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Innovation only makes a difference when systems are ready to adopt it.

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From operating theatres to national policy forums, Mads Koch Hansen has spent his career at the intersection of clinical care and healthcare innovation. Now leading Denmarkâ??s medtech industry association, Medicoindustrien, he draws on this diverse experience to champion a more integrated, forward-looking approach to health technology. In this wide-ranging conversation, Hansen explores how Denmark can harness AI-driven tools, smarter regulation, and value-based procurement to deliver care closer to patients and cement its role as a European medtech leader.

What experience do you bring to your role at MedicoIndustrien, and how has it shaped your approach to leading the organisation?

I trained as a medical doctor and spent 18 years in clinical practice, primarily as an anaesthesiologist working across operating theatres, intensive care units, and emergency outreach. My early leadership role as head of department at a smaller hospital sparked a strong interest in innovation; we helped develop a digital system to manage operating theatres, based on a PhD project from Aarhus University, which was adopted nationwide within two years. This experience demonstrated the speed and scale at which meaningful health technologies can be deployed when needs and solutions align.

My perspective widened further during my five years as president of the Danish Medical Association, where I engaged with ministers and policymakers on system-wide reform. Later, as Chief Medical Officer of a hospital, I focused on embedding innovation and using data more systematically to drive quality. While Denmark has extensive health data, we are still learning how to translate it into meaningful improvements for patients, providers, and industry alike.

When the COVID-19 pandemic struck, I remained in a hospital leadership role, overseeing major operational shifts at pace. Afterwards, I stepped into independent consulting before taking up my current position at MedicoIndustrien. At first, it seemed an unexpected move, but I quickly recognised the opportunity to act as a bridge, translating between the needs of the healthcare system, the priorities of patients, and the solutions emerging from industry. That translation is essential as reforms continue across Europe, and in many cases, technology will be the key to making them work.

What are the key roles and activities of Medicoindustrien in supporting Denmarkâ??s medtech ecosystem?

MedicoIndustrien represents close to 90 percent of medtech companies with commercial operations in Denmark, comprising around 230 members. These include both long-established manufacturers â?? such as Coloplast, Ambu, and Ferrosan â?? and a significant number of start-ups and small enterprises taking their first steps in the market. Even pharmaceutical companies like Novo Nordisk are active members, given the medtech components in products like their insulin pens.

Our primary aim is to support our members by fostering collaboration, facilitating knowledge exchange, and providing a strong, unified voice on shared challenges. We operate 22 expert groups, where professionals from across the sector â?? particularly in R&D and regulatory affairs â?? come together to discuss common obstacles and interpret complex regulatory frameworks. These forums are strictly non-commercial in nature, focused instead on helping members navigate operational and compliance hurdles. In parallel, we convene groups that address broader commercial topics while maintaining a clear boundary around tender-specific discussions.

We also act as an interlocutor between the industry and the regional health authorities that oversee procurement and hospital services in Denmark. By raising principle-level issues on behalf of our members, we offer public-sector stakeholders a structured, non-commercial partner with which to engage. Beyond this, our advocacy efforts led by our chairman, Rasmus Holter Le Fevre, extend to wider industry priorities, including accelerating the adoption of breakthrough technologies in hospitals and strengthening Denmarkâ??s positioning as a medtech innovation hub. In all these activities, we seek to support not only our members, but also the health system as a whole.

How would you assess the current state of Denmarkâ??s medtech sector and its role within the broader economy?

Medtech is a critical component of Denmarkâ??s healthcare and industrial landscape, yet it has traditionally received less visibility than the pharmaceutical sector, whose size and influence often place it at the forefront of public and political attention. This disparity has also extended to industry representation, where medtech, despite its growing relevance, has at times remained in the background.

Today, the sector directly employs around 16,000 people, with many more working across the broader network of suppliers and service providers. Although detailed economic figures are somewhat dated, the industry is clearly expanding. At the European level, medtech and pharma are broadly equivalent in employment terms, each supporting approximately 900,000 jobs, but their structures differ substantially. Medtech is largely built around small and medium-sized enterprises, while pharma tends to be dominated by major multinationals, often through consolidation.

This distinction is reflected in industry associations as well. MedicoIndustrien represents more than 230 companies, while Lif, the Danish pharmaceutical association, includes far fewer due to the concentration of large players in that space. For us, it is essential â?? particularly in European policy discussions â?? to ensure that the voices and needs of smaller and mid-sized medtech companies are fully understood and not lost in broader narratives shaped by larger actors.

To what extent does Denmarkâ??s Life Sciences Strategy reflect the needs of the medtech sector, and what are the most urgent priorities it must address?

This latest iteration of the Life Sciences Strategy marks a clear improvement in terms of recognising the medtech sectorâ??s role and priorities. Unlike previous strategies, which were more heavily weighted toward pharmaceutical interests, the current version gives medtech a much stronger voice, something we have worked actively to secure.

The most critical issue now reflected in the strategy is the need for reform of the European Unionâ??s Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). After nearly a decade in development, these frameworks have introduced substantial barriers to market access across Europe. As a result, many companies are looking to the United States or Asia as more viable alternatives due to their clearer and more predictable regulatory processes. It is encouraging that Denmark has committed to advocating for change at the EU level as part of its national strategy.

This problem is not merely procedural, it strikes at the heart of Europeâ??s promise of a single market. As the Draghi report highlights, what we call a common market is in reality a collection of 27 separate systems. Each country interprets and implements the rules differently; in Denmark alone, five regional health authorities may apply the same regulation in slightly different ways. To make Europe competitive again, we need more than unified regulation, we need consistency in how that regulation is interpreted and enforced. That is the only way companies can bring innovation to patients across borders without unnecessary delay or duplication.

How does Denmark compare to other markets in terms of medtech competitiveness, and what changes are needed to improve innovation access?

Denmark is widely regarded as a diligent rule-follower, often implementing national and European regulations to their fullest extent, sometimes more strictly than required. While this reflects a strong regulatory culture, it also creates barriers for medtech companies, particularly those seeking to bring new technologies to market. Over-implementation makes it difficult to establish Denmark as a production hub or testbed for innovation, and this rigidity ultimately affects patients, who may be left without access to the latest medical technologies.

One of the most significant bottlenecks lies in the European CE marking process. The approval system, overseen by Notified Bodies, is not only costly but also lacks transparency and predictability. Companies can wait years for a decision without knowing whether their product will be approved, or

what changes are needed if it is not. By contrast, the US Food and Drug Administration offers a more structured approach: companies engage early, receive clear guidance, and typically obtain an answer within 180 days. Europe should not only aim to match this efficiency but set a new benchmark for responsiveness.

Several changes are urgently required. The mandatory five-year recertification of all devices should be reconsidered in light of robust post-market surveillance systems. More importantly, approval timelines must be shortened and made predictable. When applications are rejected or delayed, companies deserve clear, actionable feedback. Transparency and time certainty are not luxuries; they are prerequisites for enabling innovation. If European healthcare systems are to evolve, as they must, patients need timely access to the best technologies available. Regulation must be a safeguard, but also a facilitator.

How would you assess the current state of medtech clinical trials in Denmark, and what steps are needed to strengthen collaboration and ensure long-term growth?

Denmark offers a strong foundation for medtech clinical trials, built on trusted relationships between companies and clinical professionals and anchored by leading institutions like Rigshospitalet in Copenhagen. These partnerships provide a valuable platform for testing and refining technologies in real-world settings, ultimately benefiting companies, hospitals, and patients alike. However, cost remains a significant barrier, particularly for small and mid-sized firms. The regulatory fees required by the Danish Medicines Agency place a disproportionate burden on smaller players, even though larger pharmaceutical companies may absorb these costs with relative ease. Encouragingly, this issue is now recognised within the national life sciences strategy, and steps are being taken to ease the financial pressure.

While medtech trials are typically smaller in scale than pharmaceutical ones â?? owing to the nature of the technologies involved and the size of the companies â?? this does not diminish their clinical relevance. Devices often require surgical intervention or are implanted directly into the body, making large-scale studies impractical, but the impact of the results is equally significant. To sustain and expand this ecosystem, we need to move beyond transactional collaboration and toward more structured partnerships involving academia, clinical teams, and patients. Transparency and fairness are key to enabling these relationships. With the right frameworks in place, Denmark can further consolidate its position as a trusted hub for medtech innovation, where promising technologies can be evaluated rigorously and brought to market efficiently.

What impact will Denmarkâ??s healthcare reform, aimed at bringing care closer to patients, have on the medtech sector?

The healthcare reformâ??s objective to shift care from hospitals to community and home settings places medtech in a pivotal position. As clinical contact becomes more decentralised, technology becomes essential â?? not merely complementary â?? for maintaining safe, continuous care. Devices that enable remote monitoring, support self-management, and ensure timely clinical intervention are increasingly central to the success of this transition.

We already see this in areas such as diabetes, where AI-driven sensor and pump systems allow families to manage the condition with greater confidence and less disruption to daily life. Parents no longer need to constantly monitor their childâ??s blood sugar; instead, smart alerts prompt them only when necessary. This kind of technological support enables a near-normal routine and significantly

reduces the emotional and logistical burden of chronic disease.

In surgical care, Denmark has long led in shifting procedures to outpatient settings, but further progress will depend on technologies that support recovery beyond the hospital, tools that provide both patients and clinicians with the confidence that early discharge does not compromise safety. Similarly, in oncology, there is increasing potential for technology to address persistent effects of treatment, such as neuropathy or oedema, by enabling patients to manage symptoms more proactively at home.

Looking ahead, what changes do you hope to see in Denmarkâ??s healthcare system and in Medicoindustrienâ??s priorities?

Iâ??m encouraged by the recent agreement between the government and the regions for 2026, which secured DKK 4.2 billion (approximately USD 640 million) for modernising hospital infrastructure. My hope is that these funds are primarily channelled into adopting new technologies rather than simply upgrading facilities. The healthcare system must evolve towards a model in which hospitals focus on acute care â?? surgery and intensive treatment â?? while most other patient needs are addressed in community settings or at home.

This shift demands substantial investment in advanced technologies. Across the industry, we are seeing a wave of AI-powered solutions designed to relieve healthcare professionals of routine, time-consuming tasks. These tools allow clinicians to focus on analysing patient data, engaging in meaningful conversations, and providing guidance rather than spending time on repetitive processes. Their roles will not diminish but change, becoming more strategic and patient-facing.

Such innovations can also significantly improve patient autonomy. With wearable devices and remote monitoring solutions, individuals with chronic conditions can manage their health from home, only requiring clinical input when alerts are triggered. Likewise, post-surgical patients can recover in a safe, monitored environment outside hospital walls.

Importantly, this evolution also holds the potential to ease the burden on overstretched healthcare staff. Technology should not accelerate their workload but help them care more effectively for a larger number of patients by quickly flagging those who require intervention. Many of the tasks currently performed manually in hospitals will eventually be automated, allowing healthcare workers to focus their expertise where it adds the most value.

Over the next five to ten years, these changes will be fundamental. Technology will not only reshape how care is delivered but will also underpin a more sustainable and responsive healthcare system.

What final message would you like to share about Denmarkâ??s medtech sector?

A key priority moving forward must be a shift from procurement based solely on price to one grounded in long-term value. While many purchasing decisions still default to the lowest-cost option, this approach fails to recognise the broader benefits that innovative technologies can deliver over time. A slightly higher initial investment often translates into improved outcomes for patients, more efficient healthcare delivery, and ultimately, greater societal benefit.

To make this shift meaningful, we also need to address the fragmented nature of market access across Europe. Todayâ??s patchwork of national systems and procurement rules creates unnecessary hurdles for companies and slows the adoption of innovation. A more unified European

framework that embraces value-based procurement would support faster access to cutting-edge solutions and strengthen the overall competitiveness of the medtech ecosystem.

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