



**LÆGEMIDDELSTYRELSEN**  
DANISH MEDICINES AGENCY

REVISED IN DECEMBER 2019

# The Danish Medicines Agency's strategy for medical devices



© Danish Medicines Agency, 2019.

You may cite the text in this publication provided that you clearly indicate that the text comes from the Danish Medicines Agency.

Any use of the images in the publication is not allowed.

Danish Medicines Agency  
Axel Heides Gade 1  
2300 Copenhagen S,  
Denmark  
dkma.dk

**Language**

English

**Version**

1.0

**Version date**

December 2019

# 1 Introduction

---

## **Our mission**

Effective, safe and accessible medicines and safe medical devices that benefit society

## **Our vision**

The Danish Medicines Agency: Among Europe's best in class

This means

- Active dialogue and collaboration – value to citizens
- Quality and on-time delivery
- Professional expertise and commitment – a fantastic place to work!
- Help boost Denmark as a leading life science nation
- Driver of European collaboration and a strong international position

Our culture and values support and guide our employees towards becoming Europe's best in class. Through collaboration, our performance and improvement culture allows us to consistently pursue our guiding values; and to be attentive, professional, efficient and European.

The Danish Medicines Agency's overall strategy and underlying sub-strategies describe how we will join Europe's best in class. The medical devices strategy contributes to this work.

In acknowledgement of the ongoing development in our field and the fact that many of the initiatives we launch within the scope of our strategy go beyond the current strategy period, we will be reviewing our strategy once a year. At this annual review, we will extend the period accordingly to ensure our strategy will be adjusted to the strategic challenges in the short and long terms. We will take an inside-out approach, among other things consisting of an external analysis and feedback from our stakeholders.

Our vision of becoming one of Europe's best in class was formulated at the end of 2017. At the time, we knew that several of our areas had to go through a consolidation and validation phase before we could take the leap into European excellence. As we approach 2020, we have both achieved consolidation and joined Europe's best in class on many parameters. For example, we are among the top five that take the most European licensing cases, and we rank third in the benchmarking of the 28 European medicines agencies in terms of organisational maturity. In other areas, we are still working to conclude our consolidation and validation process – our national review times are an example thereof.

Our goal of reaching a European best-in-class level is in many areas achieved through consolidation. It includes timely national assessment times, control and inspections at a level matching our risk-based approaches, full compliance with the pharmacovigilance standards as well as modernisation and simplification of our IT landscape. As 2019 comes to an end, we have come far with this consolidation.

The medical devices strategy contributes to this work. We have come far in the past years  
The Danish Medicines Agency's strategy for medical devices

with our development and goal fulfilment, but we are not there yet.

The medical devices area is undergoing a major transformation these years. New medical device regulations become effective in 2020 and will include stricter requirements for clinical investigations and notified bodies as well as reclassification of devices with corresponding increased requirements for certification and vigilance. Add to this that pharmaceutical development and medical technologies in several areas are approaching each other and in many cases are integrated and converged.

The rapid technological development within medical devices with wider use of artificial intelligence, health apps and other forms of advanced software requires of us as an authority that we follow and respond to this development. Our desire for strengthened market surveillance – with increased use of data and more data sources – requires a focus that is equally dedicated. The medical devices area must especially interact closely with our newly established Data Analytics Center (DAC) and other internal capacities within data analysis and use of artificial intelligence.

At the Danish Medicines Agency, we have started to massively grow our capacity within medical devices. At the beginning of 2017, about 12 employees were handling the medical devices area, but after we have finished recruiting staff, some 40 employees will be dedicated to the medical devices area in spring 2020.

To follow up on this transformation and development, we have drawn up a new medical devices strategy in response to the most important strategic challenges in the area.

## 2 About medical devices and the tasks of the Danish Medicines Agency

---

Medical devices comprise a wide range of products, which are primarily used for prevention, diagnosis, relief or treatment of diseases. Medical devices cover anything from glasses, contact lenses, hearing aids, dental crowns and wheelchairs to insulin pumps, pacemakers, knee or hip implants and heart-lung machines.

In addition, new medical devices are being developed continuously, including devices that break with existing frameworks, such as health apps, patient reported outcomes (PROs) and diagnostic tests for use in precision medicine, algorithms and artificial intelligence for diagnosis and decision support as well as artificial intelligence in the medical device itself.

The rapid development in the field of medical devices benefits both the public and society. It leads to new diagnostic and treatment possibilities, but also to more effective treatments – and thus better quality and patient safety for everyone. But there are also a number of challenges in terms of application, benefits and regulatory/ethical aspects.

The Danish Medicines Agency administers legislation in this area and is thus responsible for monitoring the safety of a medical device throughout its life cycle – from the first test in the healthcare service till removal from the market. We assess clinical investigations, monitor notified bodies, inspect companies, register companies and products, deal with medical device incidents, provide guidance on marketing and carry out market surveillance of medical devices.

Market surveillance of medical devices is a central element of the Danish Medicines Agency's focus on patient safety and the availability of safe medical devices for the people. Given the current technological and capacity-related development in the medical devices area, our resources will always be one step behind. We therefore take a risk-based approach to the surveillance of medical devices on the market – making sure to concentrate our efforts where patient safety will benefit the most.

In order to provide common standards and to support user safety, governmental regulation of medical devices is increasingly becoming a pan-European issue – and with global common areas and collaboration.

# 3 Strategic challenges

---

The most important strategic challenges of the Danish Medicines Agency in the upcoming strategy period will be to:

- strengthen the data-driven market surveillance of medical devices and the user safety simultaneously in step with the growing complexity and volume of medical devices
- strengthen our proactive and explorative approach to the technological development, whereby we will use our improved technological overview, appropriate competencies and strategic collaborations to enhance the opportunities for responsible use of new technologies, including the provision of better advice to the healthcare system and the industry
- ensure the effective implementation of new EU regulations
- ensure a close collaboration between the medical devices and the pharmaceutical areas with a view to handling the technological and scientific convergence of new technologies and new medicines/advanced therapy forms
- improve our influence in the EU on the path to become a key driver in Europe

We will continue to expand and develop data applications (including registry data) for our detection of trends and tendencies in medical device incidents so that we can respond early and proactively.

A stronger regulation of medical devices requires resources and close coordination between the European government authorities, e.g. to handle the necessary joint inspections of notified bodies and provide a consistently high quality in the inspection of medico-technical companies. Through strengthened European commitment and influence in the EU, the Danish Medicines Agency can contribute (even) more actively to the patient safety of the Danish population, and on the international scene, as well as strengthen Denmark's position within *life science*.

# 4 Objectives and focus areas

---

To respond to the strategic challenges, priority will be given to the five areas listed below.

## 4.1 Effective market surveillance for the benefit of the public and society

We will enhance our overview and identify trends and risks associated with medical devices, including in vitro diagnostic devices. To gain such overview, we will need to strengthen our data-driven approaches and exploit emerging digital opportunities and potentials. In the strategy period, the available data must be strengthened to enable active monitoring of the safety related to the use of medical devices.

The surveillance implies that we react on trends and follow up on problems associated with medical devices at hospitals, in medical practices, in municipalities and other healthcare providers.

We have started collaborations with relevant players to identify information and potentials of the national implant register, in the specialised nationwide clinical quality databases, in the Danish Patient Safety Database (DPSD) and in several other information systems. We will continue to pursue the opportunities in existing as well as new registers in the healthcare area.

The establishment of a strengthened data basis will take place in close collaboration with the Data Analytics Center of the Danish Medicines Agency.

It is expected that the new EU regulations will provide the framework for the common European database, EUDAMED, and contribute to improved surveillance of products on the European market.

Our reinforced data-driven approach will enhance our overview and improve the accuracy of our vigilance and market surveillance, thus strengthening our risk-based approach.

Our journey towards a more data-driven market surveillance will take place on the basis of a responsible application of data, giving high priority to data-ethical standards. The public can and should be comfortable about the way we use data.

Our aim is to exploit, in a responsible manner, the potentials of registers and other relevant data sources to strengthen the vigilance and market surveillance of medical devices so that the public will experience the least possible errors, failure and defects related to medical devices.

## 4.2 Strengthened dialogue, vision and collaboration with device users

Close dialogue with the outside world and collaboration partners is essential to our work, and attentiveness is one of our core values at the Danish Medicines Agency.

We wish to strengthen existing collaborations and build up new collaborations and partnerships with healthcare professionals, the public, scientific societies and other authorities, nationally as well as internationally. We will present ourselves as our customers' most important entry point when it comes to medical devices, so that we will continuously hear of suspicions and 'yellow flags' in relation to medical devices.

In the strategy period, we will focus on what we can do to ensure we interact more with the patients/the public, including how we can communicate and gather relevant information on safe medical devices.

Our strengthened dialogue and communication will also include campaigns and other communication forms – including optimised digital user interfaces – targeting the relevant players to tell them about the duty to and importance of reporting medical device incidents.

Citizens' and healthcare professionals' increasing demand for trends and tendencies with selected types of medical devices will also be covered by the strengthened communication.

The objective is to give the Danish Medicines Agency, via a strong customer focus, dialogue and partnerships with key stakeholders, a strengthened knowledge base through which to promote the safety of medical devices.

#### 4.3 A proactive and explorative organisation, supporting the digital and technological development

The technological development of medical devices is rapid, and correspondingly the volume of data and capacity to process data have grown exponentially.

The development holds new opportunities for the development of new medical devices, for market surveillance of devices and the access to relevant data in our work to ensure medical devices are safe. But the development is also a challenge when we look at how we traditionally have acted as an authority, and the development could move quicker than the area's legal framework and the current procedures for approving medical devices. It is a strategic challenge not only to shape the *content* of the new regulation, but also to keep pace *procedurally* with the developmental dynamics in relation to algorithms, computing power, materials, etc.

For our authority to be at the forefront of development, we must be proactive and explorative as an organisation. We must be ready to adapt and change in step with development.

We must specifically build up knowledge, networks and capacity within artificial intelligence, wearables and other areas in which medical devices are linked with new and advanced software solutions. Throughout the strategy period, we will identify trends, reach out to relevant knowledge environments as well as develop and recruit the needed capacity within data and technology.

The objective is for the Danish Medicines Agency to have a proactive and explorative organisation that supports and uncovers the opportunities in the technological development within artificial intelligence, advanced software and other areas of development to find out how the new technologies can promote safe medical devices and strengthen patient treatment in a safe and ethically responsible manner.

## 4.4 Increasing impact on the European agenda

We will ensure the implementation of the new regulations on medical devices and in vitro diagnostic devices taking effect in 2020 and 2022.

The regulations should strengthen the protection of EU citizens' health and safety related to the use of medical devices, and support innovation. The regulations set new requirements for both national authorities, notified bodies, industry and the collaboration across authorities in Europe.

We must exert influence in the EU working parties, in relation to the Commission and in EU networks to impact the regulation and interpretation of the new regulations for the benefit of Danish citizens. It is essential that Denmark contributes with resources and strengths in the European collaboration. This is particularly relevant in the control and monitoring of notified bodies, the data-driven market surveillance and clinical investigations.

This will strengthen the safety of medical devices and make it possible to offer guidance to both the health service and industry.

The market for medical devices is global, and our vision and collaboration go beyond Europe. Also on the global scene will we look for collaboration opportunities and discuss mutual challenges and learn from each other.

The objective is for the Danish Medicines Agency to be a driving force in the European collaboration and take leadership in the development and implementation of the new regulatory framework. However, we also want the agency to go even further and to continuously question if the existing framework for approval and market surveillance of medical devices is appropriate to the technological development and the public's expectations in the area.

## 4.5 Supporting the access to safe medical devices for patients and public

The public and the healthcare professionals should have continuous access to new and innovative high-quality medical devices. We will work to minimise the risk of supply failure – whether due to the capacity of the notified bodies, Brexit or other circumstances – through a quick and flexible review of exemptions for market access. Likewise, we will support early discussions with other relevant players in the healthcare system when there are supply challenges, including offer regulatory guidance.

Innovation in Danish life science is beneficial for both the public and the industry. We will support an optimal framework for the development of innovative medical devices, and we and the industry have a mutual interest in always ensuring the availability of high-quality medical devices and keeping the market free of dubious and at times dangerous products.

The Danish Medicines Agency will provide guidance to companies and researchers about the opportunities within the applicable legislation on clinical investigations and access to the market.

The objective is for the Danish Medicines Agency, in a wider context, to work for the availability of safe medical devices on the Danish market. Close dialogue and collaboration with the industry and research environment are key elements for fulfilling this.

# 5 Overall delivery plan in the strategy period

---

The strategy's objectives and focus areas build on the present approach, and overall it will strengthen the Danish Medicines Agency and help us achieve a leading position in Europe. The implementation of the above efforts will be a considerable and ambitious quality improvement and will contribute significantly to safe medical devices on the market.

The strategy is translated into local action plans annually that will lead to a number of deliveries over the coming years. The central deliveries in the strategy period are to:

- establish a Danish database for active monitoring of the safety related to the use of medical devices. The data basis must be continuously expanded throughout the strategy period and be linked to EUDAMED once that has been implemented.
- ensure a substantial expansion of expertise in areas such as artificial intelligence, advanced data analysis, etc.
- strengthen existing collaborations and build up new collaborations and partnerships with healthcare professionals, patient organisations, scientific societies and other authorities.
- build up a proactive and explorative organisation that supports and uncovers the opportunities in the technological development within artificial intelligence, advanced software and other areas of development
- continue to be a driving force in the EU collaboration and take leadership in the development and implementation of the new regulatory framework for approval and market surveillance of medical devices
- ensure access to medical devices in Denmark and maintaining a close dialogue and collaboration with the industry and research environments to jointly ensure that safe high-quality medical devices are on the market.