

The Danish Healthcare System & Market Access in Denmark

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Medtech Denmark

Agenda

- Introduction to us – Mads & Lene
- Introduction to Medtech Denmark & our members
- The Danish Healthcare System
- Market Access in Denmark
- Q&A



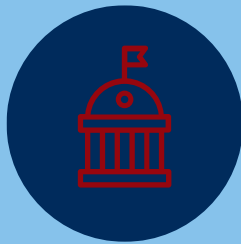
MedTech Denmark / Medicoindustrien

The industry organization for companies, which develop, manufacture or sell medical devices in Denmark

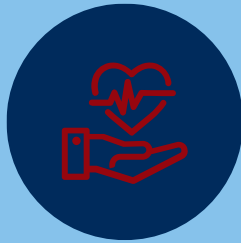
- A broad member base:, app. 250 companies:
 - Danish manufacturers
 - Subsidiaries of international manufacturers and distributors
 - Start-ups
 - Consultancies within MedTech
- Main focus:
 - We take care of the political interests of the member companies, both on a national level and in regard to EU-regulation, based on input from the companies
 - We have more than 20 network and expert groups, where people from the industry meet to discuss specific areas relating to the industry
 - We advise our members on tenders, regulatory challenges, and market access.
 - Our training department MedTech Academy offers around 60-80 medtech-specific courses per year, primarily targeted at our member base.
- Areas that we cover:
 - Market Access in Denmark
 - Sector specific and horizontal regulation in the EU
 - General framework conditions in regard to innovation, uptake, R&D, production, and export

Denmark's Healthcare System

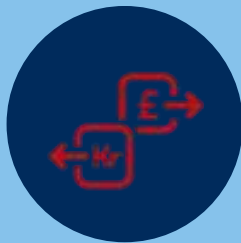
Denmark - healthcare characteristics



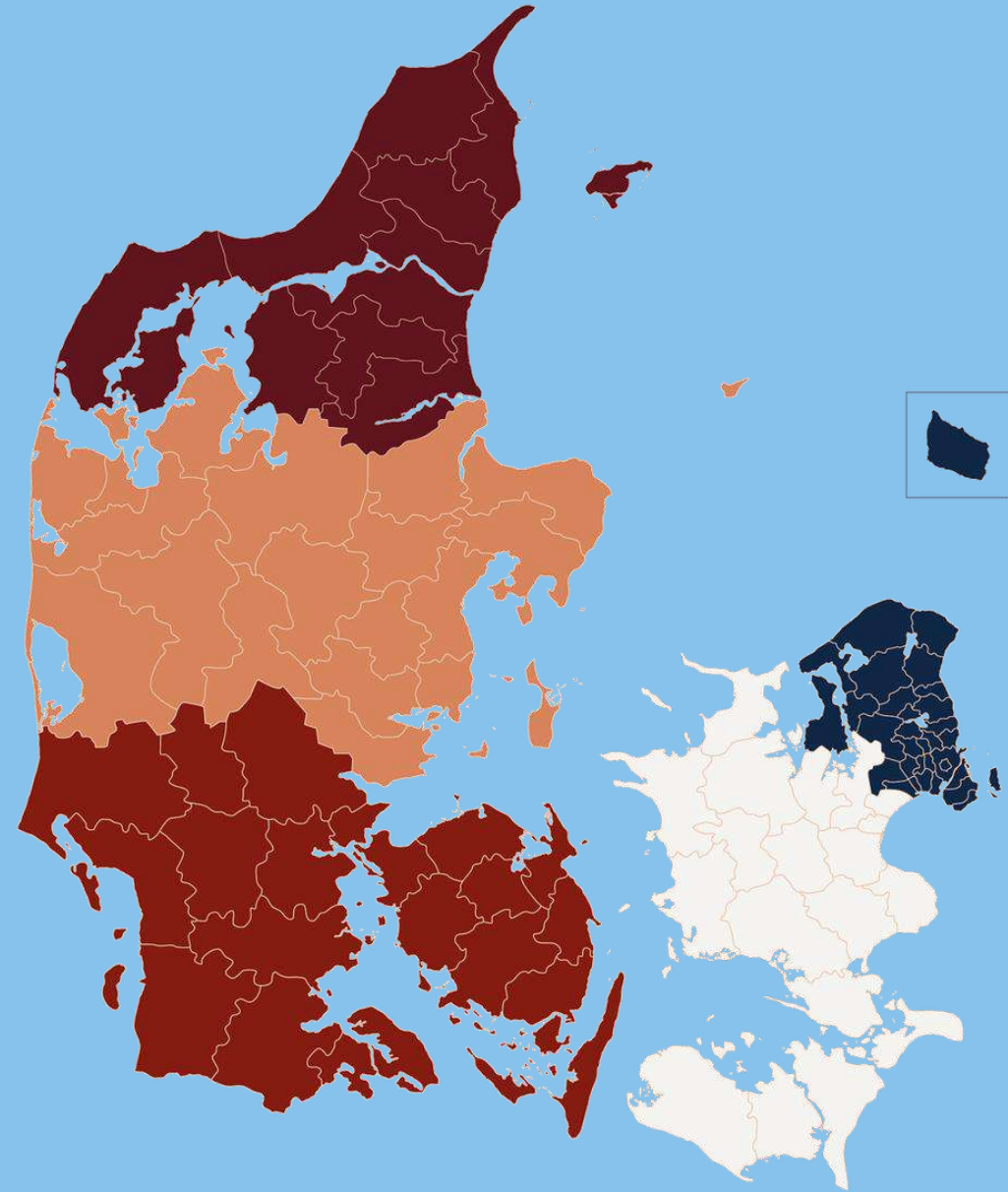
Universal health coverage



World class life-science industry



10.8% of GDP spent on health (2024)



Challenges in Denmark



Danes live longer

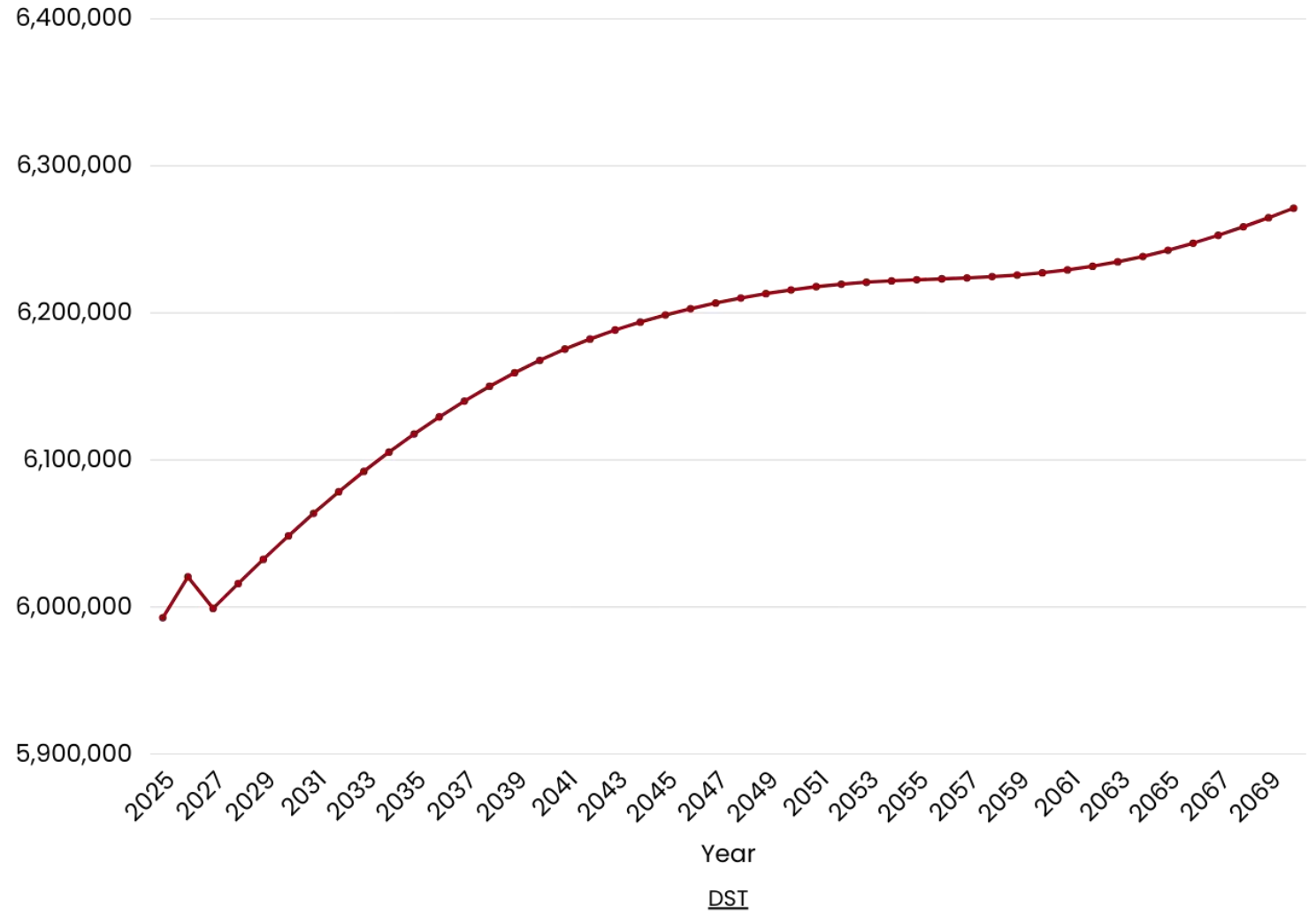


50 % of adults +65 have multiple diseases



Shortage of healthcare staff

Expected population development





Aging population and more chronic diseases



Staff retention challenges



Rising expectations and demographic shifts

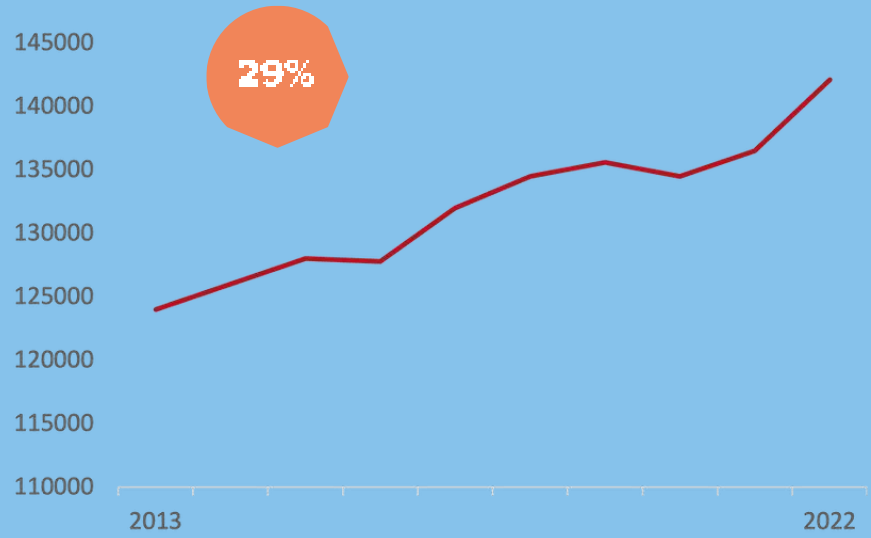


Complex tasks and need for skilled staff

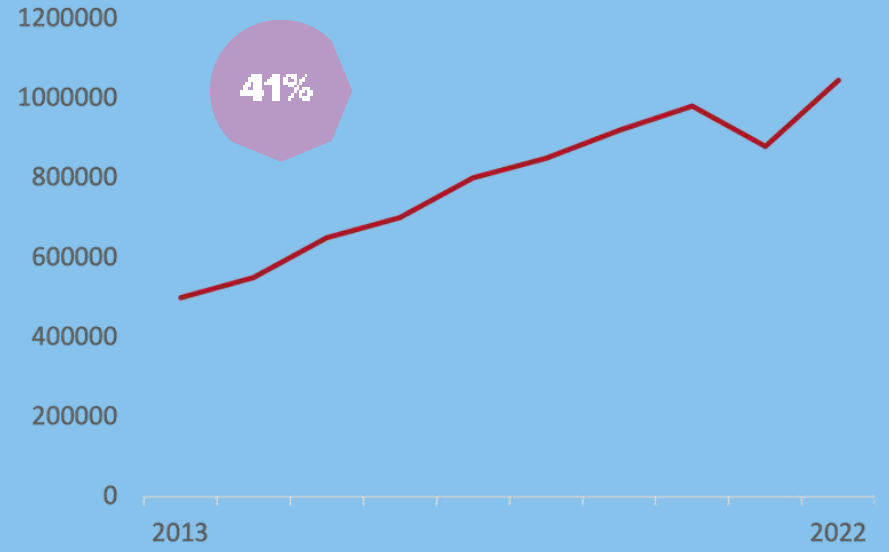


Poor connection and high work pressure

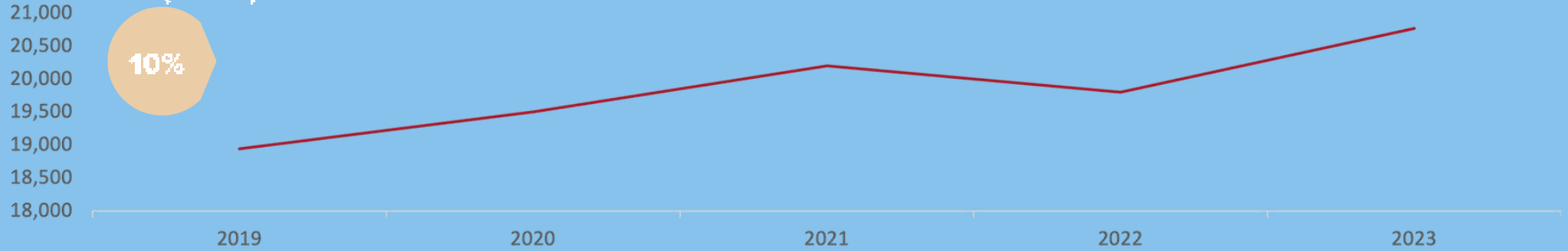
Hospital admissions



Outpatient treatments



Number of times a GP is contacted (x1000)



The Danish health system – *Key features*

Source: The Ministry of Health

84%

Universal coverage

16%

Self-funded coverage

- **Population: Nearly 6 million people**
- **27% of population is age 60+**
- **In 2024, Denmark's healthcare expenditure was 10.8% of the country's GDP**

Denmark's GDP grew by 3% in 2024 – indicating robust economic growth



Dentist



Medication
outside hospital



Corrective lenses
Hearing aids

Healthcare Expenditures

Expenditure	Total cost 2023 [EUR]
Hospitals (including psychiatric hospitals and hospital medicines)	14,826,201
Primary sector practitioners	1,568,181
Medicine subsidies	1,060,738
Other (administration, IT etc.)	769,898
Healthcare expenditures – total	18,225,008
Primary sector's share of total expenditures	16%

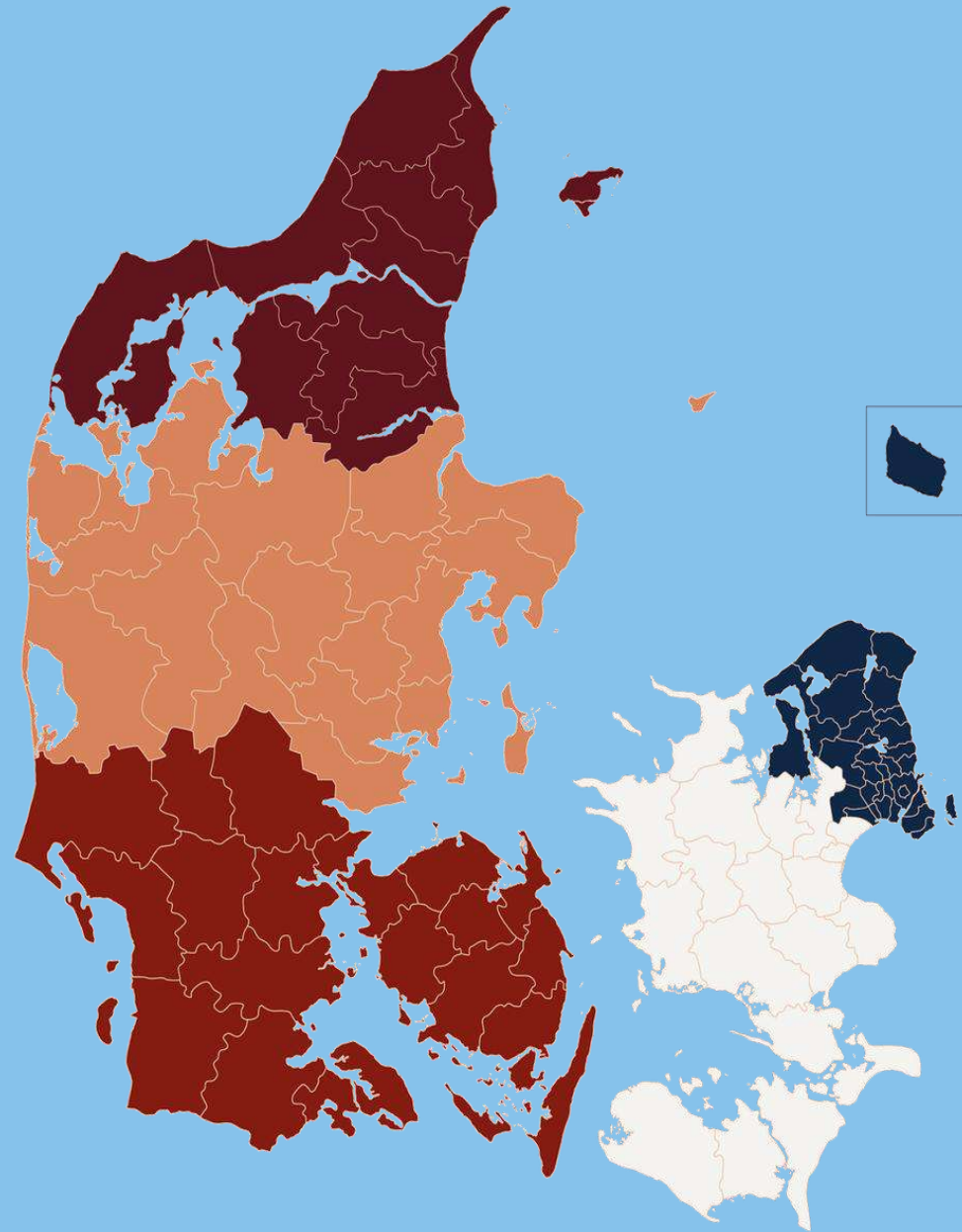
Who is responsible for what?

State

- Legislation and supervision
- National health policy
- The overall framework of the healthcare economy
- No direct role in delivery of health services
- Specialty planning

Regions

Municipalities



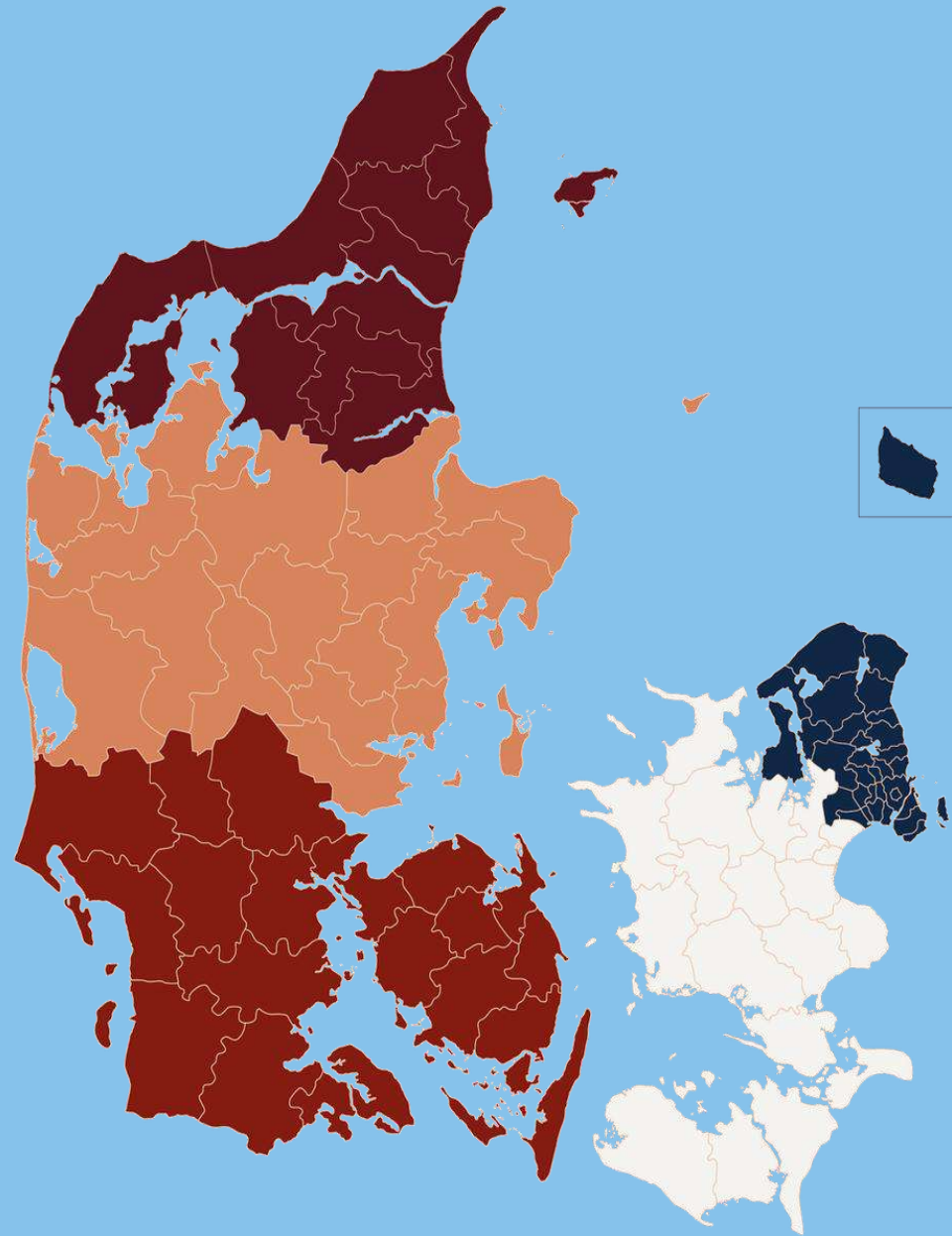
Who is responsible for what?

State

Regions

- **Planning and delivery of hospital services**
(including emergency care, somatic and psychiatric)
- **Healthcare services provided by general practitioners (GPs)**
- **Specialist practitioners and other specialists**
(physiotherapists, psychologists)

Municipalities

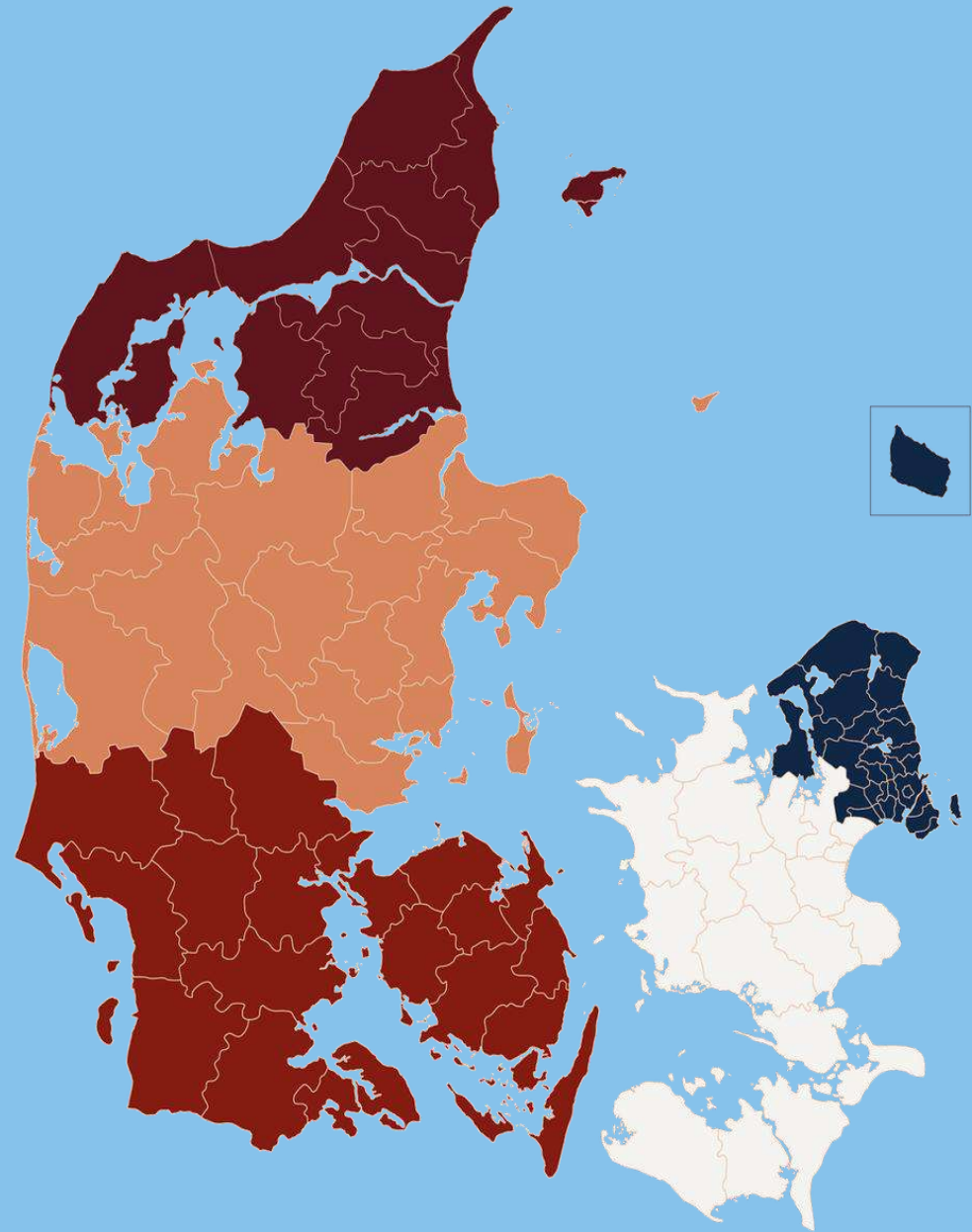


Who is responsible for what?

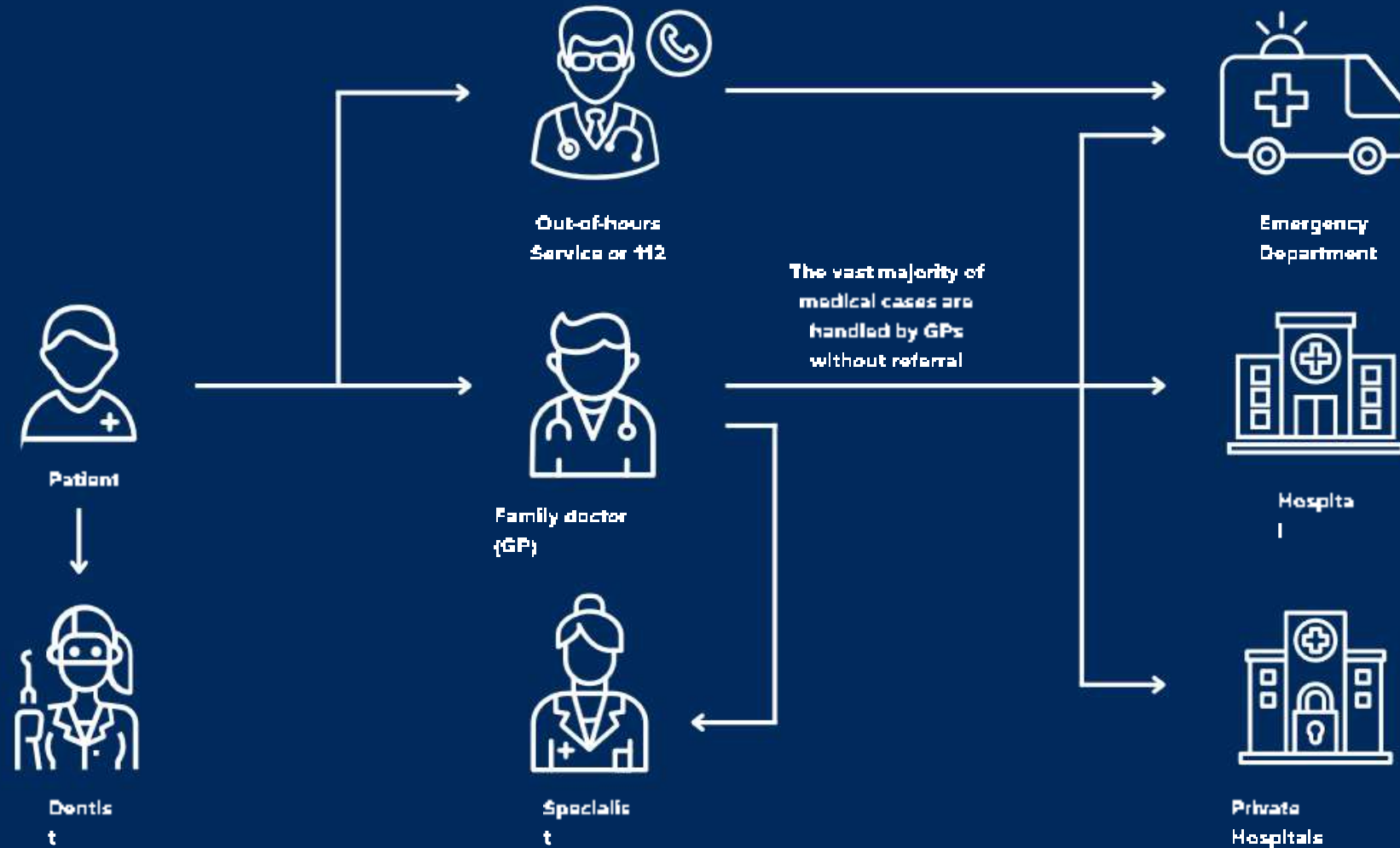
State Regions

Municipalities

- Home care
- Rehabilitation programs for elderly
- Rehabilitation services outside hospitals
- Treatment of drug and alcohol abuse
- Prevention and health promotion
- Public Health nurses (for children) and elderly/home care
- Children's dental services



GPs are the main entry point



General Practitioners

≈3,500

General Practitioners

≈50

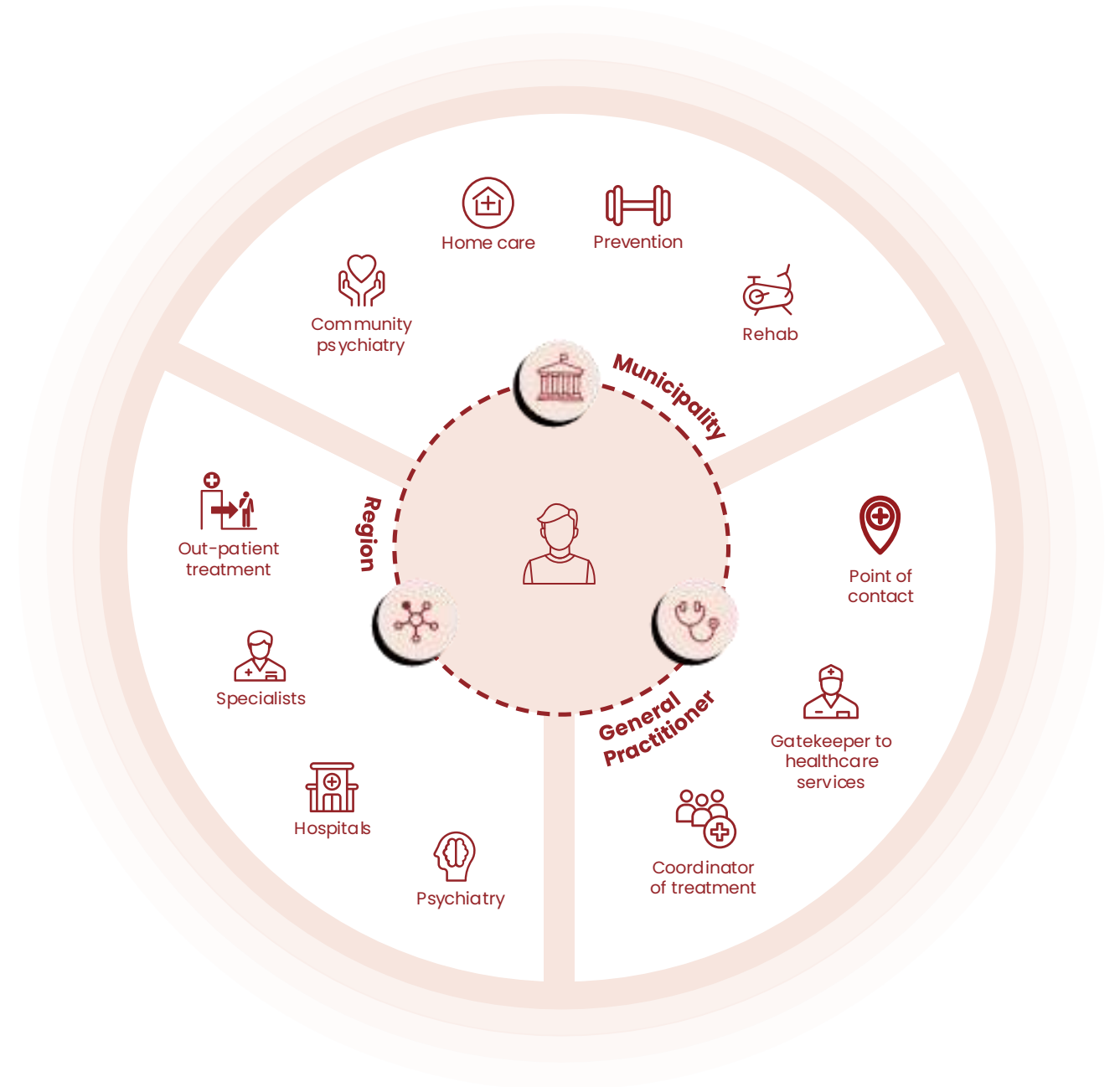
Patient contacts per day
(incl. email, video and
telephone)

>5,000

General Practitioners
by 2030

Cross-sector collaboration

The challenge of coordination between sectors



Private hospitals



The private sector handles fewer complex surgeries



Every 10th doctor at Denmark's hospitals have a second job at a private hospital



Approximately 10% of the surgeries in Denmark were performed at a private hospital in 2023 compared to 2% 20 years ago

Patient pathway through the healthcare system

Electronic communication throughout
a patient's course of treatment



Appointment
with GP is made
electronically



Tests are ordered and
results are delivered
electronically to the GP



All referrals to the
hospital or specialists
are made electronically



The citizen is admitted to
the hospital – electronic
notification is sent to the
GP and Municipality



A notification about discharge
and rehabilitation programme is
sent to the GP and Municipality
electronically when the citizen is
discharged

Basic Requirements for Market access in Denmark

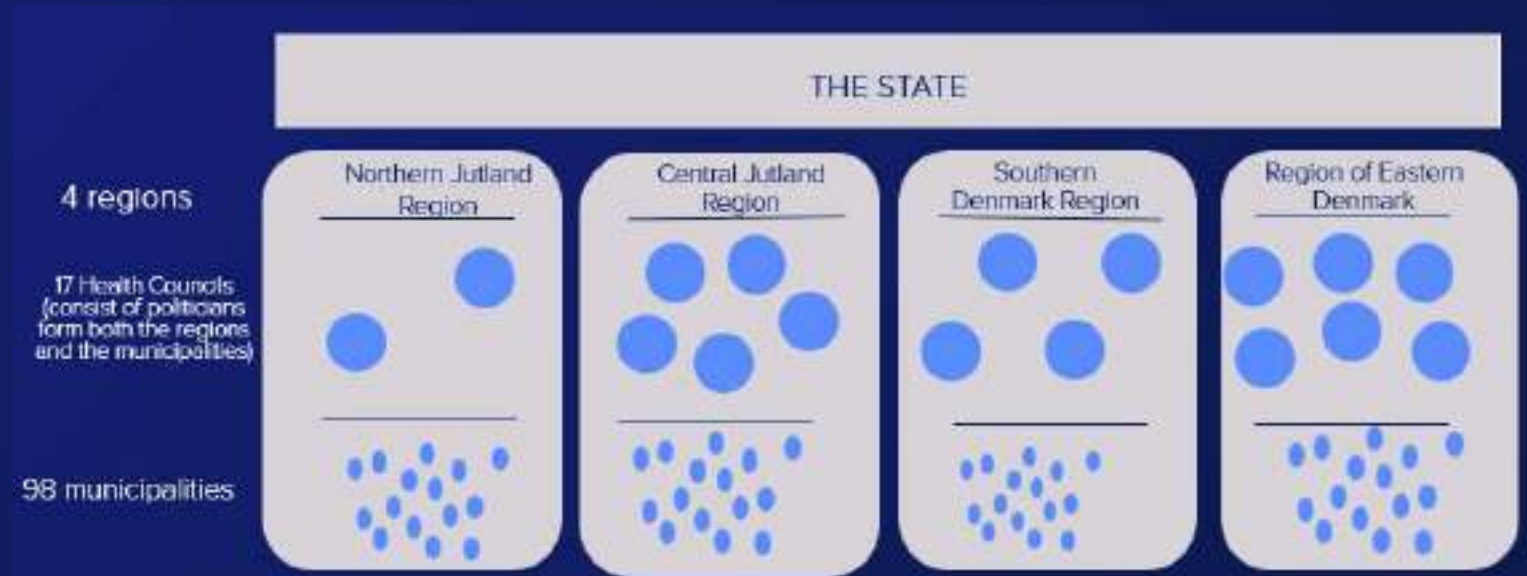
- CE-mark
- Registration in Denmark:
 - Manufacturers, authorised reps, importers and distributors and specialised retailers within medical devices established in Denmark need to register to the Danish Medicines Agency, DKMA.
- Language requirements:
 - Danish on labelling & IFU for both lay and professional users
 - Derogation is possible, however, rarely granted



Market Access in Denmark – a tender based market!

A broad landscape of stakeholders that differs across device categories.

- Public healthcare system: EU Procurement Directive dominates!
- 3 procurement sectors:
 - Regions (4 new structure/ 5 old structure)
 - Municipalities (98)
 - Private hospitals and MD-clinics (minor)
- Centralised procurement body: SKI
 - some assistive devices and certain types of equipment used in primary care
- Centralised procurement body: Amgro (medicines, hearing aids and some additional devices)



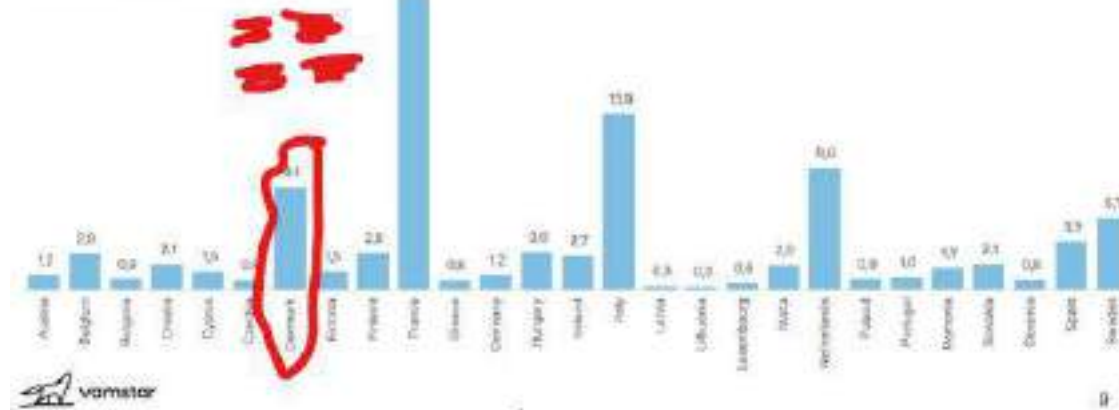
Purchasing power is becoming increasingly concentrated in the medtech sector, while the companies remain relatively small

- Small and medium-sized enterprises face intense competition.
- Small companies often need to adapt their products and processes to meet tender and regulatory requirements.
- Of the 407 tenders published in Denmark under CPV 33100000 in 2024, 76 were valued at over 5 million euros.
- VBP approach is limited by governmental economic agreements with regions and municipalities
- The VBP approach demands a tighter connection between procurement (buying) and operation (doing) – however the two follow separate budgets (stipulated by the economic agreements)

France has the highest average tender size, reaching €24.6 Mn

- The average tender size across all countries is approximately €2.6 Mn.
- 6 countries exceed the global average tender size, including Denmark, France, Italy, Netherlands, and Spain.
- 21 countries fall below the average tender size, with notable ones being Austria, Belgium, Bulgaria, Croatia, and Cyprus.

Average Value of Tenders
(Published on TED in 2024)



37,000
medical technology
companies in Europe
90% SMEs

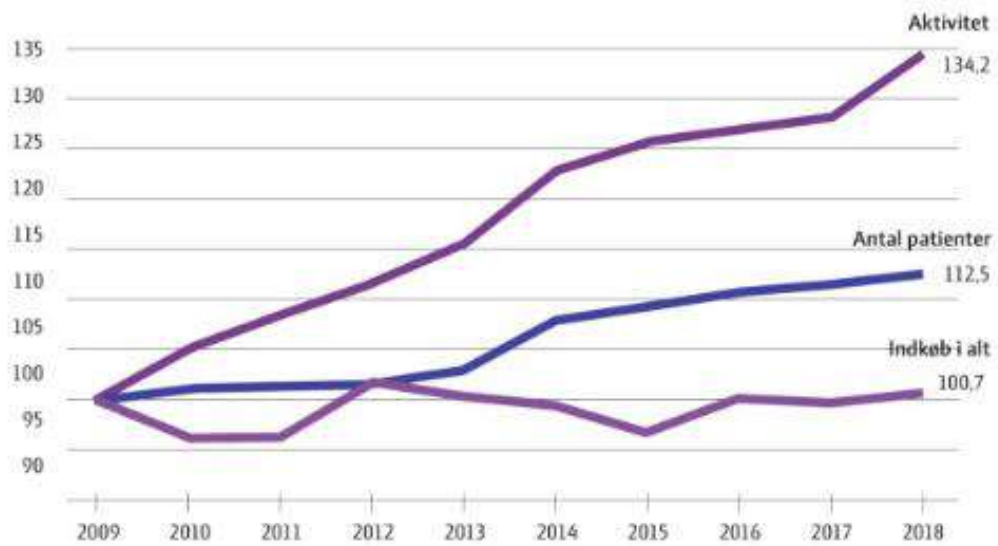
Purchasing expenses remains low even if activity & number of patients treated keep rising.....

Graf from the latest purchasing strategi from the Regions.

<https://www.e-pages.dk/regioner/177/>

Udviklingen i sygehusaktivitet, antal patienter og indkøbsudgifter

Index 2009 = 100



REGIONERNES INDKØBSSTRATEGI 2020-2025



The Danish App Board

<https://laegemiddelstyrelsen.dk/da/udstyr/naevnet-for-sundhedsapps/>

Scope: Health Apps – CE-marked & non-CE-marked

Not really a market access route

However, an app can get recommended

Denmark does not currently have a DiGA



The screenshot shows the website of the Danish Medicines Agency (Lægemiddelstyrelsen). The header includes the agency's name and logo, along with navigation links for 'Hjem', 'Om os', 'Rådgivning', 'Mediciner', 'Celle', and a search icon. Below the header is a blue navigation bar with categories: 'Godkendelse og kontrol', 'Evaluering og produktregisteret', 'Tilbud og præk', 'Nyt og oplysning', 'Medicinske udstyr', and 'Særlige produktgrupper'. The main content area features a large image of a hand holding a smartphone, with the text 'Nævnet for Sundhedsapps' overlaid. Below the image is a red 'HEALTH APPS' tag and the title 'Nævnet for Sundhedsapps'. The text below the title reads: 'Flere og flere danskere bruger hver dag sundhedsapps på deres smartphone, tablet eller en anden platform. Sundhedsapps giver en lang række nye muligheder - eksempelvis i form af inspiration til en sund livsstil, forebyggende sundhedsrådgivning eller mulighed for at følge et sygdomsforløb. Indenrigs- og sundhedsministeren har nedsat Nævnet for Sundhedsapps, der vurderer og anbefaler sundhedsapps til borgere og sundhedspersoner.'

Concluding remarks and Q&A

