

# NORDIC MARKET ACCESS HANDBOOK

Accelerate your understanding of the Nordic healthcare market - an introduction on how it operates

HEALTH  
TECH NORDIC.





# HEALTHCARE REINVENTED BY THE NORDICS

Our region features world-class healthcare, life science and research institutions, mobile technology, highly skilled hardware and software expertise, design and a thriving gaming industry. To facilitate your understanding of the Nordic market, we have prepared a handbook to navigate compilation of key areas in Sweden, Norway and Denmark (Iceland and Finland coming).

This handbook provides access to information and resources - from a quick overview of how health systems are organized all the way to key insights of progress in digitalization. Everything you need to introduce your solution in the Nordics.

The information presented reflects the current landscape, II QTR 2022. We constantly work to update the handbook as it evolves to fulfill your needs. Please feel free to contact us with feedback.





SWEDEN

# MARKET INTELLIGENCE

This document is general in its content and aims to provide general information, it does not intend to be a comprehensive overview of the current requirements for market access. This document is not intended to be or should be construed and relied upon as a legal assessment or recommendation on a specific issue or case. /February 2022



# SWEDEN OVERVIEW

## QUICK FACTS

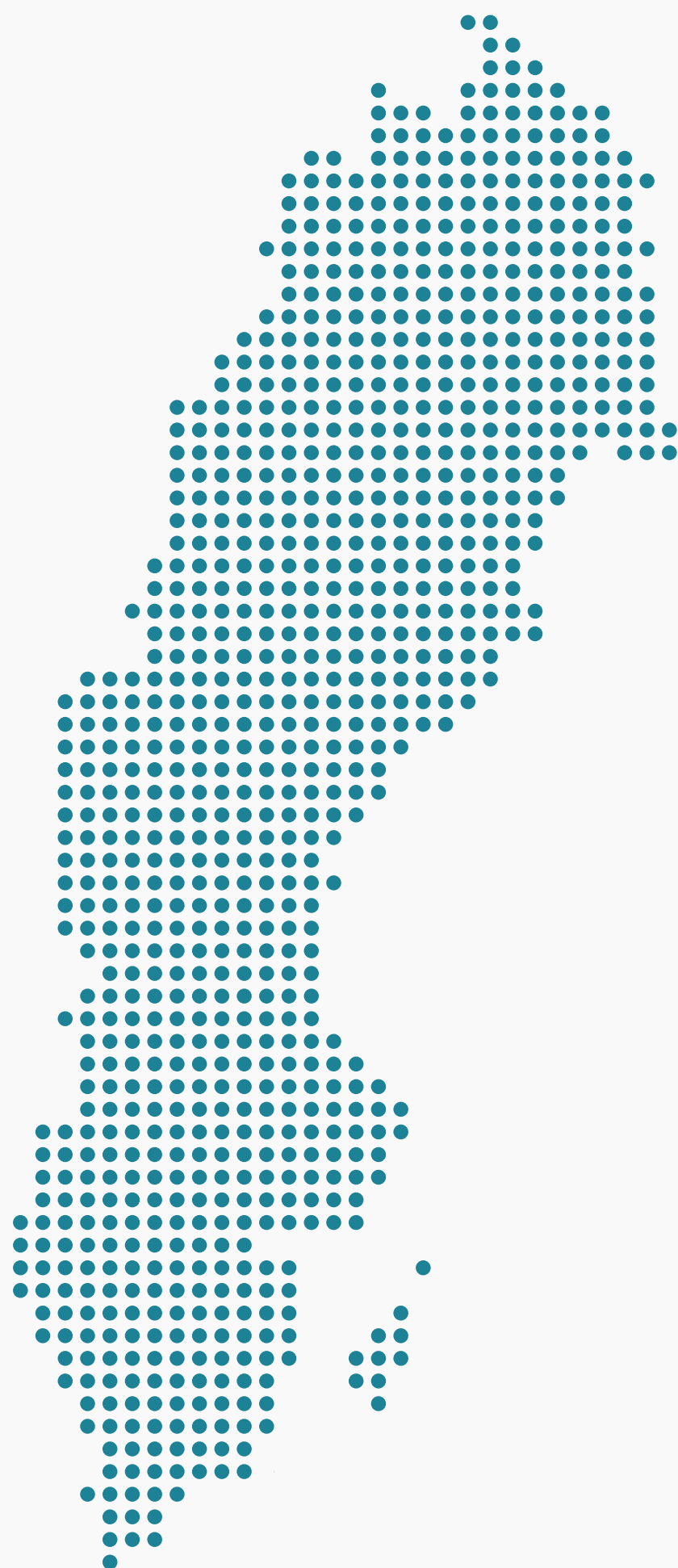


Photo: iStockphoto

### POPULATION SIZE: 10,500,000

### CURRENT GOVERNMENT: CENTRE-LEFT

### HEALTHCARE SYSTEM OVERVIEW:

- Single payer system with primarily public provision, based on tax contribution
- Access is universal and largely free at the point of use
- Patients can freely choose their preferred hospital
- Political focus is on innovation, sustainability & digitization
- The system is largely decentralized. Health services are provided across 21 regions and 290 municipalities.
- The central government plays a large role in oversight & regulation

### NORDIC HEALTH TECH COMPANIES

See HealthTech Nordic's [website](#) for an overview of participating health tech companies in Sweden, and the Nordics.

### CUSTOMERS:

- 1/ Digital care:**  
KRY, Doktor.se, Min Doktor.
- 2/ Major hospitals:**  
Karolinska University Hospital, Sahlgrenska University Hospital, Skåne University Hospital.
- 3/ Large private care takers:**  
Aleris, Praktikertjänst, Capio.
- 4/ MedTech:**  
Getinge, Essity, Mölnlycke healthcare.
- 5/ Pharma:**  
AstraZeneca, Swedish Orphan Biovitrum- SOBI, Recipharm.



# SWEDEN OVERVIEW SUMMARY

## REGULATORY



- Sweden abides by MDR and GDPR
- The Swedish Medical Product Agency ([Läkemedelsverket](#)) is responsible for regulating medical devices and pharmaceutical
- Whether apps need to be classified as a medical device or not depends on the intended purpose of the device (according to MDR)
- Risk Classification is the same as in EU, UK and Norway

## REIMBURSEMENT



- There is no national policy/guideline/process in place for approving, prescribing and reimbursing health apps. Instead, start-ups need to negotiate with customer or participate in tenders

## COMMERCIAL POTENTIAL



- The largest buyer of Life Science and HealthTech is the public sector
- Mature digital market
- Innovative Private caretakers open for B2B

## EASE OF DOING BUSINESS



- Ranks high in most international comparisons such as macroeconomics, innovation, skilled workforce, business climate and low corruption
- Very skilled workforce, but labor shortages in IT and health
- Sweden has a high degree of digital maturity in healthcare and elsewhere

## CUSTOMER ACQUISITION



- B2C: The market is easily approachable. More than half of Swedes use digital health services. Public B2B: Low due to complicated tender system and customer acquisition process. Private B2B: High due to few barriers of entry. B2B2C (e.g., GP/insurer): Medium due to lack of incentive structures and reimbursement mechanisms.
- Market growth: Healthcare spending ~11% of GDP, and grew 57% between 2000 and 2019.

## CULTURAL



- Market split: 85% is Public spending, 15% is private spending
- Key values are democracy, Equality, Inclusivity, Individualism & Indulgence
- ~89% of Swedes speak English.
- Ease of translating solution from Danish or Norwegian into Swedish is very high

# 01/HEALTH SYSTEM

/SE

# HEALTH SYSTEM DEEP-DIVE

Photo: iStockphoto



## HEALTH SYSTEM STAKEHOLDERS

- **In a Nutshell**, Sweden’s universal health system is nationally regulated and locally administered. The Ministry of Health & Social Affairs sets overall health policy, regions finance and deliver health care services, and the municipalities are responsible for the elderly and disabled. Funding: primarily from regional and municipal taxes. Grants are provided by central gov. Covered services incl. inpatient, outpatient, dental, mental health, long-term care, and prescr. drugs. Regions set provider fees at all levels of care and copayment rates for services such as primary care and hospitalizations. Dental and pharm. benefits determined nationally and subsidized. – Source: *Anna H. Glenngård, Lund University School of Economics and Management.* [commonwealthfund.org](https://commonwealthfund.org)
- The Swedish healthcare market, an overview.  
Webinar.: [play.quickchannel.com/play/d731w8h](https://play.quickchannel.com/play/d731w8h)
- **Government’s Role and key Independent Agencies:**  
All three levels of Swedish government are involved in the health care system.
- National level/ Ministry of Health and Social Affairs: Responsible for overall health care policy and regulation and sets budgets for government agencies and grants to regions, working in concert with 8 national government agencies.
  - Regional level, 21 regional bodies responsible for financing and delivering health services to residents.
  - Local level, 290 municipalities responsible for elderly care and disabled, incl. long-term care. Local and regional authorities are guided by local priorities and national regulation. Nationally, they are

represented by [SKR](#) + 10 government agencies:

- [socialstyrelsen.se](https://socialstyrelsen.se) : Supervises and licenses all health care personnel, disseminates information, develops national guidelines for medical care and ensures application. Also maintains health data registries and official statistics.
- [ehalsomyndigheten.se](https://ehalsomyndigheten.se): Promotes information-sharing among health, social care professionals and decision-makers. It store and transfers electronic prescriptions. Also responsible for statistics on drugs and pharmaceutical sales.
- [ivo.se](https://ivo.se): Supervises health care, social services, and activities on support and services for people with disabilities. Issues permits in those areas. [Vård- och omsorgsanalys \(vardanalys.se\)](https://vard-och-omsorgsanalys.vardanalys.se) analyzes and evaluates health policy and the availability of health care information to citizens. [The Public Health Agency of Sweden \(folkhalsomyndigheten.se\)](https://folkhalsomyndigheten.se) provides the national government, government agencies, municipalities, and regions with evidence-based knowledge regarding infectious-disease control and public health.
- [Home \(sbu.se\)](https://home.sbu.se): Promotes cost-effective health care technologies. It reviews and evaluates new treatments from medical, econ., ethical, and social points of view.
- [tlv.se](https://tlv.se) Principal agency for assessing pharmaceuticals. It decides whether drugs and medical devices should be included in the National Drug Benefit Scheme; prescription drugs and medical devices are priced based on value. It includes dental care.



# HEALTH SYSTEM DEEP-DIVE

## HEALTH SYSTEM STAKEHOLDERS

- [lakemedelsverket.se](https://lakemedelsverket.se) National authority-Regulation and surveillance of the development, manufacture, and sale of drugs and other medicinal products.
  - [DIGG – Myndigheten](https://digg-myndigheten.se) för digital förvaltning | DIGG – Agency for digital gov. Helps structure the digital landscape for public actors. sustainable welfare society, by intensifying digitalisation. Together with public adm, “we strive to make the transition happen – and benefit all.” [Swedish Authority for Privacy Protection | IMY](https://imy.se)
    - Role: uphold the protection of personal data, monitoring and proper handling.
- **Role of Private Health Insurance:** Approx. 13 % of employed residents have private supplemental coverage, mostly for improved access to private specialists. Mainly delivered in the form of supplementary coverage, accounts for less than 1% of health expenditures. It is purchased mainly by employers and is used primarily to guarantee quick access to an ambulatory car specialist and to avoid wait lists for elective treatment. In 2017, 633,000 individuals had private insurance, representing roughly 13 percent of all employed individuals ages 16 to 64 years.4 (source or sources) 4: Swedish Insurance Federation, [svenskforsakring.se](https://svenskforsakring.se); accessed April 16, 2018.
- **Role of Primary Care:** Regionally Administered, In its majority, based on a “Primary Care Center” system instead individual GP, which means that it is team based. Comprises GPs, nurses, midwives, physiotherapists, and psychologists, is the main form of practice. There are an average of four to five GPs in a primary care practice. Primary care consists of over 1K health centers district nursing clinics and other family doctor and family doctor

Photo: iStockphoto





# HEALTH SYSTEM DEEP-DIVE

## HEALTH SYSTEM STAKEHOLDERS

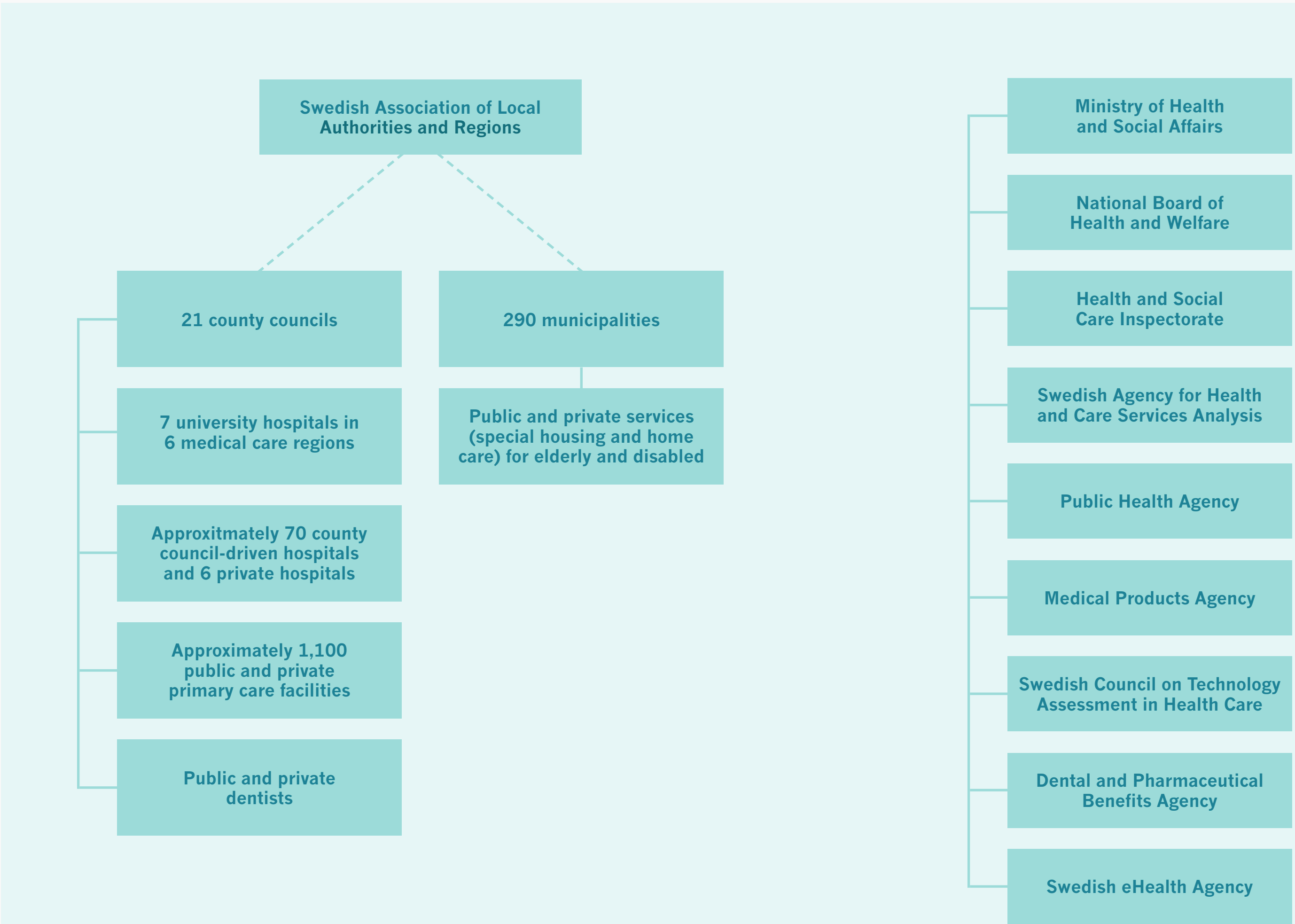
clinics. According to the Health Care Act, regions are obliged to introduce care choice systems that give citizens the right to choose between different care providers in primary care. All care providers who meet the requirements decided by the region in the care choice systems have the right to establish themselves in primary care with public compensation.

→ **Hospital and Specialist Care:** Full service hospitals are regionally managed and include emergency and specialist care. About 8 of these are university hospitals , where mostly of the highly specialized care and research takes place. Some heathcare services can also be outsourced to contractors. Outpatient specialist care is provided at university and regional hospitals and in private clinics. In both cases, specialists are salaried employees (of hospitals and clinics). Patients are free to choose a specialist. Municipalities are responsible for the patients once they have been discharged from the hospital. Source: *Anna H. Glenngård, Lund University School of Economics and Management.* [commonwealthfund.org](https://commonwealthfund.org)

[healthmanagement.org/c/icu/issuearticle/swedish-healthcare-overview-of-the-health-system](https://healthmanagement.org/c/icu/issuearticle/swedish-healthcare-overview-of-the-health-system)

[commonwealthfund.org/international-health-policy-center/countries/sweden](https://commonwealthfund.org/international-health-policy-center/countries/sweden)

## HEALTH SYSTEM STRUCTURE ORGANIZATION OG THE HEALTH SYSTEM IN SWEDEN



Source: Adapted by the author from A. Anell, A. H. Glenngård, and S. Merkur. "Sweden: Health System Review". Health Systems in Transition, vol. 14, no. 5, 2012, p. 19. Source: [commonwealthfund.org/](https://commonwealthfund.org/)



# 02/INDICATOR

/SE



# INDICATOR REIMBURSEMENT

## WHAT IS THE MECHANISM FOR REIMBURSEMENT?

There is no national policy/guideline/process in place for approving, prescribing and reimbursing health apps. Instead, start-ups need to negotiate with customer or participate in tenders

**Primary care:** Fixed capitation for registered individuals (60%–95% of total payment), Fee-for-service Performance-related bonuses (0%–3% of payments) for achieving quality targets related to patient satisfaction, care coordination, compliance with evidence based guidelines, and other metrics.

**Outpatient/Specialist care:** Public & private specialists paid through a combination of global budgets & per-case payments based on diagnosis-related groups (DRGs)-regional level.

**Hospital care:** A mix of global budgets, DRGs, and/or performance-based methods. Global budgets, set by regions, is most common. When DRGs used, they constitute less than half of total payments. Performance-based payments related to meeting quality targets constitute less than 5 percent of total payments. Payments based on historical (full) costs. [commonwealthfund.org/international-health-policy-center/countries/sweden](https://commonwealthfund.org/international-health-policy-center/countries/sweden)

## BASED ON YOUR SOLUTION, WHAT IS THE EASE OF REIMBURSEMENT?

**Preventive solution:** As in other European countries, it is more difficult to get reimbursed for preventive solutions than for non-preventive solutions. This is particularly the case if there is limited evidence of the clinical effectiveness of the preventive solution.

**Non-preventive solution (e.g., treatment, diagnostic):** A structured, nation-wide process for reimbursement of apps/other digital solutions does not exist. The stakeholders has to be processed case by case.

Photo: iStockphoto





# INDICATOR

## REIMBURSEMENT

### PATIENTS COPAYMENTS AND SAFETY NETS

TYPICAL PATIENT COMPAYMENTS AND SAFETY NETS		
SERVICE	FEES PER ENCUNTER/SERVICE <sup>7</sup>	MAXIMUM OUT-OF-POCKET COSTS PER YEAR (SAFETY NET)
Primary care visits	SEK 150-300 (USD 16-33)*	
Specialist consulation	SEK 200-400 (USD 22-44) without referral from primary care	Maximum out-of-pocket for health care visits: SEK 1,100 (USD 120)
	SEK 0-400 (USD 0-33) with referrai from primary care	
Hospitalization (per day or visit) including pharamaceuticals	SEK 50-100 (USD 5.5-11.0) per day (adults)	Exempt from copayments for outpatient visits: children/youth under age 20 and adults over age 85
Prescription drugs (outpatient)	Drugs covered by National Drug Benefits Scheme: Individuals pay full cost up to annual maximum of SEK 1,125 (USD 123), after which subsidy gradually increases to 100%	Maximum out-of-pocket for outpatient drugs: SEK 2,250 (USD 246); children under age 18 exempt from copayments
	Prescription drugs and medical products not reimbursed under the National Drug Benefits Scheme: Patients pay full price	
Dental Care	Adults receive fixed annual subsidies of SEK 300-600 (USD 33-66) to help pay for preventive dental care, depending on age	Free dental care for children/youth under age 23
		No cap om adult user charges for dental care
Source: SALAR (Swedish Association of Local Authorities and Regions), Patientavgifter i öppen hälso- och sjukvård är 2018.		
*One region (Sörmland) does not charge for primary care visits.		

<https://www.commonwealthfund.org/international-health-policy-center/countries/sweden>



# INDICATOR

## PUBLIC CUSTOMERS

### PUBLIC CUSTOMERS AND PROCUREMENT

**Customers:**

**Public health care providers:**

*General Practices (Vårdcentraler).* There are approximately 1100 General Practices in Sweden, of which 60% are public\*

**1/ Municipalities. There are 290\*\* municipalities in Sweden, and their care provision includes:**

- Nursing homes
- Homecare of the elderly
- Disabled people
- People with psychological disorders
- Support and services for people released from hospital care
- School healthcare

**2/ Hospitals. There are over 100 hospitals: 85 public, 15 private-owned, 7 University hospitals.**

- Norrland's University Hospital, Umeå
- Örebro University Hospital, Örebro
- Akademiska Hospital, Uppsala
- Karolinska University Hospital, Stockholm
- Linköping University Hospital, Linköping
- Sahlgrenska University Hospital, Gothenburg
- Skåne University Hospital, Malmö & Lund

\* <https://www.ekonomifakta.se/Fakta/Valfarden-i-privat-regi/Vard-och-omsorg-i-privat-regi/vardcentraler-i-privat-regi/>

\*\* <https://skr.se/skr/tjanster/kommunerochregioner/faktakommunerochregioner.1022.html>

Photo: iStockphoto





# INDICATOR

## PUBLIC CUSTOMERS

Photo: iStockphoto



### PUBLIC CUSTOMERS AND PROCUREMENT

#### Procurement:

- All procurement to region, government agencies, municipalities and regions are governed by public procurement law.
- All 21 regions and the 290 municipalities manage their own procurements. Sometimes a few regions cooperate in different tender clusters.
- The responsible purchaser manages the tender but they always use a reference group which is represented by experts from the healthcare system.
- The contracts are usually 24 months with a possibility of extension of 1 + 1 year
- The tenders are often evaluated on quality and price weighted.
- There is also possible to evaluate tenders on functional requirements
- It is recommended to have a meeting with the purchasers early in the process and discuss what effects your solution brings (cut costs for example) and how the functional requirements could be written.

[upphandlingsmyndigheten.se/en/government.se/government-policy/central-government-administration/public-procurement---how-it-works-in-sweden/konkurrensverket.se/globalassets/dokument/informationsmaterial/rapporter-och-broschyrer/informationsmaterial/swedish-public-procurement-act.pdf](http://upphandlingsmyndigheten.se/en/government.se/government-policy/central-government-administration/public-procurement---how-it-works-in-sweden/konkurrensverket.se/globalassets/dokument/informationsmaterial/rapporter-och-broschyrer/informationsmaterial/swedish-public-procurement-act.pdf)



# INDICATOR REGULATORY

## BASED ON YOUR USER/PAYER, DOES YOUR DEVICE NEED TO BE CLASSIFIED AS A MEDICAL DEVICE?

Regulatory compliance is an essential part of the journey when developing safe health tech solutions for the European and global markets. Sweden falls under the scope of MDR (already in force since May 2021 for medical devices), IVDR (for in vitro diagnostics and entering into force 2022-2027) and GDPR (on data privacy).

**Does you App or tech product need to be classified as a medical device?** It depends on the intended purpose and intended user. If used for a [medical purpose](#) (e.g., diagnosis or prediction of a disease or alleviation of disability), then you need to register as a medical device. If the software / product on the other hand is used for general purposes, even in health-care setting (e.g. staff admin), then you do not need to register as a medical device. Apps that support general lifestyle & well-being, for example, do not usually need to be registered as a medical device but on the other hand please note, that medical use is not limited to a healthcare setting and covers for instance also homecare. Please note, that even if your product is outside of the MDR scope, you may still need to work on a CE mark and there are standards to follow such as for usability.

Be aware that there are additional MDR requirements that must be fulfilled such as risk identification, mitigation and documentation, etc.

**Do you already have a product on the market?** Products sold prior to May 2021 can still be sold under an exemption until expiry of the MDD certificate or May 2024, however with very limited changes to

their performance (just bug fixes). Thereafter or when the old certificates automatically expire, MDR rules will apply.

**Who in Sweden is responsible for regulating medical devices and pharmaceuticals?** The Swedish Medical Product Agency which, in Swedish called [Läkemedelsverket](#).

**How to classify a medical device and build a technical file?** Follow the guidelines of the Swedish Medical Product Agency. Check out for webinars for relevant topics and if it is the first time you do it, take help from consultants and other experts. The more claims you make on your product, the higher the risk, the higher the classification.

**Risk classification in Sweden (same in all European Union member states and Norway):** Medical devices are categorized into four classes according to their risk: Class I, Class IIa, Class IIb, and Class III. Class I medical devices are associated with the lowest risk, while Class III devices are associated with the highest risk. Compared to the previous legislation, MDD, many software based medical devices have been upgraded to class II, which require a notified body for CE mark approval.

**Data privacy: GDPR** applies to all personal data but the more sensitive the data, the more measures needed. Figure out purpose for data processing, and what legal ground (e.g. agreement or consent), make sure to have relevant agreements for data controlling and processing in place and [ethical permits](#) if such are needed.

In addition to GDPR, healthcare derived personal data is also covered by the national law [Patientdatalagen](#), which puts restriction on data usage and transfer.

Finally, bear in mind that the healthcare sector to a large extent is public and there are rules and agreements on appropriate interactions with public officials such as on antibribery and anticorruption. A good rule of thumb: There is no such thing as a free lunch. More info can be found here: [swedishmedtech.se/sidor/de-nya-samverkansreglerna-1.aspx](#)

Photo: xxx





# INDICATOR

## COMMERCIAL POTENTIAL

### WHAT IS THE EASE OF SELLING OUTSIDE THE REGULAR REIMBURSEMENT SYSTEM?

- The Swedish healthcare system is primarily funded by taxes. The market is fragmented with smaller private players.
- The easiest way to get into a market outside the regulated public sector is to turn to the digital care givers and private care giver who are growing fast in Sweden (especially within primary care and digital care).

Photo: iStockphoto



### DIGITALIZATION

- Sweden is digitally mature and many services are available online, but the fact that healthcare is supplied and paid for mainly by the fragmented public sector have created hurdles for efficient digitisation.
- Online ‘meet a doctor’ solutions are widely available, from both regions and private sector. Patients can access part of their records online, as well as manage their prescriptions through digital means.
- There is a lack of standardisation of formats, and there is also a “Patient data law” to be taken into account. Integration of services that cover several steps in the patient journey become difficult and expensive to implement for suppliers.
- Hospital and primary care personnel in general do not yet have mobile devices as work tools.
- An integrated view of a patient’s interactions with the healthcare system is possible through a national patient overview service.
- The sector is not very data driven even though e.g. national quality registries are widespread, at times going back 40 years or more.
- The private sector for healthcare delivery is managed region by region, and while the search for efficient digital tools is of high interest there, the impact is limited by silo:ed payment schemes from the regional payers.
- *Digitalization in Municipalities:* +- 76% of municipalities have introduce the digital night supervision. for the elderly in own homes; +-62% of the municipalities offer GPS alarms in elderly care and 45% for disability. Source: Sarah Wamala Andersson Professor i hälso- och välfärdsteknik Mälardalens Högskola (no link)

# INDICATOR COMMERCIAL POTENTIAL

## PRIVATE CUSTOMERS AND PROCUREMENT

**Customers:**

These organizations, as well as others, may purchase a digital health solution

**Primary care\*:**

- Capio
- Aleris

**Three largest digital care companies\***

- KRY:
- Doktor.se
- Min Doktor

**Large private care takers within elderly care\***

- Attendo Care
- Ambea
- Förenade Care

\*Vårdrapporten November 2020

## POTENTIAL HOME-MARKET CUSTOMERS OUTSIDE THE REIMBURSEMENT SYSTEM

**Health insurance companies\*:**

Only 1% of the Swedish people have a healthcare insurance. The largest companies are IF, Euroaccident, Länsförsäkringar,

**Pharma\*\*:**

- Astra Zeneca. pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of pharmaceuticals across the world. Integrated in AZ, The BioVentureHub is an innovative 4D (drugs, devices, diagnostics, digital health) ecosystem
- Swedish Orphan Biovitrum- SOBI, a big pharma company focused on innovative solutions for rare diseases.
- Recipharm- A world leading CDMO.
- Pfizer Health- one of the world's largest pharma compaines driving innovation.
- Fresenius Kabi- Global pharma company with core business clinical nutrition. Production site in Uppsala.

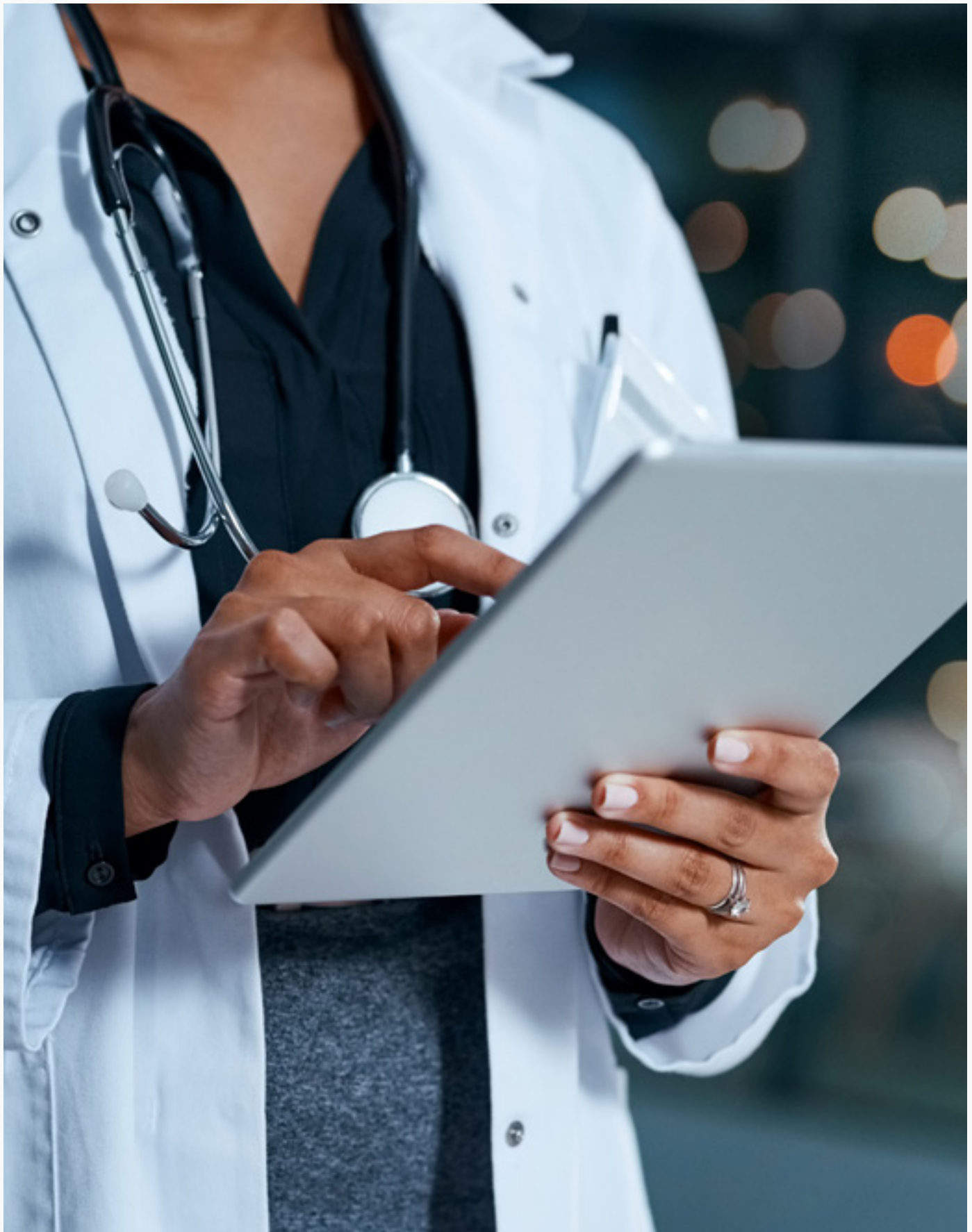
**Medtech and health care**

- Getinge AB,
- Essity AB
- Mölnlycke Health Care AB

\*svenskforsakring.se/statistik/marknadsstatistik/forsakringsmarknaden/

\*\*largestcompanies.se/topplistor/sverige/de-storsta-foretagen-efter-omsattning/bransch/tillverkning-av-farmaceutiska-basprodukter-och-lakemedel

Photo: iStockphoto





# INDICATOR

## EASE OF DOING BUSINESS

Photo: iStockphoto



### DEGREE OF BUREAUCRACY

- In terms of **Sales**. For Larger business in the public health service, the law on public procurement is strictly followed, which is done in larger announced calls. The same is valid for procurements in municipalities. Exceptions are made for smaller pilot projects in direct relation to individual clinics. Government is highly digitized, with most applications and processes provided digitally across government, county, municipality and clinic.
- The level of **corruption** in Sweden is very low, according to a 2011 pan-European study by Transparency International's 2017 Corruption Perception Index ranks the country 6th plac out of 180 countries.

### SKILL AND WORKFORCE AVAILABILITY

Overall, there is high availability of skilled workers in Sweden. There is a high degree of knowledge workers.

The country offers mandatory language training to all children. A very large percentage of the population are fluent in English. A significant percentage also speak German, French, Spanish. Due to the relatively high immigration to Sweden, several languages are also spoken in Sweden, such as Arabic and Persian. The higher education system is compatible with the rest of Europe. Unemployment rate in Sweden is between 7-8%

#### Highest-Demand Occupations 2018-2030:

- 326 000 Personal care workers
- 281 000 Health professionals

### MACROECONOMIC STABILITY

- According to the world bank, GovData360 Sweden ranks at the top in terms of macroeconomic stability and in the top according to world economic forum 2019
- Offering a legally, politically, economically and socially stable framework, Sweden is an attractive place for foreigners to launch a new business

### IS THERE A NEED FOR A LEGAL ENTITY?

A Swedish limited company is preferred but not mandatory. International registration of limited companies is handled at verksamt.se

### INNOVATION CAPABILITY

EU Innovation Scoreboard 2021, published by European Commission\*

<b>1/</b> Sweden	<b>6/</b> Germany
<b>2/</b> Finland	<b>7/</b> Luxemburg
<b>3/</b> Denmark	<b>8/</b> Austria
<b>4/</b> Belgium	<b>9/</b> Estonia
<b>5/</b> Netherlands	<b>10/</b> France

\* [DocsRoom - European Commission \(europa.eu\)](#)

### BUSINESS RANKING

Forbes Best Countries for business 2018 Ranking \*

<b>1/</b> UK	<b>6/</b> Canada
<b>2/</b> Sweden	<b>7/</b> Denmark
<b>3/</b> Hongkong	<b>8/</b> Singapore
<b>4/</b> Netherlands	<b>9/</b> Australia
<b>5/</b> New Zealand	<b>10/</b> Switzerland

\* [Best Countries for Business List \(forbes.com\)](#)

# INDICATOR CUSTOMER ACQUISITION



Photo: iStockphoto

## BASED ON YOUR BUSINESS MODEL, WHAT IS THE EASE OF CUSTOMER ACQUISITION?

- **B2C:** The market is easily approachable. More than half of Swedes use digital health services. Swedes consume digital media for several hours a day, and can be easily addressed through advertising.
- **B2B – Public Sector:** It can be difficult to go to market and sell products to healthcare professionals. The public tender system may delay the customer acquisition process significantly, and prevent sales of novel and innovative solutions..
- **B2B – Private Sector:** The market is easily approachable, with few barriers of entry. Private healthcare professionals may easily be approached with novel and innovative solutions.
- **B2B2C (e.g., GP, private healthcare providers):** Medium due to a recognition that technologies are needed to alleviate system pressures, a relatively high digital affinity amongst clinicians and patients’ trust in public authorities to handle private data appropriately. However, a lack of established reimbursement mechanism for software as a med device (e.g., DiGA) in Sweden

## POPULATION SIZE AND MARKET GROWTH

- Population: 10,500,000. Sweden spends approximately 11% of its GDP on healthcare per year. In 2020, Sweden spent 11,4% share of its GDP on healthcare\*. Healthcare spending, as a % of GDP, grew 57% in Sweden between 2000 and 2019.\*\*
- From the total healthcare expenditure, approximately 85% is public and 15% is private.\*\*\*

## OTHER:

**Services covered:** The national, publicly financed health care system fully covers the following services:

- primary and preventive care
- specialist care
- hospital care, including inpatient prescription drugs
- mental health care
- long-term care
- dental services. For children under age 18. For adults above age 18 with qualified condition. (The age above 18 where this is covered differs between the different regions).

**Cost-sharing and out-of-pocket spending:** There is an out of pocket scheme in the Swedish healthcare system. This is applied, but not exclusive to, GP and specialist consultation (SEK 150-400), as well as and hospitalization per day (SEK 50-100). Maximum out of pocket cost is limited to SEK 1100 per year per patient (2022). Private clinics and hospitals may charge up to 100% of the cost for treatment. For more information, see <https://www.commonwealthfund.org/international-health-policy-center/countries/sweden>\*\*\*\*

\*OECD (2022), Health spending (indicator). doi: 10.1787/8643de7e-en (Accessed on 15 February 2022). <https://data.oecd.org/healthres/health-spending.htm>

\*\*WHO Global health expenditure database, <https://apps.who.int/nha/database/ViewData/Indicators/en>



# REFERENCES

DIGG – Myndigheten för digital förvaltning | DIGG – Agency for digital governmnet. Helps structure the digital landscape for the public actors. Wants to achieve a sustainable welfare society, by intensifying the digitalisation of Sweden. Together with the entire public adm, “we strive to make the transition happen – and benefit all.”  
[Swedish Authority for Privacy Protection | IMY-](#) *IMY’s role is to uphold the protection of personal data, monitoring that they are handled correctly and do not fall into the wrong hands.*

Läkemedelsverket [www.lakemedelsverket.se/sv](#)  
Tandvårds- och Läkemedelsförmånsverket [www.tlv.se](#)  
Socialstyrelsen [www.socialstyrelsen.se](#)  
Inspektionen för Vård och Omsorg (IVO) [www.ivo.se](#)  
Hälso- och Sjukvårdens Ansvarsnämnd (HSAN) [https://www.socialstyrelsen.se/om-socialstyrelsen/organisation/rad-och-namnder/halso--och-sjukvardens-ansvarsnamnd/](#)  
Myndigheten för Vård och Omsorg [www.vardanalys.se](#)  
Folkhälsomyndigheten [www.folkhalsomyndigheten.se](#)  
Statens beredning för medicinsk och social utvärdering (SBU) [www.sbu.se](#)  
Försäkringskassan [www.forsakringskassan.se](#)  
eHälsomyndigheten [www.ehalsomyndigheten.se](#)  
[Swedish Authority for Privacy Protection | IMY-](#) IMY  
[DIGG – Myndigheten för digital förvaltning | DIGG](#) - DIGG

Hälso- och Sjukvårdens Ansvarsnämnd (HSAN) [https://www.socialstyrelsen.se/om-socialstyrelsen/organisation/rad-och-namnder/halso--och-sjukvardens-ansvarsnamnd/](#)  
Statens beredning för medicinsk och social utvärdering (SBU) [www.sbu.se](#)  
Försäkringskassan [www.forsakringskassan.se](#)

eHälsomyndigheten [www.ehalsomyndigheten.se](#)

**Sarah Wamala Andersson Professor i hälso- och välfärdsteknik Mälardalens Högskola (ask if it can be used as a source)**  
58% of the municipalities have a management systemwhich includes welfare technology  
• About 48% of the municipalities can receive applications forincome support via an e-service. • In 56% of the municipalities, all home care staff candocument in the business system when they workoutside the office • About 76% of the municipalities have introduced digitalnight supervision for the elderly who live in ordinary housing. • About 62% of the municipalities offer GPS alarmsin elderly care and 45% in the field of disability.  
(Soft funding/Grants/Investors)  
Vinnova [www.vinnova.se/sok-finansiering/hitta-finansiering/](#)  
Almi företagspartner [www.almi.se](#)

Tillväxtverket [https://tillvaxtverket.se/finansiering/for-foretag.html](#)  
Regional org.  
VGR Företagsfinansiering [https://www.vgregion.se/regional-utveckling/verksamhetsomraden/naringsliv/foretagsfinansiering/](#)  
MedTech4Health [https://medtech4health.se/](#)

Consider adding:  
*System integrators:* Cerner, TietoEvry, Cambio, CombuGroup  
Vårdföretagarna, 230 företag verksamma inom hemtjänst eller äldreboenden, Aleris Attendo, Frösunda, Vardaga [https://www.vardforetagarna.se/bransch-aldreomsorg/](#)

Financing  
(Soft funding/Grants/Investors)  
Vinnova [www.vinnova.se/sok-finansiering/hitta-finansiering/](#)  
Almi företagspartner [www.almi.se](#)  
Tillväxtverket [https://tillvaxtverket.se/finansiering/for-foretag.html](#)  
Regional org.  
VGR Företagsfinansiering [https://www.vgregion.se/regional-utveckling/verksamhetsomraden/naringsliv/foretagsfinansiering/](#)  
MedTech4Health [https://medtech4health.se/](#)  
The Swedish Private Equity & Venture Capital Association (SVCA) [www.svca.se](#)

The Swedish Private Equity & Venture Capital Association (SVCA) [www.svca.se](#)

Office for Clinical Studies [www.kliniskastudier.se/english](#)  
Upphandlingsmyndigheten [www.upphandlingsmyndigheten.se](#)  
Upphandlingsmyndigheten, Hitta affären i offentlig sektor [https://www.upphandlingsmyndig-heten.se/gora-affarer-med-offentlig-sektor/hitta-affaren-i-offentlig-sektor/#registrering\\_i\\_databaser\\_f%C3%B6r\\_att\\_f%C3%A5\\_information\\_och\\_kunna\\_l%C3%A4mna\\_anbud](#)

Pricing & Reimbursement 2020, Sweden [www.globallegalinsights.com/practice-areas/pricing-and-reimbursement-laws-and-regulations/sweden](#)

\* [https://www.ekonomifakta.se/Fakta/Valfarden-i-privat-regi/Vard-och-omsorg-i-privat-regi/vardcentraler-i-privat-regi/](#)  
\*\* [https://skr.se/skr/tjanster/kommunerochregioner/faktakommunerochregioner.1022.html](#)

[www.lexology.com/library/detail.aspx?g=9ee07906-44d1-4b46-818a-caa0cfd2eb62](#)  
Data privacy guideline: [https://www.cnil.fr/en/privacy-impact-assessment-pia](#)

**Where to start?** The **claims you make** on your product have a direct impact on what classification your product/app gets, the higher the risk, the higher the classification. Additional MDR requirements: risk identification, mitigation and documentation, a clinical plan for building evidence for safety and performance of the device throughout its whole life cycle which goes beyond reporting adverse events to the relevant authority. Evidence can be based on literature, quality register studies and clinical investigations on patients (the latter two requiring also ethical permits). Also required is a dedicated person for regulatory compliance (which can be a consultant) and a quality management system (in compliance with ISO 13485).  
**Do you already have a product on the market?** Products sold prior to May 2021 can still be sold under an exemption until expiry of the MDD certificate or May 2025, however with very limited changes to their performance (just bug fixes). In 2025, when the old certificates automatically expire, MDR rules will apply.

[https://www.imy.se/](#)

**”Digitalization” situation and vision: PETER!**  
Sarah Wamala Andersson Professor i hälso- och välfärdsteknik Mälardalens Högskola (ask if it can be used as a source)  
58% of the municipalities have a management system which includes welfare tech • About 48% of the municipalities can receive applications for income support via an e-service. • In 56% of the municipalities, all home care staff can doc. in the business system when they work outside the office • About 76% of municipalities have introd. digital night superv. for the elderly in own homes. • About 62% of the municipalities offer GPS alarms in elderly care and 45% for disability.  
**Vision E-häsla 2025:** [https://www.statskontoret.se/publicerat/publikationer/publikationer-2021/vision-e-halsa-2025--ett-forsok-att-styra-genom-samverkan/](#)

\*OECD (2022), Health spending (indicator). doi: 10.1787/8643de7e-en (Accessed on 15 February 2022). [https://data.oecd.org/healthres/health-spending.htm](#)

\*\*WHO Global health expenditure database, [https://apps.who.int/nha/database/ViewData/Indicators/en](#)

\*\*\*[https://scb.se/hitta-statistik/statistik-efter-amne/nationalrakenskaper/nationalrakenskaper/halsorakenskaper/pong/statistiknyhet/halsorakenskaper-2019/](#)

\*\*\*\*The Commonwealth Fund, [https://www.commonwealthfund.org/international-health-policy-center/countries/sweden](#)



NORWAY

# MARKET ACCESS HANDBOOK

This document is general in its content and aims to provide general information, it does not intend to be a comprehensive overview of the current requirements for market access. This document is not intended to be or should be construed and relied upon as a legal assessment or recommendation on a specific issue or case. /February 2022



# NORWAY OVERVIEW

## QUICK FACTS



Photo: iStockphoto

### POPULATION SIZE: 5,400,000

### CURRENT GOVERNMENT: CENTER-LEFT

### HEALTHCARE SYSTEM OVERVIEW:

- Single payer system with primarily public provision, based on tax contribution
- Access is universal and largely free at the point of use
- Patients can freely choose their preferred hospital
- Political focus is on innovation, sustainability & digitization
- The system is largely decentralized. Health services are provided across 4 health regions and 356 municipalities.
- The central government plays a large role in oversight & regulation

### NORDIC HEALTH TECH COMPANIES

See HealthTech Nordic's [website](#) for an overview of participating health tech companies in Norway, and the Nordics. A more comprehensive list of Norwegian health tech companies are available on Norway Health Tech's [website](#).

### CUSTOMERS:

- 1/ Major hospitals:**  
Oslo Universitetssykehus, Haukeland, St. Olavs, Universitetssykehuset I Stavanger, Universitetssykehuset I Tromsø.
- 2/ Large Municipalities:**  
Oslo, Bergen, Trondheim, Stavanger, Kristiansand.
- 3/ Large private healthcare providers:**  
LHL-hospitals, Alleris, Teres, Volvat.

# NORWAY OVERVIEW SUMMARY

## REGULATORY



- Norway abides by MDR and GDPR
- Not all apps need to be classified as medical devices. Whether apps need to be classified as a medical device depends on the intended use of the device
- The Norwegian Medicines Agency is the primary regulatory authority managing the certification and use of medical devices
- Overall, there are many similarities with Sweden and Denmark in this regard

## EASE OF DOING BUSINESS



- Ranks high in most international comparisons such as macroeconomics, stability, innovation, skilled workforce, business climate and low corruption.
- Very skilled workforce, but labor shortages in IT and health.
- Norway has a high degree of digital maturity in healthcare and elsewhere

## REIMBURSEMENT



- Digital solutions can be reimbursed in Norway. However, there is no national policy/guideline/process in place for approving, prescribing and reimbursing health apps.
- Instead, start-ups need to participate in tenders or negotiate with customers (regions and municipalities) directly and live up to their individual requirements.
- Healthcare providers must negotiate reimbursement with government (HELFO)

## CUSTOMER ACQUISITION



- B2C: High due to health-conscious culture that appreciates technology; Public B2B: Low due to complicated customer acquisition process. Private B2B: High due to fast and streamlined purchasing processes. B2B2C (e.g., GP/insurer): Medium due to lack of incentive structures and reimbursement mechanisms
- Population size: Small (5.4M), urban & aging population, low fertility
- Market growth: Public healthcare spending grew 32% between 2014 and 2020.
- Market split: 86% is Public spending, 14% is private spending (2020)

## COMMERCIAL POTENTIAL



- Norway has a large and mature healthcare sector with an identified need for innovative solutions that cut cost and improve quality and efficiency.
- Healthcare providers (e.g., hospitals & GPs) are highly digitized.
- There is a focus on an aging population & improved operational efficiency

## CULTURAL



- Key values are democracy, individualism, indulgence and sustainability
- ~86% of Norwegians speak English and communicate well with Swedish people. Reading Danish is very easy as the written languages are practically identical, but speaking Danish is limited due to large differences in pronunciation



# 01/HEALTH SYSTEM

/NO

# HEALTH SYSTEM DEEP-DIVE

## HEALTH SYSTEM OVERVIEW

- **In short**, The Norwegian health care system is founded on the principles of universal access, decentralization and free choice of provider. It is financed by taxation, together with income-related employee and employer contributions and out-of-pocket payments (co-payments). All residents are covered by the National Insurance Scheme (Folketrygden, NIS), managed by the Norwegian Health Economics Administration (Helseøkonomi-forvaltningen, HELFO). Private medical insurance is limited.
- **Role of Government:** While health care policy is controlled centrally, responsibility for the provision of health care is decentralized. Local authorities at municipal level organize and finance primary health care services according to local demand. The central Government has overall managerial and financial responsibility for the hospital sector. Norway's four regional health authorities control the provision of specialized health services by 27 health enterprises.
- **Government agencies:** The Ministry of Health and Care Services (Helse- og omsorgsdepartementet, HOD) is the legislative authority. The Norwegian Medicines Agency (Statens legemiddelverk, NoMA) (subordinate to the HOD) is in charge of marketing authorization, classification, vigilance, pricing, reimbursement and providing information on medicines to prescribers and the public. HELFO decides on reimbursement for individual patients, and monitors prescriptions issued by doctors. For private practitioners of healthcare services, an authorization from HELFO is required for public refunding of expenses. HELFO provides a complete list of practitioners approved for public refunds on their website.

Photo: iStockphoto





# HEALTH SYSTEM DEEP-DIVE

## HEALTH SYSTEM OVERVIEW

- **Legemiddelverket:** The Norwegian Medicines Agency (Statens legemiddelverk, NOMA) safeguard public and animal health by ensuring the efficacy, quality and safety of medicines and by enforcing the medical devices regulation. Usually referred to as “Legemiddelverket”, they are responsible for national medical device certification.
- **E-health:** The Norwegian government is actively investing in E-health. An overwhelming majority of these initiatives are investigated, operated and developed by the directorate for e-health (Direktoratet for e-helse) and Norsk Helsenett SF.
- **Hospitals:** Most hospitals in Norway are public hospitals, funded and owned by the state. A small number of hospitals are privately owned. However, most private hospitals are funded by the public.
- **Municipalities** are responsible for financing and delivering nursing home care, home nurses, school health services, home help, general practitioners, and general rehabilitation.
- **General Practitioners:** All Norwegian citizens are invited to choose their general practitioner (GP) / family doctor from a list. 99% of Norwegians have chosen to do so. The GP act as gatekeepers for specialized care. When necessary, the GP will refer patients to specialists, hospital care or healthcare services provided by municipalities.
- **Helsenorge.no** is a public website for all residents of Norway. Free content on healthcare is provided by various players in the health sector, and Norsk Helsenett is responsible for the operation and development of the [website](#). The site serves 2 purposes; (1) Providing fact checked and updated information

about health, lifestyle, illness, treatment and patient privileges. Patients can also Here you can also search for GPs who have a vacancy. All content is delivered by public health actors and hospitals in Norway. A complete list of contributors can be found here. (2) Self-service solutions where patients can see health information that is registered about them. Patients can view and edit their core medical record, change GPs, get an overview of prescriptions and check vaccine status.

- **Pharmaceutical system:** All major international pharmaceutical companies are represented in Norway, but only a few of them have established their own manufacturing units in the country. In Norway there are 3 wholesalers providing a full range of products to the market, belonging to the leading European pharmaceutical distribution companies. Each of the wholesalers is vertically integrated with their own pharmacy chain. Only community and hospital pharmacies are allowed to dispense medicines. Grocery stores, gasoline stations e.g. are allowed to distribute a restricted list of OTC.
- **Role of private health insurance:** Complementary voluntary health insurance, purchased on an individual basis, is relatively rare. Approximately 650.000 (2020) Norwegians have access to private health insurance, often through their employer.
- **For further info see:** [The Norwegian Government](#), [Directorate of Health](#), [Norwegian Data Protection Authority](#). Please note that only a fraction of the information is provided on the English version of their websites, and the Norwegian sites contain more content, detail and references.

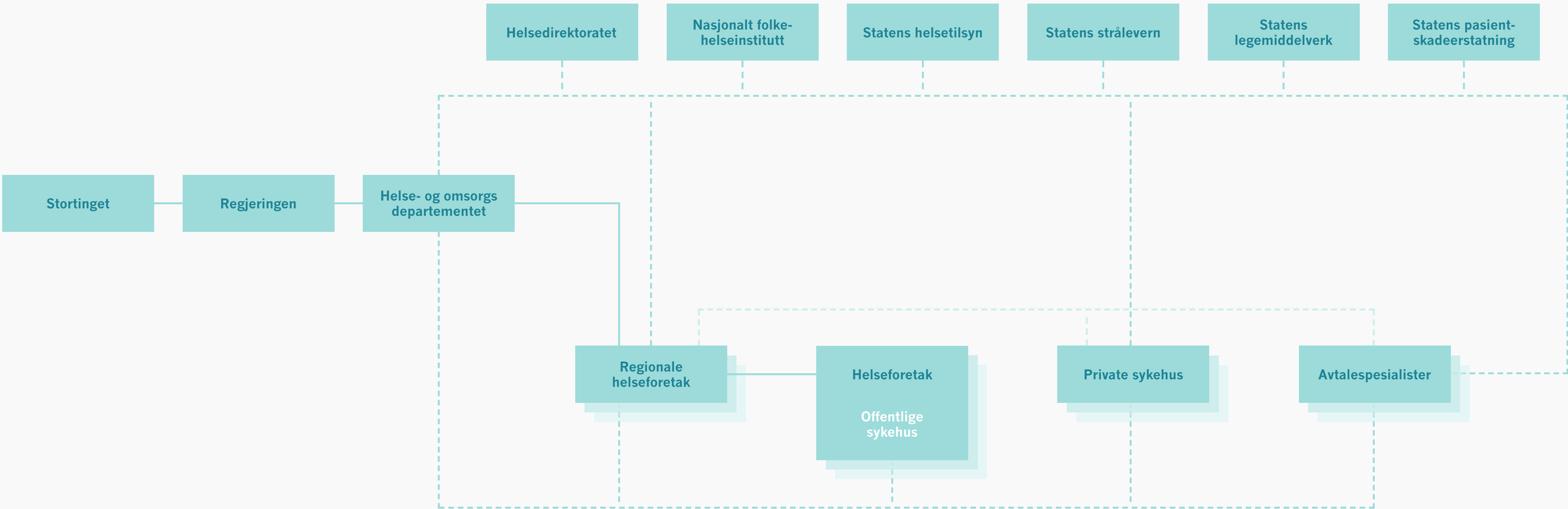
Photo: iStockphoto



# HEALTH SYSTEM VISUALIZATION

## HEALTH SYSTEM STRUCTURE

- Notes:**
- 4 health regions (Helseforetak) organize the majority of specialist services
  - Municipalities (not shown) are providers of a wide range of primary healthcare services



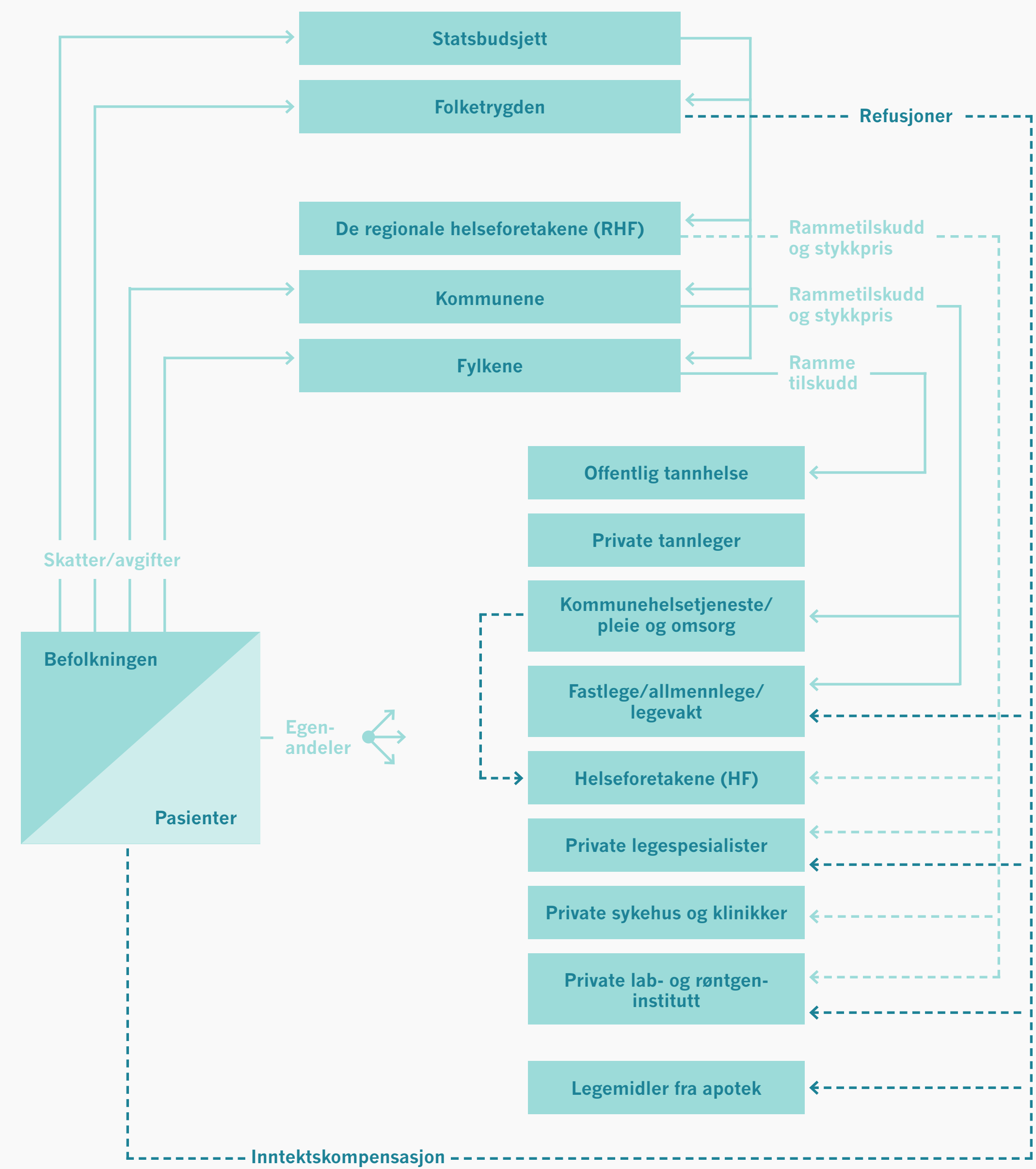


# HEALTH SYSTEM VISUALIZATION

## REIMBURSEMENT MECHANISM (SIMPLIFICATION)

**Notes:**

- About 84% of healthcare expenditure in Norway is publicly financed, while the other 16% comes primarily from patient co-payments
- Taxes are collected at the national, county and municipal levels, then re-allocated to hospitals and general practitioners





# 02/INDICATOR

/NO



# INDICATOR REGULATORY

## DOES YOUR APP NEED TO BE CLASSIFIED AS A MED DEVICE?

- **Norway falls under MDR guidelines**, and generally comply with all major EU legislation related to healthcare and HealthTech solutions.
- **Does your app need to be classified as a medical device?**  
It depends. If the app is intended for use that falls under the definition of diagnosing, preventing, treating, or recovering from a medical condition, or it is being applied by a healthcare professional for these purposes, the app may be subject to certification. For apps that support general lifestyle & well-being, but do not promise to actively diagnose, prevent or treat an illness, there is generally no need to be registered as a medical device.
- **Who in Norway is responsible for regulating medical devices and pharmaceuticals?** The Norwegian Medicines Agency (Statens legemiddelverk, NOMA) issue certificates for medical devices and issues marketing authorization to Norwegian manufacturers of equipment. They also ensure that foreign suppliers are appropriately registered in Eudamed before entering the Norwegian market. In addition, the The Norwegian directorate for health, The Norwegian directorate for e-health, the Data Protection Agency (Datatilsynet) and HELFO will monitor and verify compliance with relevant laws.

- **What to do if you need to classify as a medical device?**  
Following the guidelines of the Norwegian Medicines Agency and the Medical Device Directive. When possible, Norway defaults to the rules and regulations of the European Union, allowing most medical devices to be used in Norway if they are previously approved for use in a European country.
- **Risk classification in Norway:** In Norway, just like in all other European Union member states, medical devices are categorized into four classes according to their risk: Class I, Class IIa, Class IIb, and Class III. Class I medical devices are associated with the lowest risk, while Class III devices are associated with the highest risk.

Photo: iStockphoto





# INDICATOR REGULATORY

Photo: iStockphoto



## COMPLEXITY OF DATA PROTECTION

- GDPR is in effect in Norway. The complexity of it is therefore comparable with countries like Denmark and Sweden.
- GDPR can be considered as the world's strongest set of data protection rules, which enhance how people can access information about them and places limits on what organizations can do with personal data.
- The key GDPR principles emphasize that information needs to be used fairly, lawfully and transparently; used for specified, explicit purposes; used in a way that is adequate, relevant and limited to only what is necessary; accurate and, where necessary, kept up to date; kept for no longer than is necessary; handled in a way that ensures appropriate security, including protection against unlawful or unauthorized processing, access, loss, destruction or damage.
- Compliance with GDPR is actively monitored by the Norwegian Data Protection Agency (Datatilsynet).



# INDICATOR

## REIMBURSEMENT FOR DIGITAL HEALTH SOLUTIONS

### WHAT IS THE MECHANISM FOR REIMBURSEMENT FOR DIGITAL HEALTH SOLUTIONS AND APPS?

- **Digital solutions can be reimbursed in Norway.**
- **However, there is no national policy/guideline/process in place for approving, prescribing and reimbursing health apps.**
- **Instead, start-ups need to participate in tenders, or negotiate with customers (regions and municipalities) directly and live up to their individual requirements.**

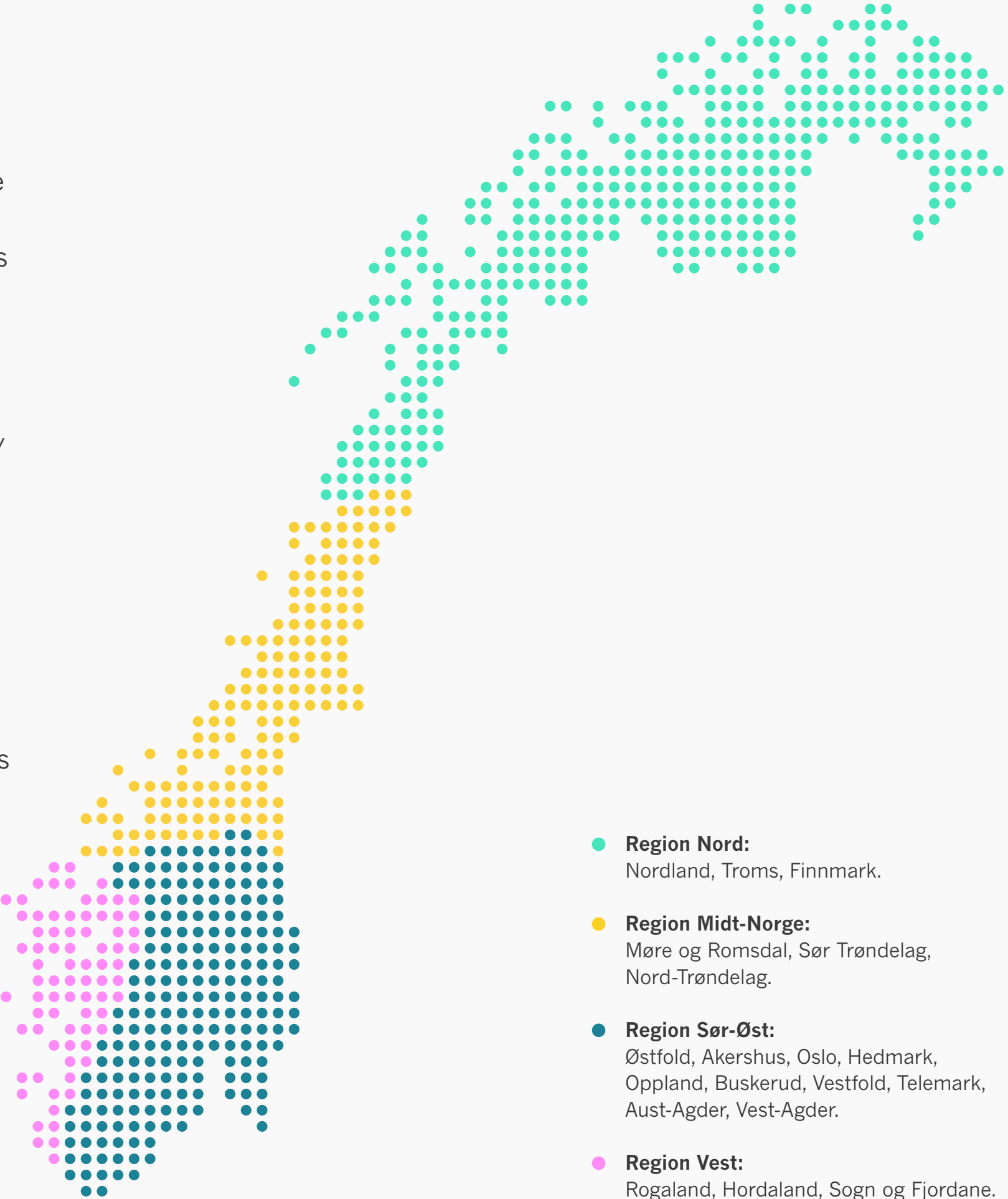
There are 4 health regions and 356 municipalities in Norway. Some regions and municipalities are more interested in piloting new technologies than others.

### BASED ON YOUR SOLUTION, WHAT IS THE EASE OF REIMBURSEMENT?

- **Preventive solution:** As in other European countries, it is more difficult to get reimbursed for preventive solutions than for non-preventive solutions. This is particularly the case if there is limited evidence of the clinical effectiveness of the preventive solution.
- **Non-preventive solution (e.g., treatment, diagnostic):** It is possible to have non-preventive solutions reimbursed. A structured, nation-wide process for reimbursement of apps / other digital solutions does not exist.

### WHAT THE FUTURE LOOKS LIKE...

- **What a future program might look like:** The Norwegian government is closely monitoring the German DiGA program.
- **Distribution:** HELFO and Helsennett have actively qualified apps for healthcare. Distribution through the Helsennett website will greatly lower the threshold for adoption of a new app in hospitals and municipalities.



# INDICATOR

# THE COMMERCIAL POTENTIAL

INCLUDING PUBLIC TENDER SYSTEM

Photo: iStockphoto



## WHAT IS THE EASE OF SELLING OUTSIDE THE REGULAR REIMBURSEMENT SYSTEM?

- Norway has a publicly funded health system. As such, the private market for health tech solutions is limited (unless you sell to consumers directly)
- HELFO is responsible for all reimbursement. Individuals, GPs and hospitals may apply for reimbursement for individual patients.

## THE PUBLIC TENDER SYSTEM:

- **Norway has a public tender system which applies to any purchase or series of purchases where the total expense to the system exceeds NOK 100.000.**
- All public tenders are posted on doffin.no.
- Because the tender begins with the hospital putting out a call for a purchase, it is generally difficult to approach the decision maker with a promotion.
- For the period a call for tender is active, it is generally illegal for the purchasing officer to communicate with any vendor regarding the goods to be purchased. The vendors may only ask questions aimed at clarifying the call for purchase, but may not negotiate or present. Any question asked will be published to other bidders along with the answer provided.
- A complete overview of all active national contracts is maintained by Sykehusinnkjøp on their [website](#). The site is a rich resource, providing detailed terms of each contract, name of active suppliers, termination date, and INCOTERMS classification of shipments under the contracts.



# INDICATOR

## THE COMMERCIAL POTENTIAL

INCLUDING PUBLIC TENDER SYSTEM

### POTENTIAL CUSTOMERS OUTSIDE THE REIMBURSEMENT SYSTEM

**Customers:** These organizations, as well as others, may purchase a digital health solution outside the reimbursement system

**1/ Private hospitals and clinics:**

- Diakonhjemmet
- Aleris
- Volvat
- For a comprehensive list, this Wikipedia article offers an [overview](#)

**2/ Private healthcare providers:**

- Norlandia
- Prima Assistanse
- Aleris
- 2Care
- There are hundreds of private healthcare providers. Many of them are local SMB businesses that can be easily approached with new products and services.

**3/ Wholesale Distributors:**

- Apotek1
- Boots Apotek
- Vitus Apotek
- Elkjøp
- Power

Photo: iStockphoto





# INDICATOR

## EASE OF DOING BUSINESS

### DEGREE OF BUREAUCRACY

- Norway ranks high on most international rankings of government stability and ease of doing business. Corruption in government is rare.
- Government is highly digitized, with most applications and processes provided digitally across government, county, municipality and clinic.

Photo: iStockphoto



### SKILL AND WORKFORCE AVAILABILITY

- Overall, there is high availability of skilled workers in Norway. There is a high degree of knowledge workers.
- The country offers mandatory language training to all children. A very large percentage of the population are fluent in English. A significant percentage also speak German, French, Spanish or Italian as a 3rd language.
- There is a significant shortage of workers in certain professions, including healthcare (doctors, nurses and careers) and in IT.
- The unemployment rate is between 2-4%
- The wealth gap is very small relative to other countries.

### MACROECONOMIC STABILITY

- Norway is a very strong and stable economy, and the national economy has shown a remarkable ability to recover quickly from international financial crises.
- Economic growth is expected to be between 2 and 5% following the corona crisis.
- The Norwegian Central Bank aims to keep inflation below 2%.
- Offering a legally, politically, economically and socially stable framework, Norway is an attractive place for foreigners to launch a new business.



# INDICATOR

## EASE OF DOING BUSINESS

### IS THERE A NEED FOR A LEGAL ENTITY?

- There is no need for a legal entity in Norway if you want to sell goods to Norway. However, if you want to open an account in Norway then you must register your business with the government (Norsk Utenlandsk Foretak – NUF)

### INNOVATION CAPABILITY

- Norway ranks high on most international rankings of innovative capability and ICT adoption.
- Norway is known for a higher degree of digital health maturity than most other European countries (the Digital Health Index by the Bertelsmann 2018)
- All GPs and hospitals use electronic medical journals. During the next 2-4 years, all medical journals will be connected in regional / national databases.

### NORWAY AND THE EUROPEAN UNION

- Through the EEA Agreement, Norway is an equal partner in EU's internal market, on the same terms as the EU member states. This includes having access to the internal market's four freedoms; the free movement of goods, persons, services and capital.
- Norway has signed the [Schengen Agreement](#), and people are generally allowed to move freely between the participating EU and EEA member states.
- Norway is not part of the EU's customs union. It sets its own tariffs on goods imported from outside the single market, but Norwegian goods (with exceptions for farm produce and fish) are imported tariff-free into the EU.
- Norway was the first country to sign a VAT cooperation agreement with the EU. This allows goods to be transported freely to the end user without a costly customs clearance, as long as the supplier collects the Norwegian VAT on behalf of the Norwegian government.



# INDICATOR

## CUSTOMER ACQUISITION



Photo: iStockphoto

### BASED ON YOUR BUSINESS MODEL, WHAT IS THE EASE OF CUSTOMER ACQUISITION?

- **DiaB2C:** The market is easily approachable. Norwegians consume digital media for several hours a day and can be easily addressed through advertising.
- **B2B – Public Sector:** It can be difficult to market and sell products to healthcare professionals. The public tender system may delay the customer acquisition process significantly and prevent sales of novel and innovative solutions.
- **B2B – Private Sector:** The market is easily approachable, with few barriers of entry. Private healthcare professionals may easily be approached with novel and innovative solutions.
- **B2B2C (e.g., GP, private healthcare providers):** Medium due to a recognition that technologies are needed to alleviate system pressures, and relatively high digital affinity amongst clinicians. Patients’ trust public authorities to handle private data appropriately. However, a lack of established reimbursement mechanism for software as a med device prevents adoption of new digital apps.

### POPULATION SIZE AND MARKET GROWTH

- Population: 5,400,000. In 2020, Norway spent EUR 38,6 billion on healthcare, a 11,3% share of its GDP. Spending has grown by EUR 1,5 billion annually 2014-2020.
- From the total EUR 38,6 billion spent on healthcare, 86% is public and 14% is private.

### OTHER:

- Services covered:** The national, publicly financed health care system fully covers the following services:
- primary and preventive care
  - specialist care
  - hospital care, including inpatient prescription drugs
  - mental health care
  - long-term care
  - dental services for children under age 18.
  - Dental services for adults above age 18 with qualified conditions.

**Cost-sharing and out-of-pocket spending:** In public healthcare, patients pay cost-sharing fee for GP and specialist consultation and materials (up to NOK 375 per consultation). Cost sharing is limited to NOK 2921 per calendar year per patient (2022). Private clinics and hospitals may charge up to 100% of the cost for treatment.



DENMARK

# MARKET OVERVIEW

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# DENMARK OVERVIEW

## QUICK FACTS

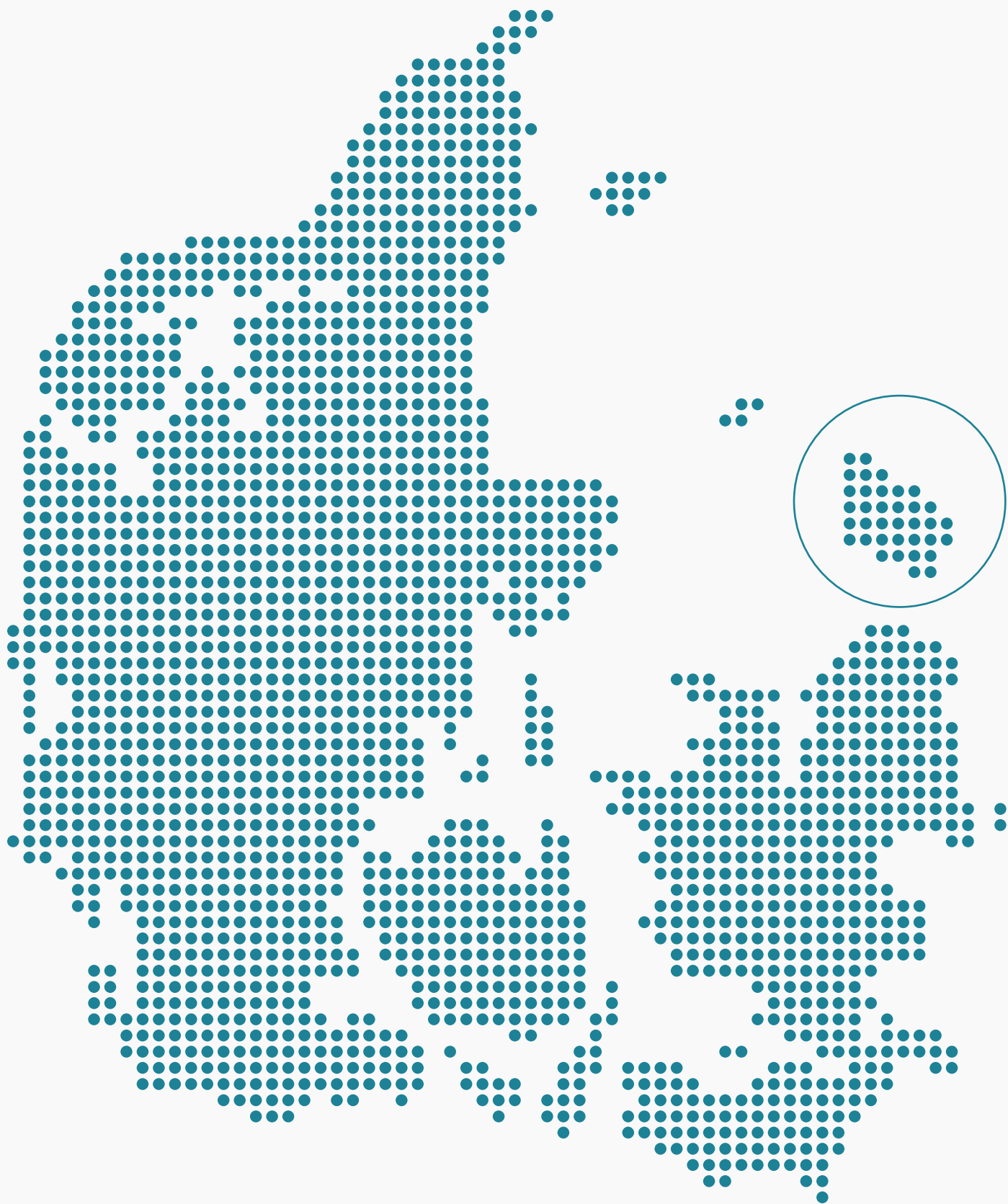


Photo: iStockphoto

### POPULATION SIZE: 5,800,000

### CURRENT GOVERNMENT: CENTRE-RIGHT

### HEALTHCARE SYSTEM OVERVIEW:

- Single payer system with primarily public provision, based on tax contribution
- Access is universal and largely free at the point of use, based on need (not income). Patients can freely choose their preferred of hospital
- Political focus is on equality, prevention & digitization
- The system is largely decentralized. Health services are provide across 5 regions and 98 municipalities. However, the central government has increasingly taken a role in overall planning & regulation

### COMPETITION:

- See Health Tech Hub Copenhagen’s [website](#) for an overview of potential competitors. Key names include:
- 1/ **Lenus:** Recent 53M euro Series A funding to provide a SaaS platform for fitness coaches
  - 2/ **Liva Healthcare:** Recent 25M euro funding round. Platform connecting patients with digital coaches for specific disease groups
  - 3/ **Cerebriu:** AI start-up to automate & improve medical imaging
  - 4/ **Corti:** AI-powered digital assistant with recent \$27M USD funding round used in emergency medicine for example

### CUSTOMERS:

- 1/ **Private health insurance:** Tryg, PFA, TopDanmark, Codan, Bupa
- 2/ **Key hospitals:** Rigshospitalet, Aarhus University Hospital, Odense University Hospital, Aalborg University Hospital
- 3/ **MedTech/Pharma:** Denmark is one of the leading countries in Europe for Pharma and Med Tech. Examples of successful companies that may also purchase digital health solutions include Novo Nordisk, Coloplast, Lundbeck, Leo Pharma, ALK and 3Shape



# DENMARK OVERVIEW

## QUICK FACTS

### REGULATORY



- Denmark abides by MDR and GDPR
- Not all apps need to be classified as medical devices. Whether apps need to be classified as a medical device depends on the intended use of the device
- The Danish Medicines Agency is the primary regulatory authority regulating the certification and use of medical devices
- Overall, there are many similarities with Sweden and Norway in this regard

### EASE OF DOING BUSINESS



- Ranks best in the world for macro-economic stability, 4th in the world in terms of ease of doing business, 10th most competitive nation in the world, 3rd in the world for dynamism, 3rd in terms of availability of skills, 11th in terms of innovative capability and 9th in terms of ICT adoption and is the most digital European country
- Very skilled workforce, but labor shortages in IT and health
- Denmark has a high degree of digital maturity in healthcare and elsewhere

### REIMBURSEMENT



- Digital solutions can be reimbursed in Denmark. However, there is no national policy/guideline/process in place for approving, prescribing and reimbursing health apps.
- Instead, start-ups need to negotiate with customer (regions and municipalities) directly and live up to their individual requirements
- There are 5 regions and 98 municipalities in Denmark

### CUSTOMER ACQUISITION



- B2C: High due to health-conscious culture that appreciates technology; B2B: Medium (due to recognition that digitalization is needed); B2B2C (e.g., GP/insurer): Medium due to lack of incentive structures and reimbursement mechanisms
- Population size: Small (5.8M), urban & aging population, low fertility
- Market growth: Healthcare spending grew 117% in DK between 2000 and 2019, while GDP and public spending ‘only’ grew by 74% and 65%, respectively

### COMMERCIAL POTENTIAL



- Denmark has a large and mature pharma and medtech industry that is increasingly digitizing. This provides a large opportunity
- Healthcare provision (e.g., hospitals & GPs) are highly digitized
- There is room to address an aging population & enhance prevention

### CULTURAL



- Key values are democracy, individualism, indulgence and sustainability
- ~86% of Danes speak English and some understand Swedish and/or Norwegian
- Ease of translating solution into Danish is very high

# 01/HEALTH SYSTEM

/DK



# HEALTH SYSTEM DEEP-DIVE

## HEALTH SYSTEM OVERVIEW

- **In short**, Denmark has a universal, decentralized health system, where the national government provides block grants from tax revenues to the regions and municipalities, which deliver health services. All residents are entitled to publicly financed care, including largely free primary, specialist, hospital, mental health, preventive, and long-term care services. Residents may purchase voluntary complementary insurance to cover copayments for outpatient drugs, dental care, and other services. Supplemental insurance, provided mainly by private employers, offers expanded access to private providers. Cost-sharing limits for adults and for children create a safety net.
- **Role of government:** The national government sets the regulatory framework for health services and is in charge of general planning, monitoring care quality, and licensing health care professionals. The national government also collects taxes and allocates funding to regions and municipalities based on sociodemographic criteria and activity.
- **The state** does not have a direct role in the delivery of health care services. Five regions governed by democratically elected councils are responsible for the planning and delivery of specialized health care services and play a role in specialized social care and coordination. The regions own, manage, and finance hospitals. They also finance the majority of services delivered by private general practitioners (GPs), office-based specialists, physiotherapists, dentists, and pharmacists, as well as specialized rehabilitation. Eighty percent of funding for the regions comes from the state, and 20 percent from municipalities.

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# HEALTH SYSTEM DEEP-DIVE

## HEALTH SYSTEM OVERVIEW

- **Municipalities** are responsible for financing and delivering nursing home care, home nurses, health visitors, some dental services, school health services, home help, substance use treatment, public health and health promotion, and general rehabilitation.
- **The general regulation**, planning, and supervision of health services, including overall cost-control mechanisms, take place at the national level through Parliament, the Ministry of Health, and **five governmental agencies**: (1) *The Health Authority*, which provides general monitoring and regulation of quality through such measures as clinical guidelines and licensing of health care personnel, usually in close collaboration with representatives from medical societies; (2) *The Medicines Agency*, which regulates market access and pharmacovigilance, among other functions; (3) *The Patient Safety Authority*, which handles patient complaints and compensation claims, collects information about errors to foster systematic learning, and provides information about treatment abroad; (4) *The Health Data Authority*, which handles data collection and infrastructure and (5) *The Danish Agency for Patient Complaints*.
- **Primary Care**: General practitioners fill a key position in the Danish healthcare system. The GP is a private company and is the patient's primary contact point to the healthcare system. The GPs play an important role as gatekeepers between the primary level and the specialized healthcare system. When necessary, the GP will refer patients to specialists, hospital care or healthcare services provided by the municipalities. Private providers, paid mostly FFS, rest through capitation.

- **Hospitals & reimbursement**: Mainly public, paid mainly through global budgets and case-based payments. Some bundled and value-based payment pilots at local level. The (DRG) reimbursement system is detailed [here](#) (ENG) and [here](#) (DK)
- **Role of private health insurance**: Complementary voluntary health insurance, purchased on an individual basis, covers statutory copayments – mainly for pharmaceuticals and dental care – and services not fully covered by the state, such as physiotherapy. Some 2.45 million Danes (42%) have such coverage, which is provided almost exclusively by the nonprofit organization Danmark. Danes can choose from two public insurance options. Practically all Danes (98%) choose Group 1 coverage, under which general practitioners (GPs) act as gatekeepers and patients need a referral to see specialists, except for a few specialties. The remaining 2 percent of Danes choose Group 2 coverage, which allows access to specialists without a referral, although copayments apply. Under both insurance options, access to hospitals requires a referral.
- **Denmark's digital infrastructure** is more mature than most European nations. Social security number were institutionalized in 1972 and data has been collected on the population ever since. Prescriptions, referrals and discharge letters are all electronic, enabled also through 2 nationwide EHR systems. **Epidemiology registers** are world-leading capturing large portions of the Danish population and cover numerous chronic and other diseases
- **For further info see**: Denmark | [Commonwealth Fund](#) and [ConsensusReportDanishHealth\\_final.pdf \(copenhagenconsensus.com\)](#) and [#SmartHealthSystems: Bertelsmann](#)

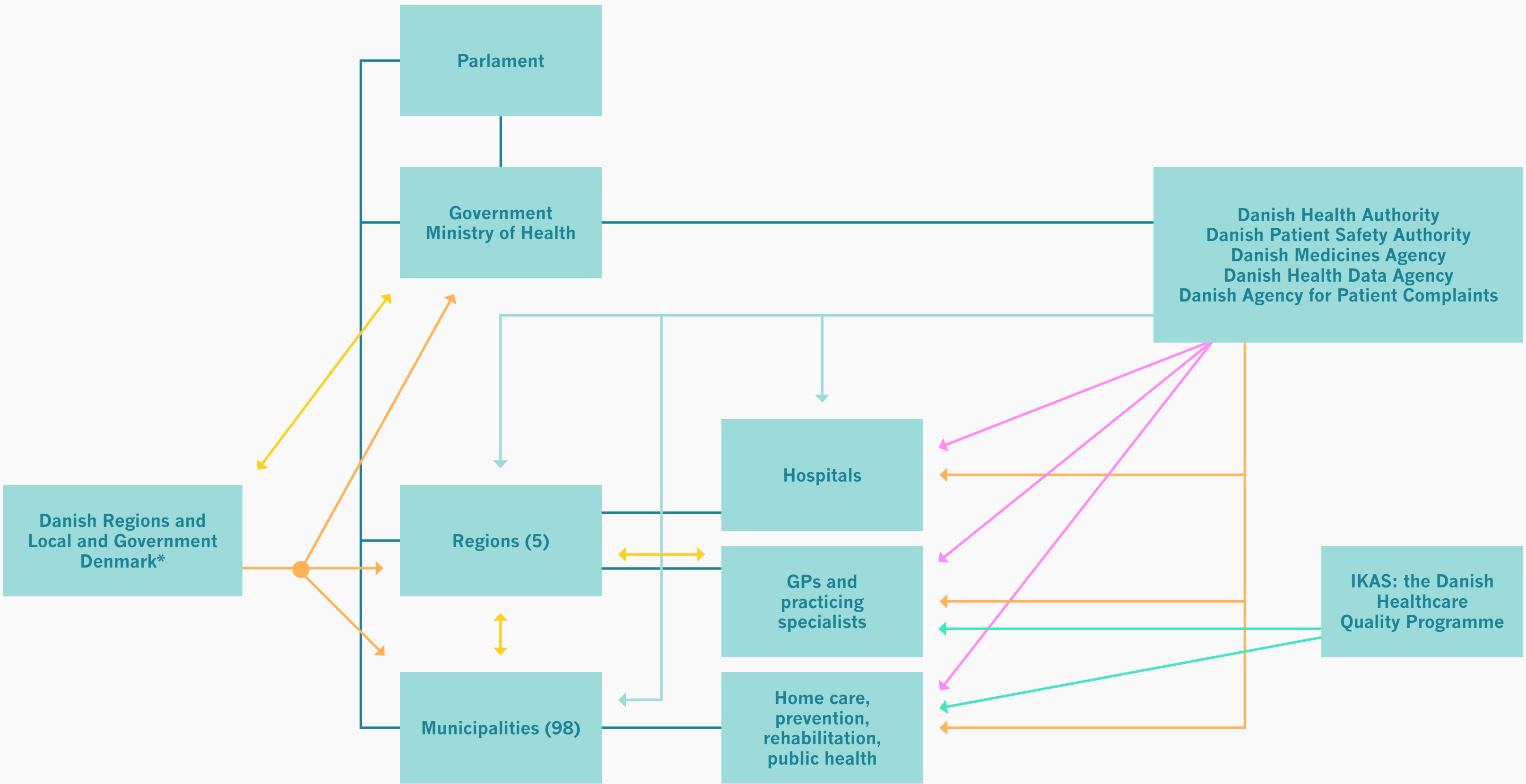
Photo: iStockphoto





# HEALTH SYSTEM VISUALIZATION

## ORGANIZATION OF THE HEALTH SYSTEM IN DENMARK



\* Danish Regions and LGD are the interest organizations for regions and municipalities. They negotiate agreements on their behalf and participate in monitoring of jointly established performance targets.  
\*\* This is being phased out GPs and specialists and is voluntary for municipalities.

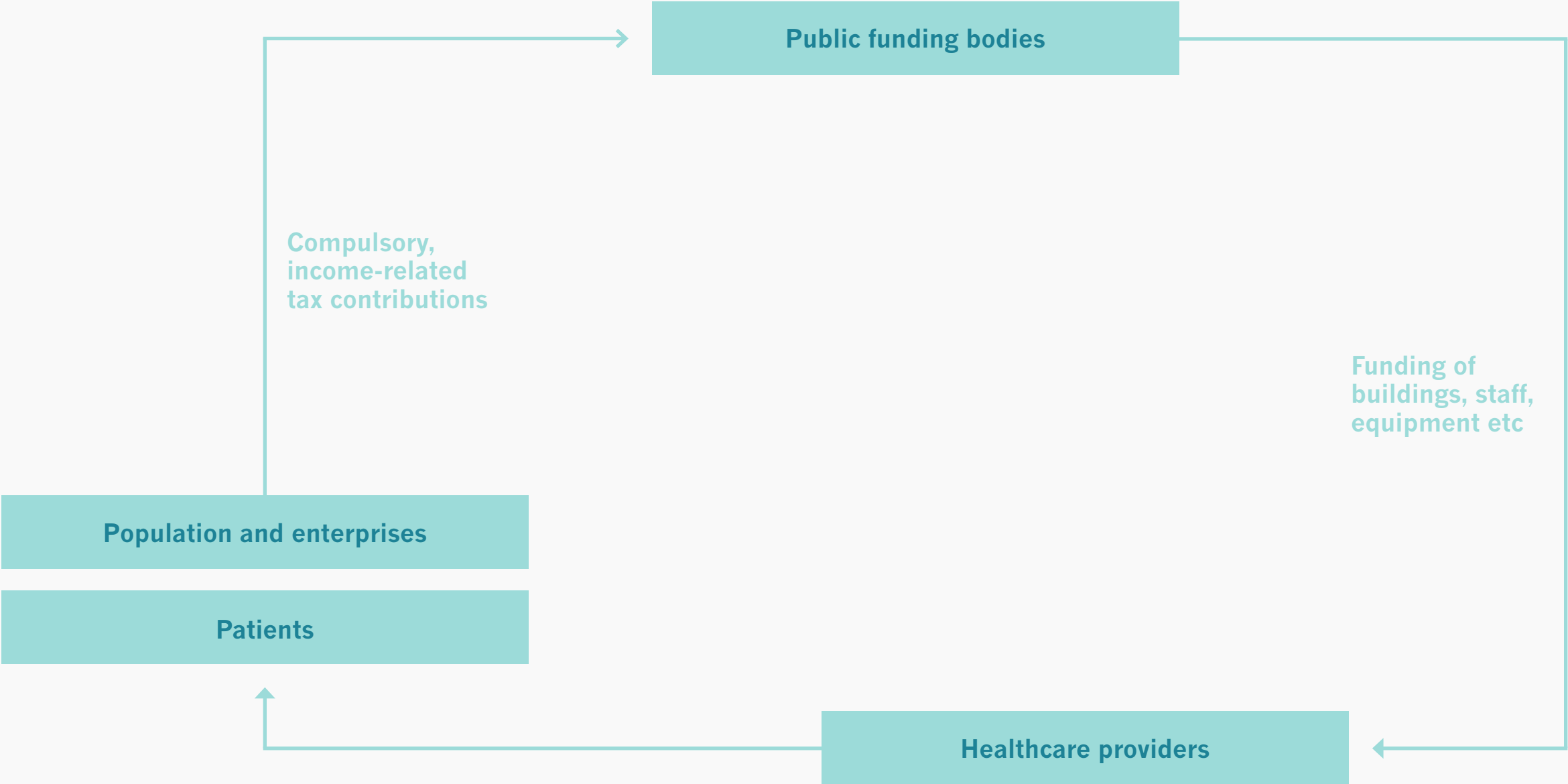
Source: K. Vrangbaek. University of Copenhagen, 2019

# HEALTH SYSTEM VISUALIZATION

## PRIMARY REIMBURSEMENT MECHANISM (SIMPLIFICATION)

**Notes:**

- About 84% of healthcare expenditure in Denmark is publicly financed, while the other 16% comes primarily from patient co-payments from un-referred healthcare services, as specialists visited without a referral carry personal costs to the patient
- Taxes are collected at the national and municipal levels, then re-allocated to hospitals and general practitioners within the regional level as well as local health centers at the municipal level





# 02/INDICATOR

/DK

# INDICATOR REGULATORY

## DOES YOUR APP NEED TO BE CLASSIFIED AS A MED DEVICE?

### Denmark falls under MDR guidelines

- **Does your app need to be classified as a medical device?**  
It depends. It depends on the intended use of the software. If the software is used explicitly for a medical purpose (e.g., diagnosis or prediction of a disease), then you need to register as a medical device. If the software on the other hand is used for general purposes, even if used in a health care setting, then you do not need to register as a medical device. Apps that support general lifestyle & well-being, for example, do not need to be registered as a medical device.
- **Who in Denmark is responsible for regulating medical devices and pharmaceuticals?** The Danish Medicines Agency which, in Danish, is called Laegemiddelstyrelsen
- **What to do if you need to classify as a medical device?**  
Following the guidelines of the Danish Medicines Agency and the Medical Device Directive. One part of the process is that you will need to get CE certified and comply with the relevant requirements for this.

- **Risk classification in Demark:** In Denmark, just like in all other European Union member states, medical devices are categorized into four classes according to their risk: Class I, Class IIa, Class IIb, and Class III. Class I medical devices are associated with the lowest risk, while Class III devices are associated with the highest risk.
- **More information** can be found at [Overview of Medical Device Regulations in Denmark | RegDesk](#) and this is especially relevant for **non-app health solutions**

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# INDICATOR REGULATORY

Photo: iStockphoto



## COMPLEXITY OF DATA PROTECTION

- GDPR is in effect in Denmark. The complexity of it is therefore comparable with countries like Sweden and Norway
- GDPR can be considered as the world's strongest set of data protection rules, which enhance how people can access information about them and places limits on what organizations can do with personal data.
- The key GDPR principles emphasize that information needs to be used fairly, lawfully and transparently; used for specified, explicit purposes; used in a way that is adequate, relevant and limited to only what is necessary; accurate and, where necessary, kept up to date; kept for no longer than is necessary; handled in a way that ensures appropriate security, including protection against unlawful or unauthorized processing, access, loss, destruction or damage



# INDICATOR

## REIMBURSEMENT FOR DIGITAL HEALTH SOLUTIONS

### WHAT IS THE MECHANISM FOR REIMBURSEMENT FOR DIGITAL HEALTH SOLUTIONS?

- Digital solutions can be reimbursed in Denmark.
- **However, there is no national policy/guideline/process in place for approving, prescribing and reimbursing health apps.**
  - **Instead, start-ups need to negotiate with customer (regions and municipalities) directly and live up to their individual requirements.**

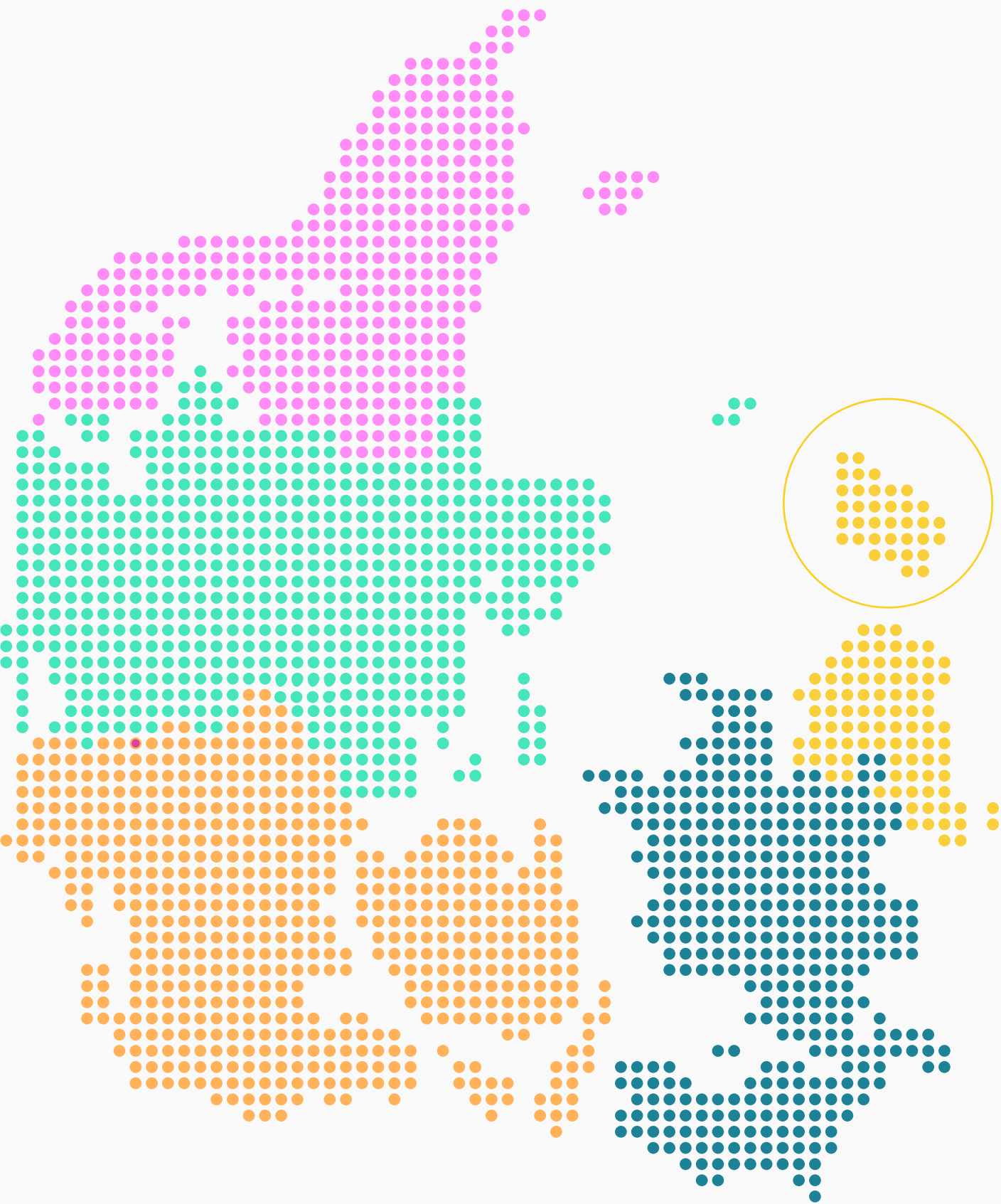
There are 5 regions and 98 municipalities in Denmark. Some regions and municipalities are more interested in piloting new technologies than others. The Novo Nordisk Foundation has recently awarded 128K DKK to Rigshospitalet in Copenhagen and Aarhus University Hospital. Click [here](#) for more info.

### BASED ON YOUR SOLUTION, WHAT IS THE EASE OF REIMBURSEMENT?

- **Preventive solution:** As in other European countries, it is more difficult to get reimbursed for preventive solutions than for non-preventive solutions. This is particularly the case if there is limited evidence of the clinical effectiveness of the preventive solution.
  - Spending on prevention is relatively low in DK 2.4%, compared to Europe (2.8%) [ec.europa.eu/Eurostat](https://ec.europa.eu/eurostat)
- **Non-preventive solution (e.g., treatment, diagnostic):**  
It is possible to have non-preventive solutions reimbursed. A structured, nation-wide process for reimbursement of apps/other digital solutions does not exist

### HOSPITAL MODERNIZATION PROJECTS THAT MAY PROVIDE AN OPPORTUNITY...

For more information on hospital construction see the link below  
[hcd-whitepaper-future-hospitals-v1-2020.pdf \(healthcaredenmark.dk\)](#)



- **National Level**  
Ministry of Health
- **Regional Level**  
5 Regions
- **Local Level**  
98 Municipalities



# INDICATOR

## COMMERCIAL POTENTIAL

EX. REIMBURSEMENT SYSTEM

Photo: iStockphoto



### WHAT IS THE EASE OF SELLING OUTSIDE THE REGULAR REIMBURSEMENT SYSTEM?

- Denmark is a primarily publicly funded health system. As such, it will be more difficult to sell outside the primary reimbursement system (unless you sell to consumers directly)

### OTHER:

- **Denmark has a large and mature pharma and medtech industry that is increasingly digitizing. This provides a large opportunity**
- Healthcare provision (ie hospitals etc) is characterised by extensive digitisation, electronic communication between healthcare providers and systematic use of data and digitised working procedures.
- The prevalence of common IT standards facilitates electronic communication between healthcare providers – hospitals, GPs, specialists, laboratories, local authorities, home care services and others:
  - All GPs keep electronic health records (EHRs), and 98 per cent exchange records electronically.
  - GPs receive all laboratory test results from the hospitals electronically.
  - 99 per cent of all prescriptions are sent electronically to the pharmacies.
  - 97 per cent of all referrals to hospitals are made electronically.
  - All referrals to medical specialists and psychologists are made electronically
- See more info [here](#)
- Some start-ups have integrated with EHRs

# INDICATOR

# COMMERCIAL POTENTIAL

EX. REIMBURSEMENT SYSTEM

## POTENTIAL HOME-MARKET CUSTOMERS OUTSIDE THE REIMBURSEMENT SYSTEM

**Customers:** These organizations, as well as others, may purchase a digital health solution outside the reimbursement system

### 1/ Private Health Insurance:

- Tryg
- PFA
- TopDanmark
- Codan
- Bupa

### 2/ Key hospitals:

- Rigshospitalet
- Aarhus University Hospital
- Odense University Hospital
- Aalborg University Hospital

### 3/ MedTech / Pharma: Denmark is one of the leading countries in Europe for Pharma and Med Tech

- **Novo Nordisk:** Focused on diabetes and obesity but expanding across related disease areas
- **Coloplast:** Develops, manufactures and markets medical devices related to ostomy, urology, continence and wound care
- **Lundbeck:** A pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of pharmaceuticals across the world. The company's products are targeted brain diseases, including depression, schizophrenia, Alzheimer's disease, Parkinson's disease and migraine
- **LEO Pharma:** Develops and markets products for dermatology, bone remodeling, thrombosis and coagulation
- **ALK:** A pharmaceutical company which specializes in the development and manufacture of allergy immunotherapy products for the prevention and treatment of allergy.
- **3Shape:** Award-winning dental lab & intraoral scanners. Digital solutions for dental specialists to digitize dentistry and improve patient experience
- **Novozymes** is a global biotechnology company focused on research, development and production of industrial enzymes, microorganisms, and biopharmaceutical ingredients

Photo: iStockphoto





# INDICATOR

## EASE OF DOING BUSINESS

### DEGREE OF BUREAUCRACY

- Denmark ranks as the 10th most competitive nation in the world out of 140 countries, ranked (World Economic Forum 2019)
- Streamlined and often digitalized processes create a good business environment. Denmark ranks 3rd in the world for business dynamism (World Economic Forum 2019)

### SKILL AND WORKFORCE AVAILABILITY

- Overall, there is high availability of skills in Denmark. Denmark ranks 3rd best in the world for this (World Economic Forum 2019)
- One of the reasons for this is the highest average number of years globally that a worker spent in schooling
- However, there are shortages in healthcare (doctors, nurses and carers) and in IT
- The unemployment rate is between 3-5% (lowest ever)

### MACROECONOMIC STABILITY

- Denmark ranks best in the world for macroeconomic stability (World Economic Forum 2019)
- Economic growth is expected to be between 2 and 4% following the corona crisis
- Offering a legally, politically, economically and socially stable framework, Denmark is an attractive place for foreigners to launch a fruitful business

Photo: iStockphoto





# INDICATOR

## EASE OF DOING BUSINESS

### IS THERE A NEED FOR A LEGAL ENTITY?

- There is no need for a legal entity in Denmark if you want to sell goods to Denmark. However, if you want to open an account in Denmark then a legal entity is needed

### INNOVATION CAPABILITY

- Denmark ranks as 11th in the world for innovative capability and 9th for ICT adoption. DK generates one of the most patents per capita in the world but commercialization is relatively limited
- Denmark is known for a higher degree of digital health maturity than most other European countries (ranking 3rd in the Digital Health Index by the Bertelsmann 2018)
- All GPs and hospitals use electronic medical journals. However, while mature digital infrastructure exists in Denmark's health system (e.g., 2 EHRs across the country), the digital health start-up ecosystem is still maturing

### OTHER

- The World Bank rates Denmark as the 4th easiest nation for doing business
- Denmark is ranked as 55th in terms of market size by the World Economic Forum
- There is a high level of trust in the Danish government and [this](#) was also experienced during COVID-19

Photo: iStockphoto





# INDICATOR CUSTOMER ACQUISITION

Photo: iStockphoto



## BASED ON YOUR BUSINESS MODEL, WHAT IS THE EASE OF CUSTOMER ACQUISITION?

- **B2C:** High due to relatively health-conscious culture that appreciates technology (e.g., 90% of Danes have a smartphone)
- **B2B:** Medium due to recognition that further digitalization is needed. There are however significant funding constraints and clinicians have experienced 'change fatigue' with the implementation of Denmark's EHR system (epic)
- **B2B2C (e.g., GP, insurer):** Medium due to a recognition that technologies are needed to alleviate system pressures, a relatively high digital affinity amongst clinicians and patients' trust in public authorities to handle private data appropriately. However, there is no formal reimbursement mechanism for software as a med device (e.g., DiGA) in Denmark

## POPULATION SIZE AND MARKET GROWTH

- Population: 5,800,000. Denmark spends approximately 11% of its GDP on healthcare. Healthcare spending grew 117% in DK between 2000 and 2019, while GDP and public spending 'only' grew by 74% and 65%, respectively
- In comparison to other countries, Denmark is relatively small in terms of population size. Healthcare spending growth has also been slightly lower than in other countries (e.g., USA)

# INDICATOR

## CUSTOMER ACQUISITION

### OTHER:

**Services covered:** The national, publicly financed health care system fully covers the following services:

- primary and preventive care
- specialist care
- hospital care, including inpatient prescription drugs
- mental health care
- long-term care
- dental services for children under age 18.

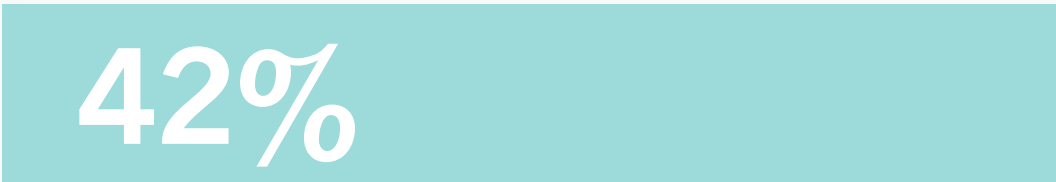
**Cost-sharing and out-of-pocket spending:** Cost-sharing is applied to adult dental care (coinsurance 35%–60%), outpatient prescriptions, temporary home care, residential long-term care, corrective lenses, and travel vaccinations.

### INSURANCE COVERAGE (% OF POPULATION)

0% 50% 100%



**Public coverage: 100%**  
Universal, sutomatic national insurance, with regions and municipalities responsible for financing and delivering care



**Private complementary coverage: 42 %**  
Voluntary individual plans cover copayments for pharmaceuticals and adult dntal care, as well as services not fully covered by national insurance



**Private supplementary cover age: 30%**  
Nonprofit plans offer expanded access to private providers; purchased mainly by private employers as fringe benefit



# INDICATOR CULTURAL

## VALUES & NORMS

- Key values in Denmark: Democracy, Individualism, Indulgence & sustainability
- Power distance and uncertainty avoidance (as the per the definition on the bottom right) appear to be meaningfully lower in Denmark than in Norway or Sweden.
- Communication style in Denmark is similarly direct as in Sweden and Norway
- Denmark has a higher focus on the ‘life’ in work/life balance an on sustainable living & green energy and recycling
- The World Economic Forum Ranks Danes as very willing to delegate authority

## ABILITY TO SPEAK ENGLISH & TRANSLATE THE SOLUTION INTO LOCAL LANGUAGE

- Approximately 86% of people speak English in Denmark, which is higher than in most European countries
- Ease of translating solution from Swedish or Norwegian into Danish is very high

**Power Distance** is defined as the extent to which the less powerful members of institutions and organizations within a country expect and accept that power is distributed unequally.

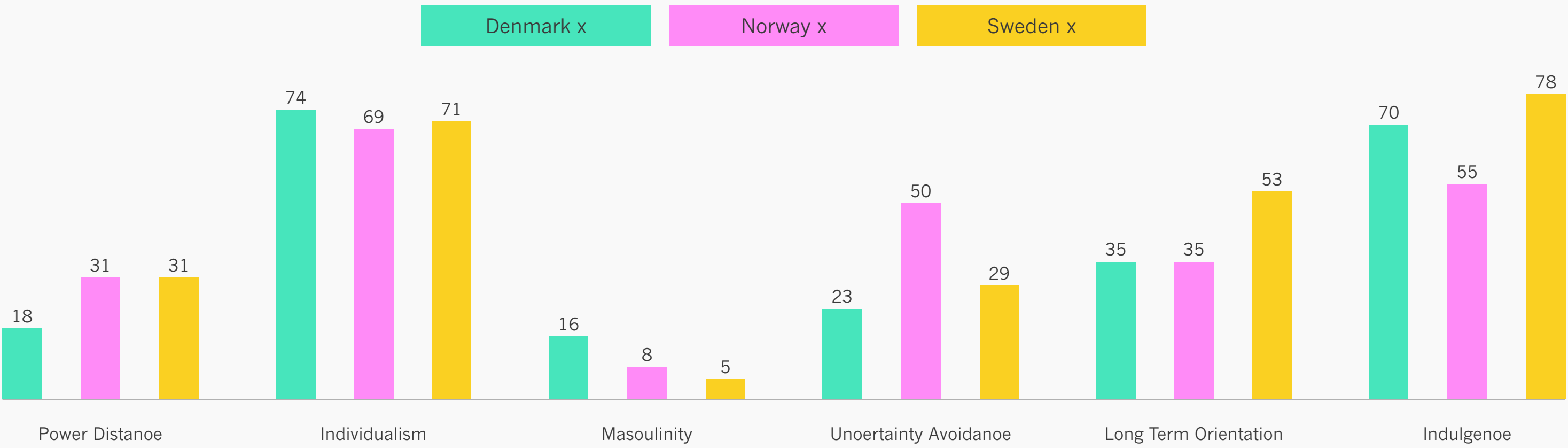
**Individualism** is defined as the degree of interdependence a society maintains among its members.

**Masculinity:** The fundamental issue here is what motivates people, wanting to be the best (Masculine) or liking what you do (Feminine).

**Uncertainty Avoidance:** The extent to which the members of a culture feel threatened by ambiguous or unknown situations and have created beliefs and institutions that try to avoid these

**Long term orientation:** how every society has to maintain some links with its own past while dealing with the challenges of the present and future

**Indulgence:** the extent to which people try to control their desires and impulses



Source: Hofsted Insights: [Country Comparison - Hofsted Insights \(hofstede - insights.com\)](https://hofstede-insights.com)

## HealthTech Nordic

c/o Innovation Skåne,  
Scheeletorget 1, 223 81, Lund, Sweden  
[info@healthtechnordic.com](mailto:info@healthtechnordic.com)

[healthtechnordic.com](https://healthtechnordic.com)