

Innovation & Safety

Regulation of digital medical devices (MDR)

OffDig Health – Aarhus 2024

**Thomas Wejs Møller, Senior Director, RA Device,
Novo Nordisk A/S**

Together we are life-changing

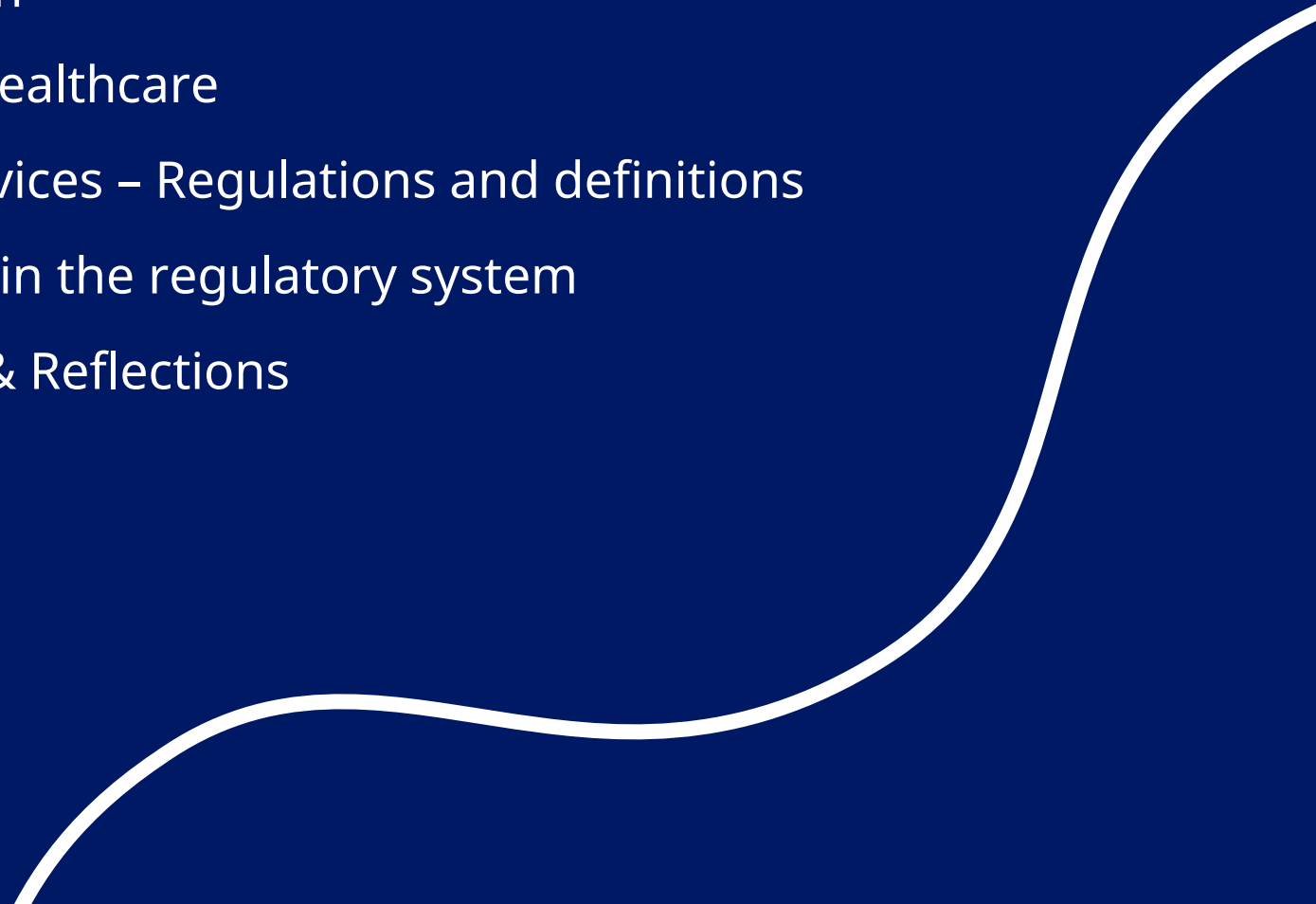
2 March 2024



Agenda



- Introduction
- Trends in Healthcare
- Medical Devices – Regulations and definitions
- Challenges in the regulatory system
- Questions & Reflections



Introduction




Thomas W. Møller

Senior Director, RA device

Novo Nordisk

Previous:

- Director of Device Division – Danish Medicines Agency
- Member Medical Device Coordination Group (MDCG)
- Elected chair of the Competent Authorities for Medical Devices (CAMD) executive group (CEG)

Novo Nordisk at a glance

Supplier of nearly
50%
of the world's insulin

Net sales
232.3
billion DKK

Affiliates in
80
countries

About
64,319
employees

Total tax contribution
51
billion DKK



R&D centres
in China, Denmark,
India, UK and US



Strategic production
sites in Denmark, Brazil,
China, France and US

Globally, serving
41.6
million people living with
diabetes and obesity

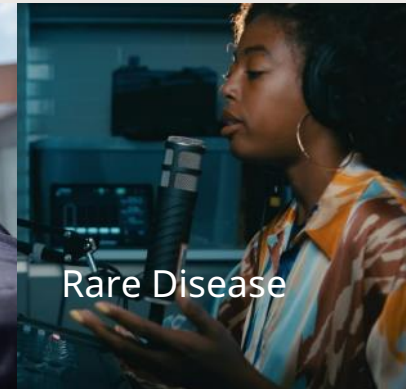
Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark.

Our purpose is to drive change to defeat serious chronic diseases, built upon our heritage in diabetes.

We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease.



Cardiovascular & Emerging
Therapy Areas



Rare Disease



Obesity

A top five
pharma company measured
by market value¹



Diabetes

Digital health solutions

We employ digital technology to help people receive the maximum therapeutic benefit from our medicines.

Novo Nordisk partners¹



Glucose data from BGM or CGM³



Dose data from smart pens⁴ NovoPen[®] 6⁺/NovoPen Echo[®] Plus

Available in **30 countries**

Mallya[®] to turn disposable pens into a smart device⁹



Tracks how much insulin was taken and when



Dose guidance from digital therapeutics e.g. regulated titration apps such as Dose Check¹⁰

Available in **4 countries**



(Combined) Data offer new insights into diabetes management

Real-world evidence from Swedish pilot, assessing dose logging data enabled by smart pens⁵

Novo Nordisk smart insulin pens led to...

43%

fewer missed meal-time insulin injections⁶

+2h

every day in good glucose control⁷

5D aspiration towards patient-focused product development

integrating drug, device, diagnostic tools, digital solutions, and data utilisation



With the **patients in focus**, to meet the current and projected future unmet needs and expectations

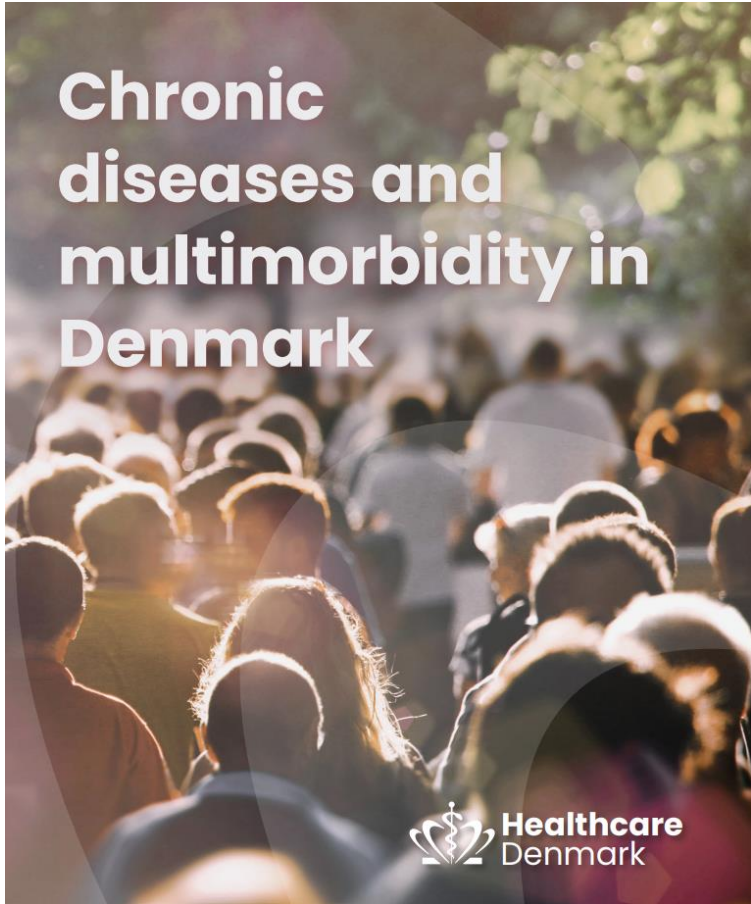


We develop One product where the **Drug**, the **Device**, the **Diagnostic tool**, the **Digital solution**, and the **Data utilisation** is fully integrated in **One project**



Within a framework of social, environmental, and financial **sustainability**.

Trends in Healthcare



Foreword

In Denmark, the number of people living with one or more chronic diseases has increased in recent years and is likely to increase even further towards 2030. To meet this challenge, the Danish Government has launched several initiatives. They represent our belief in and commitment to multisector collaboration, the patient-centred approach, digitalisation, and integrated care.



Expenditure based on number of chronic diseases¹⁰ DKK

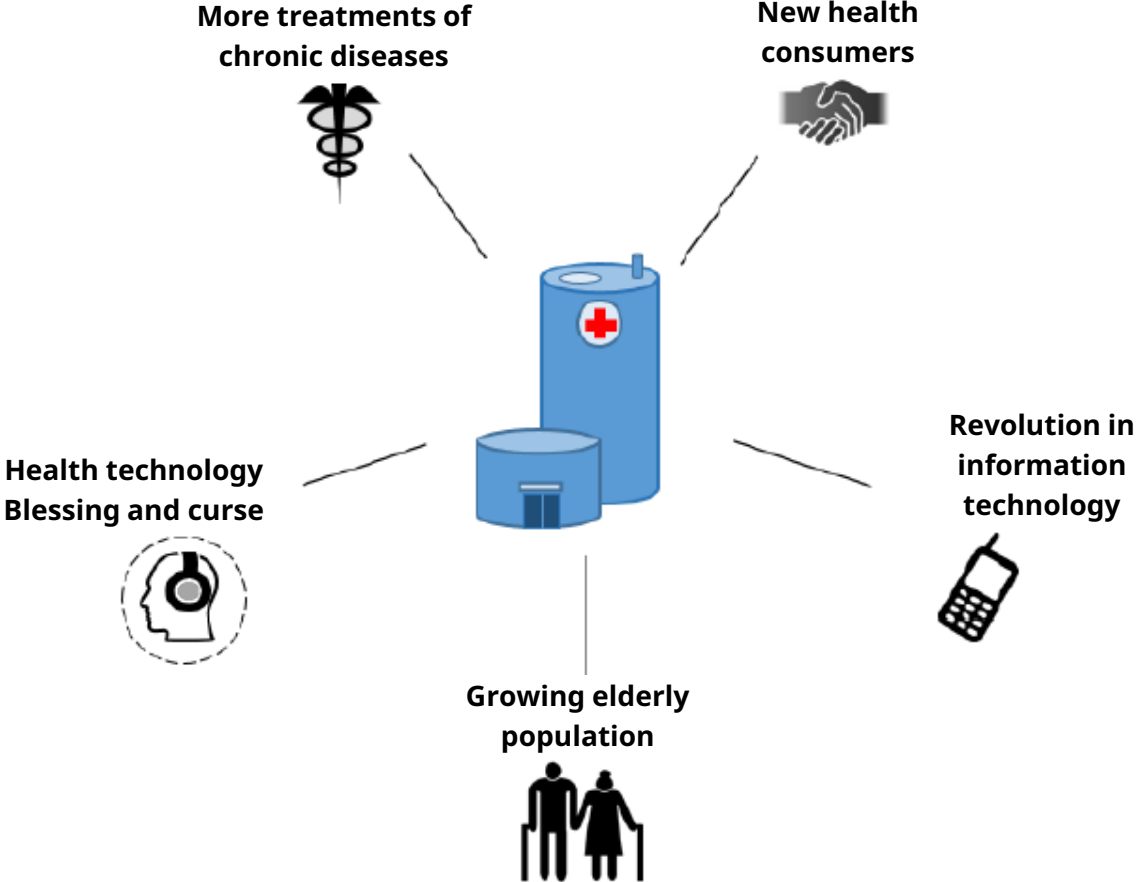
The number of people with multimorbidity will rise by 1.4% every year the next 10 years

Average cost 20,000 DKK



Development trends in Healthcare

Disruptive forces in healthcare – points to innovation as a future solution



1 pct. Takes | 30 pct. Of the expenses

Innovation is for patients

Innovation comes in many shapes. It is done for patients to improve treatments and improve conditions for living with a chronic disease.

- Precision medicine/Companion diagnostics
- Homecare / Remote Patient Monitoring
- Advanced therapies
- 3D print
- Robotics / nanobots
- Tricorders
- Digital Therapeutics
- Technology in mental health
- Wearables / nanosensors
- Smarter pacemakers
- A lab on a chip



Convergence of technologies

As innovations grows and different technological approaches to treatments converges in new innovative treatments the regulatory system must adopt to meet the new demands.

**Advanced
Therapies**



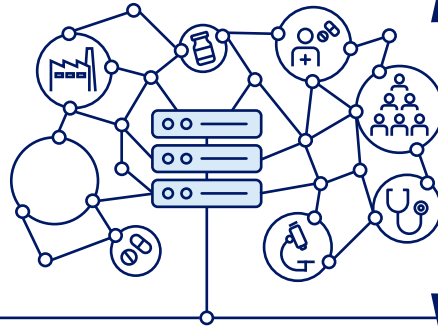
**Medical Devices
and Health
Technology**



**Innovative
Medicines**



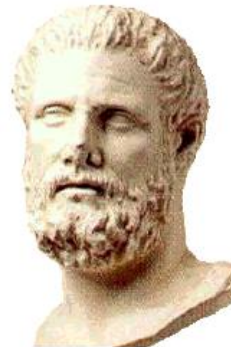
Analytics & AI



New ways of creating evidence

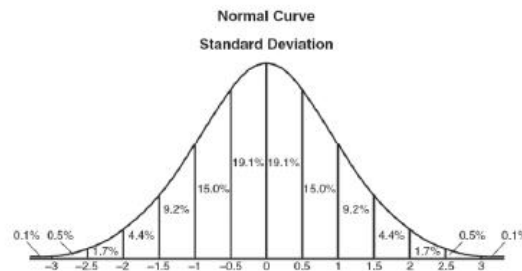
Innovation is based on evidence. Innovation is also being innovated and new ways of creating evidence being developed.

Invivo



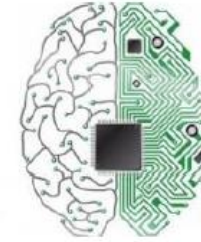
Classical clinical medicine

Invitro



EBM

Insilico



Clinical Insilico Medicine
Predictive Medicine
Personalised Medicine
Precision medicine

Medical devices – Regulations and definition

New regulations: Why?



'Scandal' of vaginal mesh removal rates revealed

Boneloc case – The Ministry of Health admit they made mistakes



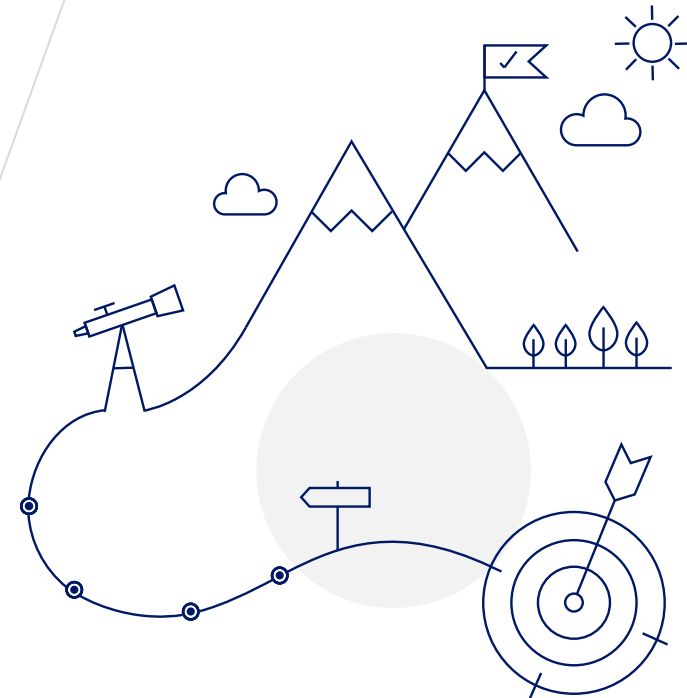
PIP BREAST IMPLANT SCANDAL:
A STORY THAT TRIGGERED
CHANGE

Telegraph UK



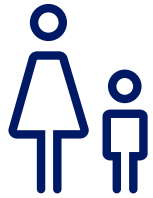
Demand for more patient safety

The changing landscape for innovations in Europe is a challenges authorities and regulations – and drive for more regulation.



Regulation aims to create the right environment

The regulatory environment is based on three regulated factors – patient safety, market access, and innovation.



**Patient
safety**



**Market
access**



Innovation

Medical Devices: Definition art. 2(1) in MDR

'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception
- products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Medical Devices



CE marking



Only CE marked medical devices can be placed on the market.

The CE mark shows that the device meets the legal requirements for medical devices.

To place a CE mark on a medical device, the manufacturer must document the product's quality, safety and performance.

Notified bodies

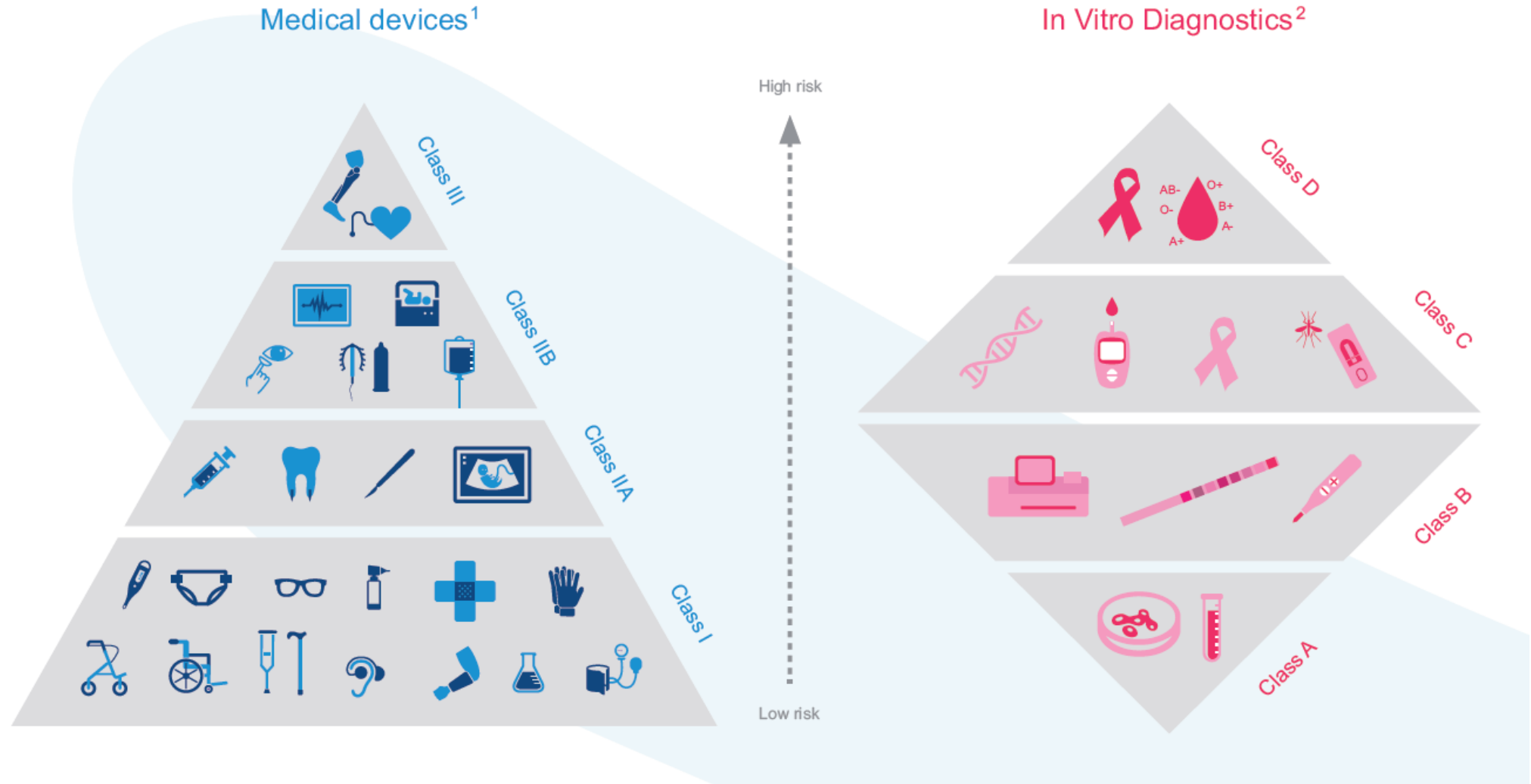
- Third party independent certification bodies
- Designated by their national Designating Authority
- Undertake relevant conformity assessment procedures for products belonging to a higher risk class than class I (and devices with a measuring function and sterile devices)

Medical Device Regulation, Article 36, Designation of Notified Bodies

Medical Device Regulation, Annex VII, Criteria for Notified Bodies

- Independence and impartiality
- Technical, scientific and medical competence
- Ability to carry out all tasks assigned
- Ensurance of subcontractor's competence
- Confidentiality
- Liability insurance

Guidelines for interpretation developed on EU level by expert working group



MDR and IVDR

From 1990s:

IVD directive (48 pages)
MD directive (96 pages)

To 2017:

IVD regulation (157 pages)
MD regulation (174 pages)



Significant changes include:

- Tighter rules for clinical investigations
- Notified Bodies
- New database (Eudamed)
- Expert Panels
- UDI
- Aesthetic products
- New classification

26th May 2021 (MDR) & 26th May 2022 (IVDR)



Guidance ▾

Standards and
indicators ▾Life
sciences ▾British National
Formulary (BNF) ▾British National Formulary
for Children (BNFC) ▾Clinical Knowledge
Summaries (CKS) ▾

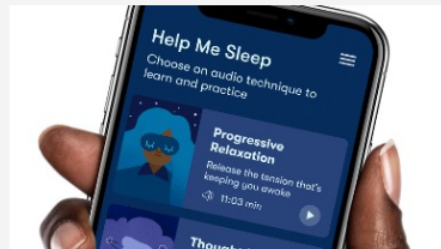
About ▾

Read about [our approach to COVID-19](#)[Home](#) > [News](#)

NICE recommends offering app-based treatment for people with insomnia instead of sleeping pills

Hundreds of thousands of people suffering from insomnia who would usually be prescribed sleeping pills could be offered an app-based treatment programme instead, NICE has said.

20 May 2022



NICE has recommended [Sleepio](#) as an effective alternative to sleeping pills, which would save the NHS money as well as reducing prescriptions of medicines such as zolpidem and zopiclone that [can be dependency forming](#). Economic analysis found

“ Our guidance on Sleepio provides GPs and their patients with evidence-based recommendations on a digital treatment option for insomnia.

Jeanette Kusel, acting
director for MedTech and
digital

Challenges in the regulatory system

The regulatory system in Europe is challenged

01 The regulatory system of medical devices and regulatory pharma system has increased interfaces

02 Many competent authorities in EU have both medical devices and human medicine responsibilities

03 Drug-device combinations represents up to 25% of the current pharma pipeline

04 The increased safety expectations from the public are similar - but the regulatory systems are different – marked surveillance vs. government approval



Medical Devices system is characterized by:

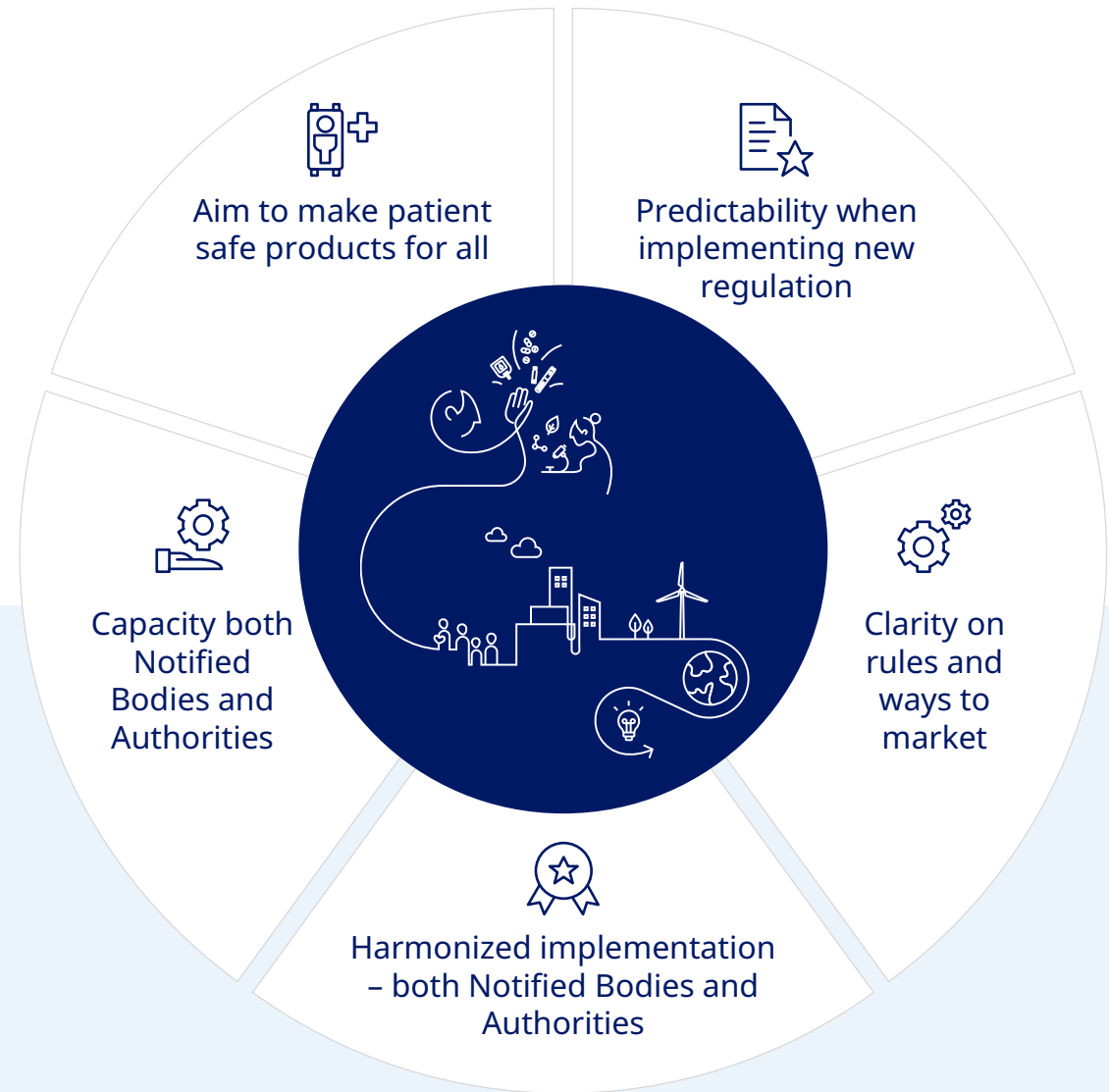
- Focus on patient safety
- A surveillance system
- +500.000 products
- The regulatory size is 10 % of pharma
- Fully distributed regulatory system
- Only focused on access to market
- Free pricing
- Asf.



Pharma system is characterized by :

- Focus on patient safety
- An approval system
- Estimated 4.000 / 14.000 products
- 10 times the regulatory size of medical devices
- A large centralized agency EMA
- Responsible for supply
- Controlled pricing
- Asf.





Overall industry needs

**Sandipa Dey, Natalia Datta
& Neetima Bhardwaj**
Global Service Centre
India

Questions & Reflections?

More about Novo Nordisk

 [Novonordisk.com](https://www.novonordisk.com)

 [linkedin.com/company/novo-nordisk](https://www.linkedin.com/company/novo-nordisk)

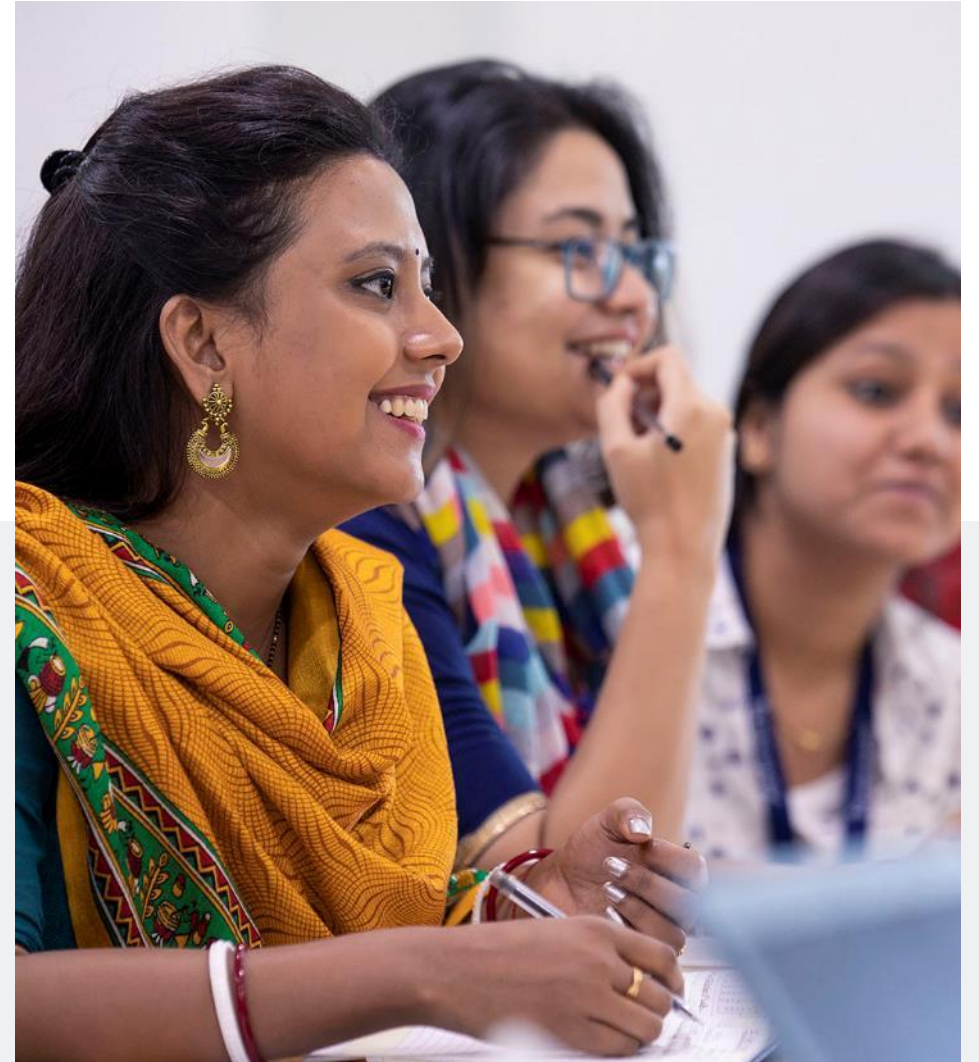
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