatory practice should be harmonized with the intent of EU legislation. Specifically, only significant changes impacting safety, performance, usability, or the device's risk-benefit profile – should trigger prior notified body review and acceptance. Routine or minor changes should be managed through robust internal quality systems, enabling manufacturers to implement incremental improvements efficiently without unnecessary regulatory delays. This targeted approach will streamline the product update process, reduce

administrative burden, and ensure that European patients and healthcare professionals have consistent access to the most current and innovative medical technologies.

- **Remove the mandatory five-year re-certification requirements for medical devices across all risk classes**

Medical devices marketed in Europe are subject to rigorous, ongoing regulatory oversight. This includes annual audits, mandatory safety reporting, comprehensive clinical evaluations, and robust post-market surveillance activities such as Periodic Safety Update Reports (PSURs), Post-Market Clinical Follow-up (PMCF), and obligatory incident reporting. These measures ensure that devices continue to meet safety and performance standards after initial conformity assessment and provide notified bodies with the authority to suspend or withdraw certificates at any time should new evidence warrant such action.

Despite this extensive framework for market surveillance, the current requirement for mandatory five-year re-certification of all medical devices creates unnecessary administrative burdens without demonstrable improvements in patient safety. This blanket policy increases regulatory costs and may discourage manufacturers from continuing to supply and update products within the European market, potentially limiting access to safe and effective medical technologies.

To address these challenges, it is recommended that the mandatory five-year re-certification requirement is eliminated for all risk classes of medical devices. Instead, regulatory oversight should focus on continuous post-market surveillance and risk-based interventions, allowing notified bodies to assess and act upon significant safety or performance concerns as they arise. This solution would streamline the regulatory process, reduce unnecessary bureaucracy, and support timely access to innovative and well-maintained medical devices for patients and healthcare professionals throughout Europe.

Recent data from Gesundheit Österreich (2025) illustrates that the existing re-certification requirements threaten the continued availability of medical device solutions across the European Union market, as these obligations are projected to create significant regulatory bottlenecks in the coming years.⁴ The expiration of

⁴ ~15,000 first-time MDR certificates still must be issued by end of 2028. During the same time period, Notified Bodies must issue 5,599 re-certifications for already MDR-issued certifications, costing the EU industry at least 112 million Euros in Notified Body fees alone (based on 20,000 median re-certification fees, not counting internal costs). See European Commission, "Evaluation of the implementation of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) – 2nd European Operators Survey" conducted by Gesundheit Österreich GmbH (GÖG), 2025.

certificates will result in the first major re-certification cycle peaking in 2027 and 2028, which will align with a period of heightened demand for new certificates.

If these re-certification requirements remain unchanged, it is anticipated that such regulatory bottlenecks will recur in cyclical five-year intervals.

- **Strengthen the Governance of MDR and IVDR**

The current lack of harmonized guidance and uniform interpretations of regulatory requirements across medical device companies and notified bodies generates uncertainty and inefficiency within the regulatory clearance process. To address this challenge, it is essential to reinforce the governance of the Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) by implementing clear, consistent, and authoritative oversight mechanisms.

Given that the European medical device industry comprises over 500,000 unique device types – and up to two million globally a sweeping structural shift to a single, centralized regulatory authority for all medical devices would present significant logistical and technical challenges. While centralization has proven effective for medicinal products under the European Medicines Agency (EMA), the sheer diversity and complexity of medical devices make it unlikely that a single central body could develop the necessary capacity and specialized expertise for effective conformity assessments.

Therefore, MedTech Denmark (Medicoindustrien) recommends maintaining the current system in which multiple notified bodies, each with specialized competencies, are responsible for medical technology regulatory clearances. However, to promote regulatory consistency and efficiency, a central governance structure should be established with the mandate to designate, oversee, and coordinate notified bodies. This governance structure would also be responsible for developing and issuing clear, unambiguous guidance to ensure that notified bodies implement MDR and IVDR requirements uniformly throughout Europe. Such a solution would streamline regulatory processes, reduce ambiguity, and enhance market access without requiring the creation of an entirely new certification and assessment infrastructure.

Additionally, this central governance structure could gradually assume responsibility for representing the EU's interests in international regulatory collaborations, such as the Medical Device Single Audit Program (MDSAP) and the International Medical Device Regulators Forum (IMDRF), thereby supporting global harmonization and strengthening the EU's position in international medical device regulation.

- **Make the Regulatory Pathway for integral Drug Device Combination Products More Efficient**

At present, companies developing medicinal products that incorporate a device component face significant regulatory hurdles, as these integral drug-device combination products (IDDCs) – such as pre-filled pens, inhalers, and syringes – must comply with both MDR Article 117 and the applicable pharmaceutical legislation. The current fragmented regulatory landscape for IDDCs lacks comprehensive guidance and clear delineation of responsibilities of the interfaces between drug and device hence, European Medicines Agency (EMA) or national competent authorities, and notified bodies. This complexity leads to regulatory inefficiency, inconsistent decision-making, and unpredictable outcomes for marketing authorization applications. Additionally, these overlapping and sometimes inconsistent requirements delay patient access to essential therapies and impose an increased administrative burden by necessitating extensive documentation of compliance to diverging regulations throughout the product's entire lifecycle.

Establishing a single accountable authority could provide the much-needed coordination, ensuring manufacturers are not caught in the interfaces between divergent regulatory pathways. Such an approach would enhance transparency, reduce procedural complexity, and facilitate more rapid market access for IDDCs. A single accountable authority needs to have access to the necessary expertise to assess both the drug part and the device component of IDDC's products, as well as the interfaces between the two.

Specifically, MedTech Denmark (Medicoindustrien) recommends:

- **Appoint a single accountable authority for Integral Drug-Device Combination Products**

Designate an EU body to lead and coordinate the comprehensive assessment and lifecycle oversight of integral drug-device combination products. This authority should possess deep expertise in the field of medical technology. Having a single accountable authority will eliminate the risk of conflicting interpretations, shorten the approval process, make timelines more predictable.

- **Enable Scientific Advice for Integral Drug-Device Combination Products**

Establish a joint scientific advisory committee that encompasses both the medicinal and device components, allowing cross-cutting issues to be addressed early and supporting effective, evidence-based development.

The implementation of these changes as part of the revision of the MDR and IVDR will enhance regulatory predictability, create a harmonized and competitive framework, streamline development processes, and accelerate patient access to innovative treatments in the EU for integral drug-device combination products.

Call for a Predictable and Efficient Regulatory Pathway for Integral Drug-Device Combination Products to Enhance Patient Access to Innovative Products in the EU

This position paper addresses critical challenges and proposes targeted improvements to the EU regulatory pathway for iDDCs as defined by Article 117 in the European Medical Device Regulation (MDR) 2017/745 . It advocates for a transparent and centralized EU framework with the designation of a single, responsible authority overseeing the drug and device components of iDDCs to streamline approvals.

Core elements to be addressed include the creation of an integrated framework for end-to-end lifecycle oversight, possibility of obtaining scientific advice, consistent GSPR expectations and lifecycle change management requirements as well as the possibility for a device platform approach. These recommendations aim to reduce the regulatory burden, improve time-to-market, and restore the EU's competitiveness as a first choice for launching innovative iDDCs.

Call for a Predictable and Efficient Regulatory Pathway for Integral Drug-Device Combination Products to Enhance Patient Access to Innovative Products in the EU

Executive Summary

This paper concerning challenges with the regulatory framework for integral Drug-Device Combination (iDDC) products is based on input gathered from members of MedTech Denmark's drug-device expert group. The expert group consist of corporate members of MedTech Denmark.

Integral Drug-Device Combination products:

Combines a drug and device into a single integrated product e.g. pre-filled pens, pre-filled inhalers, pre-filled syringes etc.

iDDCs are regulated as medicinal products *If the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable.*

(Article 9, European Medical Device Regulation (MDR) 2017/745 [1])

The European regulatory environment for iDDC products is fragmented, with lack of guidance, split of responsibilities between the European Medicines Agency (EMA)/National Competent Authorities (NCAs) and Notified Bodies (NBs), and no centralized regulatory framework, resulting in regulatory inefficiencies and unpredictable submission outcomes. Furthermore, the framework delays patient access to therapies and increases the administrative burden to demonstrate compliance across the product lifecycle.

An analysis conducted on all initial Marketing Authorization Applications (MAAs), line extension and variation procedures submitted since MDR mandatory implementation shows that **approximately 20% of all MAAs involve iDDCs.**

(May 26th, 2021 - December 31st, 2024 - Number presented by Alberto Ganan Jimenez, EMA at DIA Europe 2025, 18-20 March, Basel). – See Appendix 1

This position paper addresses critical challenges and proposes targeted improvements to the EU regulatory pathway for iDDCs as defined by Article 117 in the European Medical Device Regulation (MDR) 2017/745¹. It advocates for a transparent and centralized EU framework with the designation of a single, responsible authority overseeing the drug and device components of iDDCs to streamline approvals.

¹ Combination products where the action of the medical device is principal to that of the medicinal product are out of scope of this paper.

Core elements to be addressed include the creation of an integrated framework for end-to-end lifecycle oversight, possibility of obtaining scientific advice, consistent GSPR expectations and lifecycle change management requirements as well as the possibility for a device platform approach. These recommendations aim to reduce the regulatory burden, improve time-to-market, and restore the EU’s competitiveness as a first choice for launching innovative iDDCs.

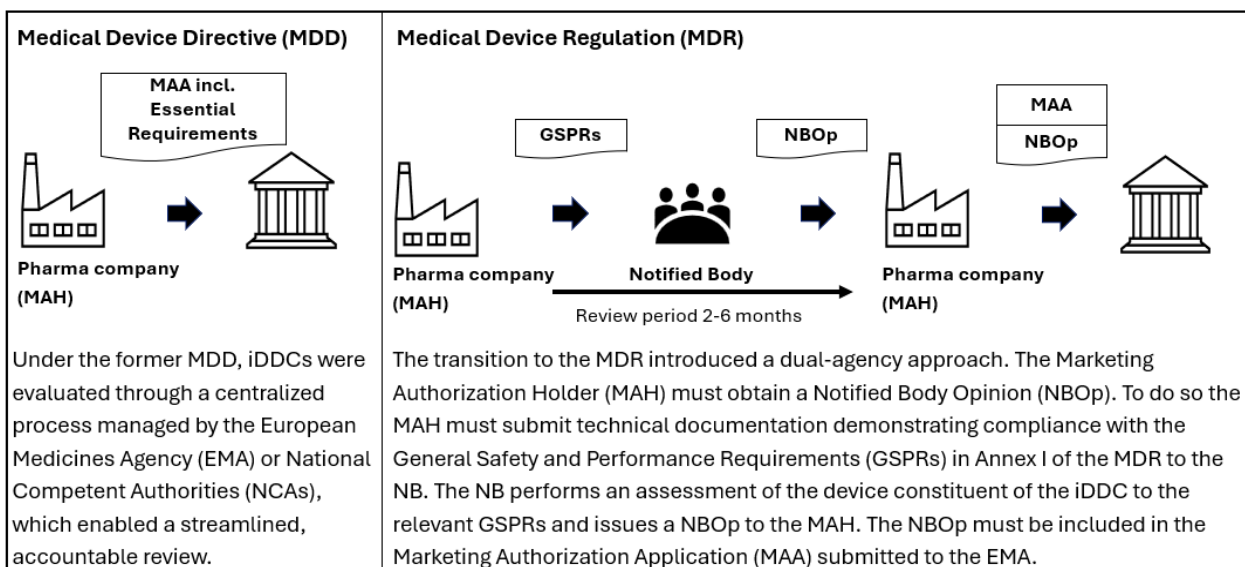
Introduction

iDDCs are increasingly vital in advancing patient care by integrating therapeutic agents with sophisticated delivery technologies, such as pre-filled pens, inhalers, and auto-injectors. These innovations enable safer, more effective, and user-friendly treatment options, especially in self-administration contexts. Despite their growing clinical and technological significance, the European Union’s regulatory framework for iDDCs remains fragmented and inconsistent, creating substantial challenges for the Marketing Authorization Holders (MAH), and regulators alike.

Regulatory framework Medical Device Directive (MDD) [1] vs. Medical Device Regulation (MDR) [2]

Under the MDR, the MAH coordinates the interaction between the EMA/NCAs and the NB without a scientific advice mechanism. The process is less predictable and prolonged, as it takes two to six months [3] for the NB to issue a Notified Body Opinion (NBOp). Furthermore, lifecycle management and submissions face added uncertainty, which is detailed below.

Figure 1



Key Challenges and Gaps

The following section addresses critical challenges and proposes targeted improvements to the EU regulatory pathway, aiming to reduce the regulatory burden, improve time-to-market, and restore the EU's competitiveness as a first choice for launching innovative iDDC products.

The lack of harmonized, fit-for-purpose regulatory guidance has led to divergent interpretations and inconsistent practices across authorities. Key regulatory areas — such as compliance with the GSPRs and change management procedures — suffer from the absence of standardized, coherent processes. This results in regulatory inefficiencies, unpredictable submission outcomes, and delays in bringing iDDC products to market.

While EMA's 2025 Q&A guidance [3] provides partial clarification, it does not fully align with existing guidance documents such as MDCG 2020-3 [4], particularly concerning post-approval changes. Without official EMA-issued guidance, industry stakeholders have relied on documents from the European Federation of Pharmaceutical Industries and Associations (EFPIA), Parenteral Drug Association (PDA) and other industry associations. These documents also point to lack of regulatory clarity.

One responsible entity:

Alignment between MDR and Directive 2001/83/EC [5] requirements would help eliminate regulatory silos and reduce complexity. Establishing a "one responsible entity" system supported by standardized tools and consistent regulatory interactions would streamline submission pathways for iDDCs. Early regulatory clarity is essential to enable timely development and ensure patient safety. Additionally, aligned guidance is needed for evaluating and documenting drug-device interactions — including variation procedures and GSPR compliance — to ensure consistent and efficient assessments across all submissions.

For iDDC products, GSPR compliance lacks regulatory alignment e.g. some GSPRs are covered by medicinal product regulation, some by medical device regulation, while others are partially applicable, leading to uncertainty in compliance expectations. Establishing formally endorsed GSPR guidance for iDDC products would provide a better overview of compliance expectations and lead to less variation in interpretations among stakeholders, more efficient reviews, aligned conclusions and ultimately shorter submission reviews and faster approvals.

Scientific advice:

Access to scientific advice that covers both the medicinal and device aspects of combination products is limited. NBs are prohibited from offering consultations, and EMA support is generally confined to pharmaceutical issues only. This absence of integrated advisory support leaves MAHs without a viable forum for resolving complex development questions that span both domains. A centralized, cross-agency advisory model would improve transparency and predictability, align expectations, and make the EU more attractive as the first choice for launching new and innovative iDDC products.

Life cycle change management:

How to handle life cycle change management remains inconsistent. EMA's Q&A guidance [6], Team NB's position paper [7] and MDCG 2020-3 rev.1 [8] offer diverging interpretations of when a new or revised NBOp is required. Additionally, the lack of aligned definitions/interpretation across NBs and with EMA provides an uneven playing field for the industry regarding e.g. post-approval changes. A cross-sectoral section on combination products into an updated change guidance as required by NBCG-MED to replace MDCG 2020-3 rev. 1 and NBOG 2014-3 [9] which provides clarity on change typing and the appropriate routes for post approval changes would significantly improve predictability for how to handle change and help ensure consistency.

Platform approach:

Many medicinal products are administered using the same device platform(s). As a result, identical or highly similar device constituent parts are often subject to repeated reviews by different NBs and EMA/NCAs, leading to regulatory inefficiencies. EFPIA's Reflection Paper [10] proposes a more efficient regulatory pathway for iDDC products by introducing the concept of a platform design space. This model allows multiple medicinal products to leverage a common device platform, minimizing redundant assessments under EU MDR Article 117.

The proposed approach involves defining platform-level fixed and variable parameters (e.g. viscosity, fill volume and injection time), and using surrogate testing to demonstrate performance across the range. This evidence enables leveraging the NBOp from one product to others on the same platform - accelerating review timelines, reducing duplicative work, and improving patient access to treatments - without compromising safety.

Conclusion / Call for Action

The current fragmented regulatory landscape in the EU impacts innovation of iDDC products negatively, it delays patient access and adds avoidable complexity for developers. To maintain Europe's global standing in healthcare innovation, there is an urgent need for the EU to transition towards a centralized and integrated regulatory framework for iDDCs.

We urge the European Commission and the regulatory bodies to take the following actions:

- **Appoint a single accountable authority for iDDCs:** Designate one EU body to lead and coordinate end-to-end review and lifecycle oversight. A single owner eliminates duplicate assessments and conflicting interpretations, shortens review cycles, makes timelines predictable and EU competitive leading to early patient access to innovative iDDC products in EU
- **Enable Scientific Advice for iDDCs:** Provide joint scientific advice board where both medicinal and device component aspects of combination products can be addressed,

enabling early resolution of cross-domain questions and supporting efficient, evidence-based development.

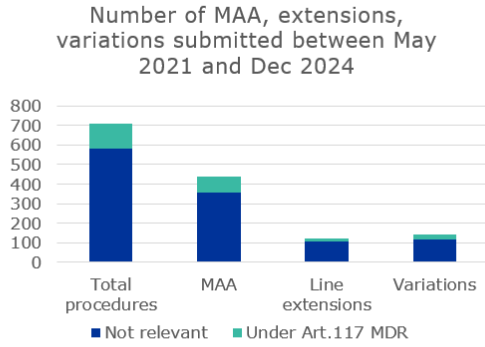
Implementing these changes will strengthen regulatory predictability, provide an aligned and competitive framework, streamline development processes, and accelerate patient access to critical and innovative therapies in EU. Immediate action is needed to align EU practices with global standards, promote transparent collaboration between regulators and industry, and re-establish Europe as a first choice for launching patient-centered healthcare innovations.

References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2. Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices
3. Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/746), 30 January 2025, Rev. 5 (EMA/37991/2019)
4. BSI paper: [MDR Article 117 Drug-device combination products application process](#)
5. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
6. Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Regulations on medical devices and in vitro diagnostic medical devices (Regulations (EU) 2017/745 and (EU) 2017/ 746) (Version 5.0, 2025)
7. Team NB, Position paper for the interpretation of device related changes in relation to a Notified Body Opinion as required under Article 117 of Medical Device Regulation (EU)2017/745
8. MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD
9. NBOG 2014-3 Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System, Nov 2014
10. EFPIA Reflection Paper: EFPIA Reflection Paper on Integral Drug-Device Combination Product Platform Approach (16/4-2021)

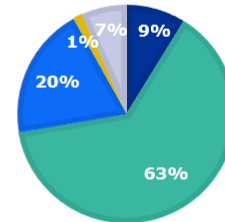
Appendix 1

EMA's experience on Art 117 applications



Risk class of the device part

■ I ■ IIA ■ IIB ■ III ■ not specified



- About **20%** of all procedures (126) **concerns integral drug-device combinations** (MDR Art. 117)
- Types of pharmaceutical forms: pre-filled syringe, pre-filled pen/autoinjectors, inhaler (1), sprays (2), applicator for implant (1).
- NBOP provided for class I (5 cases where DoC provided).

Mere innovationsvenlige regulatoriske rammevilkår for den europæiske medicobranche: Seks tiltag, der kan styrke medicobranshens konkurrencekraft

Den europæiske medicobranche er en af Europas vigtigste styrkepositioner, der gennem udvikling, produktion og markedsføring af innovativt og patientsikkert medicinsk udstyr, herunder en lang række digitale sundhedsløsninger og kunstig intelligens, bidrager til at robustgøre og fremtidssikre sundhedsvæsener både lokalt og globalt.

Men medicobranshens sektorspecifikke regulering i EU i form af MDR og IVDR er desværre blevet et kerneeksempel på, hvordan unødvendigt bureaukrati og lange certificeringsprocesser kan mindske den europæiske konkurrencekraft, uden at det skaber øget værdi for patienter, klinikere eller samfund, fordi reguleringen på flere områder er uforholdsmæssig uforudsigelig, omkostningstung og bureaukratisk.

I dette position paper præsenterer Medicoindustrien seks anbefalinger til, hvordan en innovationsdrevne revision af MDR og IVDR kan styrke medicobranshens konkurrencekraft og sikre patienters adgang til de nyeste og mest moderne sundhedsteknologiske løsninger.

Mere innovationsvenlige regulatoriske rammevilkår for den europæiske medicobranche: Seks tiltag, der kan styrke medicobranchens konkurrencekraft

Kort om medicobranchen

Den europæiske medicobranche er en af Europas vigtigste styrkepositioner, der gennem udvikling, produktion og markedsføring af innovativt og patientsikkert medicinsk udstyr, herunder en lang række digitale sundhedsløsninger og kunstig intelligens, bidrager til at robustgøre og fremtidssikre sundhedsvæsenet både lokalt og globalt. Samtidig er industrien vital for europæisk økonomi, beskæftiger 930.000 personer i Europa alene i den primære industri og står som branche for 15.700 patentansøgninger årligt.¹

Medicinsk udstyr reguleres på europæisk niveau af de to forordninger MDR (Medical Device Regulation) og IVDR (In Vitro Diagnostic Regulation). De to forordninger, der begge blev vedtaget i 2017, har strammet kravene til både fabrikanten af medicinsk udstyr og de bemyndigede organer, som certificerer udstyret. Derfor har branchen også støttet op om forordningernes tilblivelse og de intentioner, der ligger bag reguleringen.

MDR og IVDR har imidlertid været ramt af en række alvorlige implementeringsudfordringer, bl.a. grundet manglende kapacitet hos de bemyndigede organer til at certificere medicinsk udstyr i Europa, og de udvidede overgangsregler løber derfor nu til udgangen af 2028 for visse produkter, alt afhængig af risikoklasse. Forordningerne er samtidig blevet et kerneeksempel på, hvordan unødvendigt bureaukrati og lange certificeringsprocesser kan mindske den europæiske konkurrencekraft, uden at det skaber øget værdi for patienter, klinikere eller samfund, fordi reguleringen på flere områder er uforholdsmæssig uforudsigelig, omkostningstung og bureaukratisk.

På nuværende tidspunkt er den europæiske medicobranche så presset, at nye og innovative løsninger ofte lanceres i USA og Kina, før de introduceres for patienter i de europæiske sundhedsvæsenet, hvilket står i skærende kontrast til tidligere, hvor Europa var det marked, hvor de mest innovative sundhedsteknologiske løsninger blev lanceret først. Eksempelvis svarer 89 procent af større medicovirksomheder ifølge en rapport fra University of California og Boston Consulting Group fra 2022, at de foretrækker at lancere nyt, innovativt medicinsk udstyr i USA fremfor EU fremadrettet som følge af MDR og

¹ MedTech Europe, Facts & Figures, 2025: <https://www.medtecheurope.org/wp-content/uploads/2025/09/medtech-europe-facts-and-figures-2025-digital.pdf>

IVDR.² Tallene bakkes op i en rundspørge blandt MedTech Europas medlemmer, hvor omkring 50 pct. af virksomhederne vil nedprioritere det europæiske marked i fremtiden.³

Europa-Parlamentet har med parlamentsresolutionen *P10_TA(2024)0028 Urgent need to revise the medical devices regulation* fra d. 23. oktober 2024 slået fast, at der er et akut behov for at revidere forordningerne for medicinsk udstyr, så det igen bliver attraktivt at udvikle, producere og markedsføre innovativt medicinsk udstyr i Europa, til gavn for europæiske patienter, sundhedsvæsener og den europæiske konkurrencekraft på medicoområdet. Sundhedskommissær Olivér Várhelyi har ligeledes meldt ud, at en revision af MDR og IVDR er afgørende, ligesom flere medlemslande, herunder Danmark, har agiteret for en innovationsdrevne revision af MDR og IVDR.

I Europa-Kommissionens europæiske life science-strategi, der blev offentliggjort d. 2. juni 2025, er området for medicinsk udstyr fremhævet som et af de områder, hvor Europa i størst omfang er i akut risiko for at miste konkurrencekraft til andre regioner, særligt som følge af de regulatoriske udfordringer. Derfor har Europa-Kommissionen også meddelt, at man forventer at lancere et udkast til en revision af MDR og IVDR d. 10. december 2025, der skal sikre mere konkurrencedygtige regulatoriske rammer for den europæiske medicobranche og samtidig sikre patienter adgang til de nyeste og mest moderne sundhedsteknologiske løsninger.

Det er nu centralt at gøre visionerne til virkelighed og skabe strukturerne for et mere innovationsvenligt regulatorisk framework for den europæiske medicobranche.

Overordnet formål med en revision af MDR og IVDR

Europæiske patienter skal have adgang til de nyeste, mest patientsikre og innovative sundhedsteknologier. Det kræver, at det er attraktivt for producenter og leverandører af medicinsk udstyr at udvikle, producere og markedsføre medicinsk udstyr i Europa.

Derfor er en revision af MDR og IVDR et centralt skridt på vejen til at styrke medicobranskens konkurrencekraft. Den langsomme, omkostningstunge og uforudsigelige certificeringsproces, der præger området for medicinsk udstyr i Europa i dag, har bidraget til at rykke udviklingen af innovativt medicinsk udstyr væk fra Europa.

² Boston Consulting Group & University of California, Interstates and Autobahns Global Medtech Innovation and Regulation in the Digital Age, 2022: <https://web-assets.bcg.com/8c/f0/06744e8848ea9654bbd0765bf285/bcg-interstates-and-autobahns-mar-2022.pdf>

³ MedTech Europe, MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation, 2022: <https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf>

Reguleringen har vist sig som en særligt tung og bureaukratisk belastning for de små- og mellemstore medicovirksomheder, der udgør mere end 90 pct. af den samlede europæiske medicobranche. En revision af MDR og IVDR vil derfor ikke alene styrke den samlede medicoindustri, men også understøtte, at det bliver mere attraktivt at være SMV i Europa.

Seks konkrete tiltag kan styrke den europæiske konkurrencekraft på medicoområdet

En kommende revision af MDR og IVDR bør sigte efter at gøre certificeringsprocessen for medicinsk udstyr i Europa mere smidig, mindre omkostningstung og – frem for alt – hurtigere.

Konkret bør følgende punkter adresseres i en innovationsdrevne revision af de to forordninger:

- **Gør certificeringsprocessen hurtigere, mere effektiv og forudsigelig samt mindre omkostningstung**

I dag skal virksomheder gennemgå en såkaldt overensstemmelsesvurdering, også kendt som "conformity assessment", før man kan markedsføre medicinsk udstyr eller diagnostiske produkter på det europæiske marked. Processen sikrer, at de produkter, der bringes på markedet, lever op til de gældende regler og høje patientsikkerhedskrav for medicinsk udstyr og in-vitro diagnostisk medicinsk udstyr. Graden af kontrol afhænger af produkternes risikoklasse: Jo højere risikoklasse, desto strengere kontrol.

EU-forordningerne for medicinsk udstyr blev udformet for at sikre et velfungerende indre marked i EU og en høj beskyttelse af patienter og brugere. Desværre har den nuværende regulering medført, at certificeringsomkostningerne er steget betragteligt, ligesom "time-to-market" er væsentligt forøget. Samtidig kan der være store forskelle i omkostninger og tidsforbrug på tværs af de bemyndigede organer, der certificerer udstyret.

Derfor bør processen gøres hurtigere, mere effektiv og forudsigelig samt mindre omkostningstung, særligt med hensyn til de små- og mellemstore virksomheder, der tynges af de administrative byrder, forordningerne har medført.

Konkret bør der etableres klare, ensartede og bindende tidsfrister for reviews i regi af de bemyndigede organer, den strukturerede dialog mellem virksomheder og bemyndigede organer bør styrkes, ligesom de bemyndigede organer bør forpligtes

til en større grad af gennemsigtighed ift. deres gebyrstruktur samt tidsrammer for produkt- og kvalitetssystemvurderinger.

Særligt ift. at forbedre mulighederne for dialog er en tidlig markedsdialog afgørende i relation til at fastlægge niveauet for forventninger til evidens og korrekt klassificering af udstyret. Dette bør bl.a. omfatte muligheden for at anmode om videnskabelig rådgivning både uden for – og som en del af – certificeringsprocessen. En tidlig dialog vil således kunne forbedre kvaliteten af indsendelser til overensstemmelsesvurdering og understøtte et mere effektivt system, der også kan gøre processen hos de bemyndigede organer mere smidig.

Et konkret eksempel på klassificeringsudfordringer i det nuværende system findes bl.a. ift. software til medicinsk udstyr, hvor MDR Regel 11 i nogle sammenhænge fører til overklassificering af lavrisiko-software til medicinsk udstyr (MDSW). Reglen kræver rutinemæssigt, at lavrisiko-applikationer klassificeres som mindst klasse IIa, hvilket indebærer inddragelse af et bemyndiget organ. Her vil en styrket tidlig markedsdialog ift. klassificering, bedre vejledning ift. implikationer af MDR Regel 11 samt en tydeligere risikobaseret tilgang kunne sikre en mere smidig proces.

- **Indfør en dedikeret fast track-procedure for breakthrough innovation**

I dag har Europa ingen dedikeret regulatorisk godkendelsesproces for såkaldt breakthrough innovation. Det betyder i praksis, at en helt ny og innovativ sundhedsteknologisk løsning, der kan opfylde kliniske behov, som ikke i dag er dækket tilstrækkeligt, får en lige så langsommelig certificeringsproces som andre medicotekniske produkter. I Europa eksisterer der med andre ord ikke en accelereret certificeringsproces, selvom produkterne er af stor sundhedsmæssig betydning.

Dette står i modsætning til de fast-track-systemer, der findes i EU for lægemidler og avancerede terapier, ligesom det konkret på medicoområdet stiller EU væsentligt ringere end andre regioner som USA, Japan og Australien, der alle har dedikerede fast track-procedurer for breakthrough innovation inden for medicinsk udstyr.

Konsekvensen ved manglende fast track-foranstaltninger er i et sundhedspolitisk perspektiv, at de nyeste innovationer bliver lanceret senere i Europa end på andre markeder, hvorved de nyeste innovationer når europæiske patienter senere, mens det i et erhvervspolitisk perspektiv betyder, at Europa er en mindre attraktiv region at lancere nye og moderne sundhedsteknologiske løsninger i.

Derfor bør der i regi af MDR og IVDR opbygges en infrastruktur, der fremmer udviklingen og optaget af de mest innovative medicotekniske løsninger i EU til gavn for patienter og klinikere. Her er en fast track-procedure for innovativt medicinsk udstyr et centralt element.

En fast track-procedure for breakthrough innovation bør udformes på en sådan måde, at den muliggør tidligere inddragelse af eksperter, klarere vejledning undervejs i certificeringsprocessen og løbende overvågning efter godkendelse, hvilket vil sikre et højt niveau af patientsikkerhed kombineret med en forbedret effektivitet, der er afgørende for at sikre den europæiske medicobranche konkurrencedygtighed i et globalt perspektiv.

Innovation i denne sammenhæng henviser både til banebrydende teknologier samt til iterative ændringer, der dækker et hidtil uopfyldt klinisk behov gennem at forbedre funktionaliteten og ydeevnen af eksisterende teknologier, herunder bl.a. softwareopdateringer, kortere servicetid samt mere interoperable tjenester. Det kan også omhandle løsninger, der tidligere er anvendt i en rent klinisk sammenhæng, men som nu kan benyttes i hjemmet.

- **Gør processen for produktopdateringer mere smidig**

I EU skal man som medicovirksomhed indhente forhåndsgodkendelse fra det relevante bemyndigede organ, når man ønsker at foretage væsentlige ændringer af et medicinsk udstyr eller en diagnostisk test. Det bemyndigede organ vil herefter vurdere, om ændringen påvirker det oprindelige certifikat.

Reglerne på området er tydelige, idet det jf. MDR og IVDR kun er væsentlige ændringer, som skal vurderes. I praksis kræver en lang række bemyndigede organer dog, at alle ændringer notificeres, også selvom det ikke er påkrævet i reguleringen, hvilket skaber en langsommelig og omkostningstung proces for produktopdateringer, der mindsker virksomhedernes incitament til at opdatere produkter på det europæiske marked.

Kravet om at notificere alle slags ændringer – selv mindre væsentlige – skaber desuden flaskehalse, der påvirker hele certificeringssystemets effektivitet og i sidste ende efterlader europæiske patienter og klinikere med forældede versioner af medicinsk udstyr, mens resten af verden bevæger sig fremad.

Overordnet set er den måde, reguleringen administreres på i dag, derfor for langsom og uflexibel til at understøtte den løbende udvikling, som er almindelig i medicobranche og netop burde komme patienter hurtigt til gavn. Systemet

understøtter derved ikke, at patienter løbende kan få en tidssvarende teknologiunderstøttelse, da nogle produkter bliver trukket tilbage eller ikke længere opdateret, fordi processen for produktopdateringer er blevet for kompleks, omkostningstung og uforudsigelig.

Derfor er det anbefalingen, at det tydeliggøres, at man alene bør implementere det, der kræves af EU-lovgivningen. Det betyder i praksis, at kun væsentlige ændringer, der påvirker sikkerhed, ydeevne og brugervenlighed samt forholdet mellem risiko og nytte, bør notificeres og vurderes af bemyndigede organer. Andre og mindre ændringer bør kunne kontrolleres via foruddefinerede kontroller, hvilket muliggør, at rutinemæssige forbedringer kan gennemføres effektivt og uden forsinkelser af hensyn til patienternes mulighed for at få de nyeste og mest innovative løsninger.

- **Fjern de forpligtende femårige recertificeringskrav for medicinsk udstyr på tværs af alle risikoklasser**

Medicinsk udstyr på det europæiske marked er underlagt en streng, løbende kontrol, herunder årlige audits, sikkerhedsrapporteringer, kliniske evalueringer og markante post market-surveillance-mekanismer såsom Periodic Safety Update Reports, Post Market Clinical Follow-up og krav om indberetning af hændelser.

Det sikrer, at medicinsk udstyr på det europæiske marked følges tæt, efter at udstyret er blevet certificeret, ligesom de bemyndigede organer, der overvåger udstyret, til enhver tid kan suspendere eller tilbagekalde certifikater på baggrund af relevant dokumentation.

Til trods for den tætte markedsovervågning er det i dag et krav, at alt medicinsk udstyr skal recertificeres hvert femte år. Femårige recertificeringskrav er et unødvendigt og bureaukratisk regulatorisk greb, der ikke fremmer patientsikkerheden, men alene gør certificeringsprocessen omkostningsfuld og hæmmer virksomheders incitamenter til at videreføre eksisterende medicinsk udstyr på det europæiske marked.

Derfor bør de forpligtende femårige recertificeringskrav for medicinsk udstyr fjernes på tværs af alle risikoklasser.

Nye data fra Gesundheit Österreich fra 2025 illustrerer, at de nuværende recertificeringskrav også udgør en trussel mod tilgængeligheden af løsninger på det europæiske marked i en bredere forstand, fordi de nuværende krav vil skabe flaskehalse i de kommende år. På grund af certifikatudløb vil den første cyklus af

recertificeringer toppe i 2027 og 2028 samtidig med, at man må forvente en høj efterspørgsel efter nye certifikater.⁴

Tager man ikke et opgør med de nuværende recertificeringskrav, er det forventningen, at der kan opstå flaskehalse cyklisk hvert femte år.

- **Styrk governancen af MDR og IVDR**

Der mangler ensartethed i de guidances og fortolkninger af reguleringen, som medicovirksomheder og bemyndigede organer skal agere efter, hvilket skaber usikkerhed og bidrager til en ineffektiv certificeringsproces. Derfor er der et stort behov for at styrke governancen af MDR og IVDR.

I en branche, der alene i Europa dækker over 500.000 forskellige typer af medicinsk udstyr og på globalt plan markedsfører op mod to millioner typer af udstyr, vil det kræve en meget stor og vidtgående strukturændring, hvis man vil ændre certificeringssystemet fra en lang række specialiserede bemyndigede organer til én enhed, der certificerer alt medicinsk udstyr. Det fungerer på EU-niveau på lægemiddelområdet i form af EMA, der godkender lægemidler, fordi man her har langt færre typer af produkter, men det er usikkert, om et centralt agentur vil kunne opbygge den tilstrækkelige kapacitet og dybdegående faglighed, som det kræver at certificere medicinsk udstyr.

Derfor anbefaler Medicoindustrien heller ikke, at der som udgangspunkt etableres en central aktør, der skal certificere alt medicinsk udstyr på det europæiske marked. Den rolle bør fortsat ligge hos de bemyndigede organer, som hver især har deres specialkompetencer. I stedet er det anbefalingen, at der etableres en central instans, der dedikeret kan varetage rollen omkring udpegning og overvågning af de bemyndigede organer, og som kan udstede entydig guidance, således de bemyndigede organer administrerer MDR og IVDR ensartet på tværs af Europa. Det vil styrke effektiviteten i certificeringsprocessen uden at skulle opbygge en ny struktur.

En central instans vil desuden på sigt kunne varetage EU's forpligtelser og interesser i det internationale samarbejde, herunder bl.a. i IMDRF og MDSAP, hvor Europa-Kommissionen i dag repræsenterer EU.

⁴ Gesundheit Österreich GmbH, 2025, Evaluation of the implementation of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) – 2nd European Operators Survey

- **Gør godkendelsesprocessen for kombinationsprodukter mere effektiv**

Der eksisterer i dag en del regulatoriske udfordringer for de virksomheder, som producerer lægemidler, hvor der indgår et device, da de i dag er underlagt en tung proces jf. MDR art. 117 og lægemiddellovgivningen. Disse såkaldte *integrale drug-device combination products (IDDC'er)* er produkter, der kombineret et lægemiddel og et medicinsk udstyr i ét samlet produkt såsom præfyldte penne, præfyldte inhalatorer og præfyldte sprøjter.

Det fragmenterede regulatoriske framework for disse produkter betyder, at der mangler retningslinjer samt en klar opdeling af ansvarsområder mellem Det Europæiske Lægemiddelagentur/nationale kompetente myndigheder og bemyndigede organer, hvilket resulterer i regulatorisk ineffektivitet og uforudsigelige udfald af ansøgninger. Desuden forsinker den nuværende regulatoriske ramme patienters adgang til behandlinger og øger den administrative byrde ved at skulle dokumentere overholdelse gennem hele produktets livscyklus.

Her kunne én ansvarlig enhed have en koordinerende rolle, således at man som fabrikant ikke bliver kastebold mellem to systemer. Det vil gøre den samlede proces mere gennemskuelig, reducere kompleksitet og dermed sikre hurtigere "time to market". Det er helt afgørende, at en central aktør har adgang til specifikke kompetencer og en høj grad af faglighed på det medicotekniske område samt på lægemiddelområdet – samt snitfladerne mellem mellem udstyret og lægemidlet.

Konkret anbefaler Medicoindustrien:

- **Etabler én ansvarlig myndighed for integrale drug-device-combination-products**

Udpeg et EU-organ til at lede og koordinere den samlede vurdering og livscyklusovervågning for integrale drug-device combination products. Myndigheden skal have dyb faglighed på det medicotekniske område samt på lægemiddelområdet. En enkelt ansvarlig myndighed vil eliminere risikoen for modstridende fortolkninger og forkorte godkendelsesprocessen, gøre tidsestimater forudsigelige og derved bidrage til at styrke EU's konkurrenceevne på området for integrale drug-device combination products.

- **Muliggør videnskabelig rådgivning for integrale drug-device combination products**

Etabler et fælles videnskabeligt rådgivende udvalg, der omfatter både lægemiddel- og udstyrskomponenterne, så tværgående spørgsmål kan afklares tidligt og en effektiv, evidensbaseret udvikling understøttes.

Implementeringen af disse ændringer som led i revisionen af MDR og IVDR vil styrke den regulatoriske forudsigelighed, skabe en harmoniseret og konkurrencedygtig ramme, strømline udviklingsprocesser og fremskynde patienters adgang til innovative behandlinger i EU på området for integrale drug-device combination products.