



Market Access Handbook

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Market Access

- Barriers when entering new markets
- Norway / Sweden / Denmark
- Market Structure
- Public / Private procurement process
- Regulatory environment
- Qualify for public reimbursement
- Business Culture



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, Allers, 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

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 (Helseøkonomiforvaltningen, 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.

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THE COMMERCIAL POTENTIAL

INCLUDING PUBLIC TENDER SYSTEM

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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

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.**

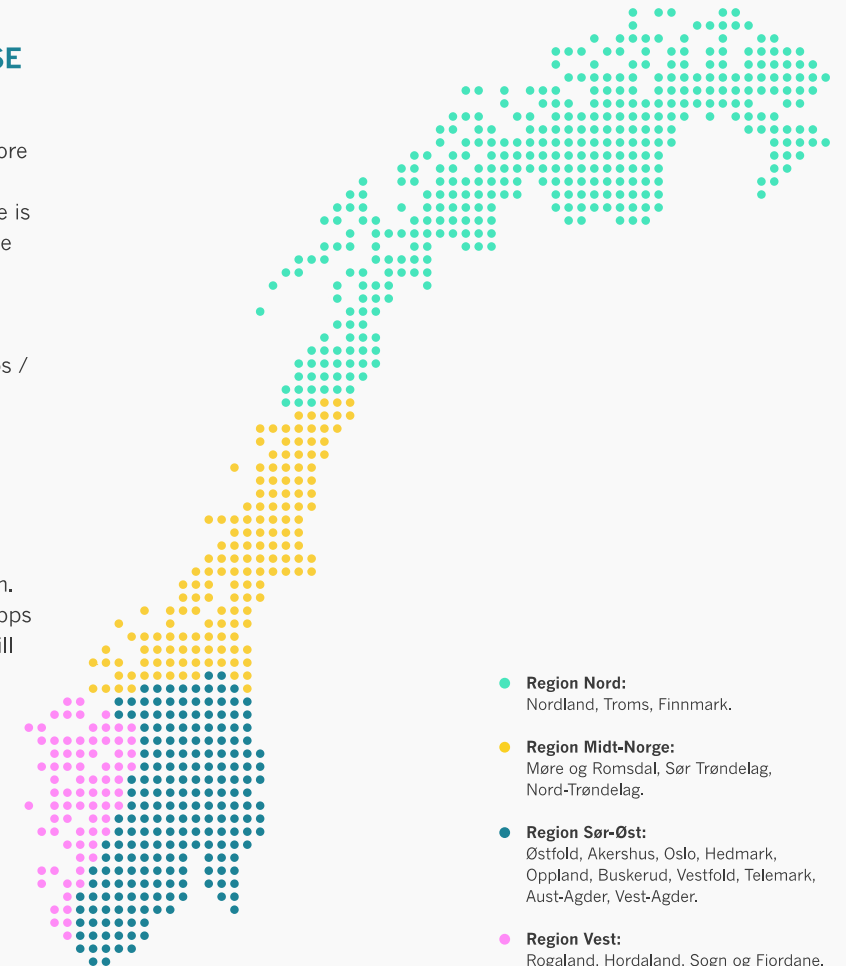
There are 4 health regions and 356 municipalities in Norway. Some regions and municipalities are more interested in piloting new technologies than others.

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.



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.

HEALTH SYSTEM DEEP-DIVE

HEALTH SYSTEM STAKEHOLDERS

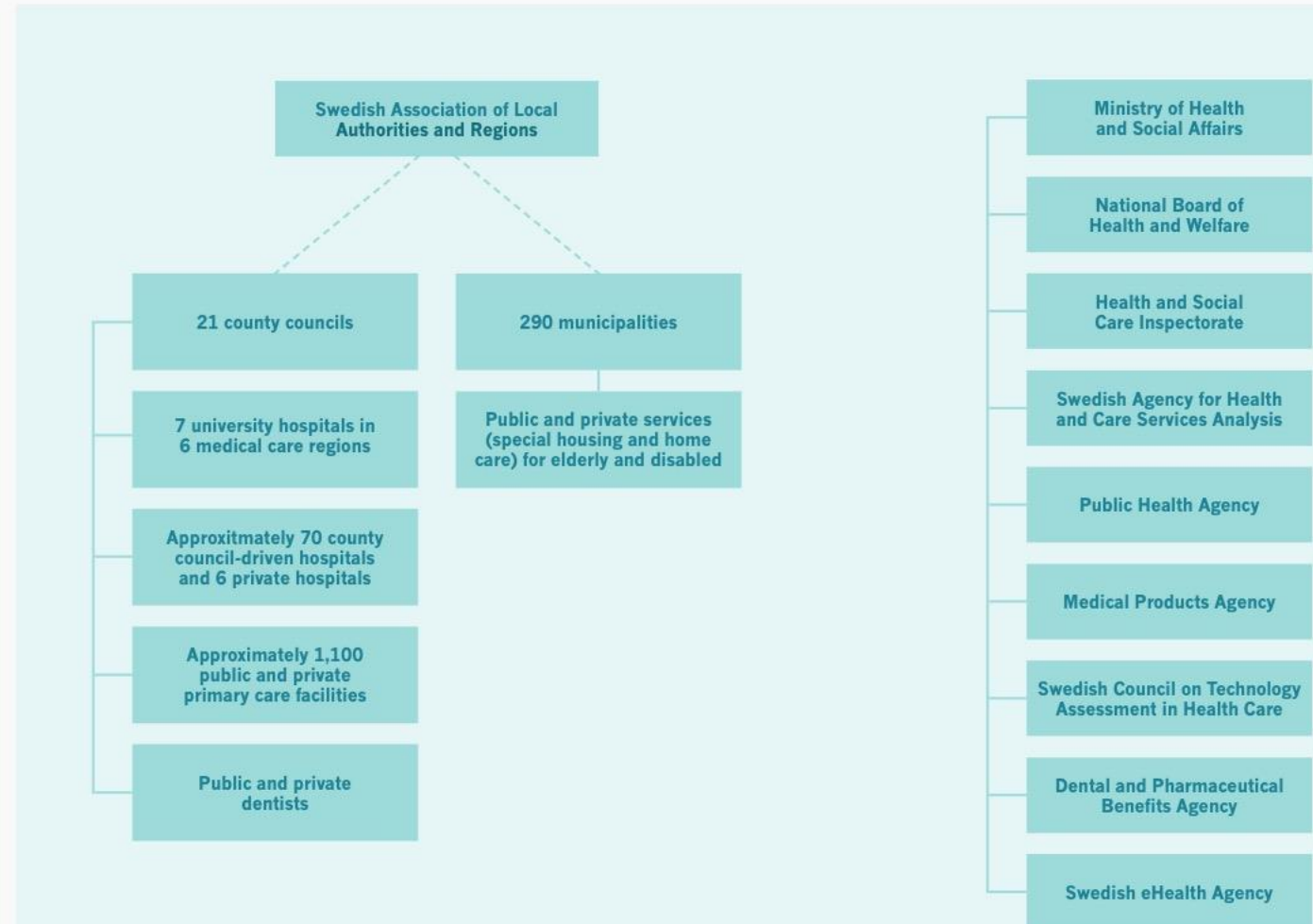
clinics. According to the Health Care Act, regions are obliged to introduce care choice systems that give citizens the right to choose between different care providers in primary care. All care providers who meet the requirements decided by the region in the care choice systems have the right to establish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

healthmanagement.org/c/icu/issuearticle/swedish-healthcare-overview-of-the-health-system

commonwealthfund.org/international-health-policy-center/countries/sweden

HEALTH SYSTEM STRUCTURE ORGANIZATION OF 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/

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 your 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



DENMARK OVERVIEW

QUICK FACTS

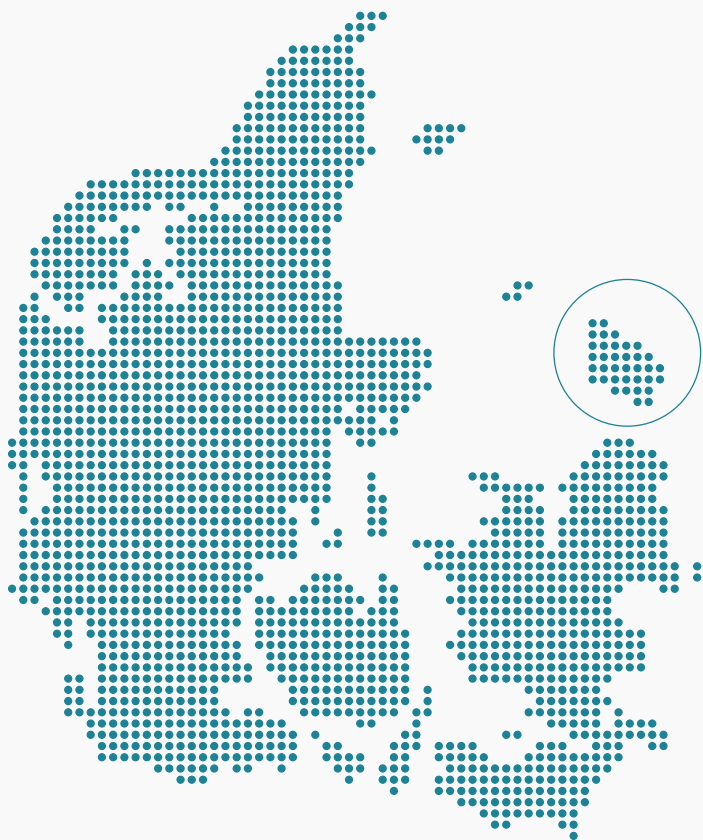


Photo: iStockphoto

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

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.

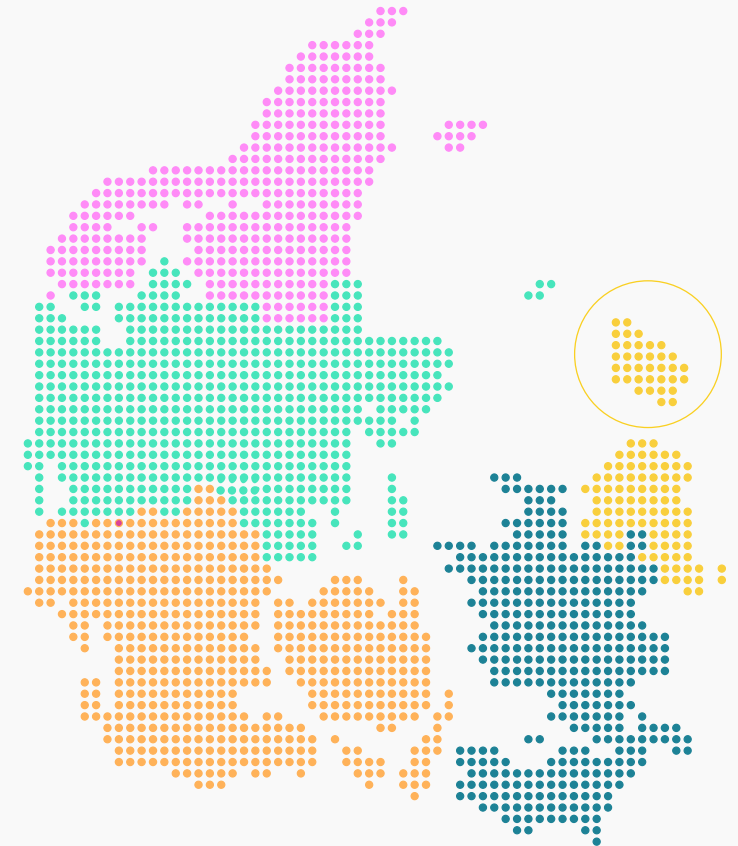
There are 5 regions and 98 municipalities in Denmark. Some regions and municipalities are more interested in piloting new technologies than others. The Novo Nordisk Foundation has recently awarded 128K DKK to Rigshospitalet in Copenhagen and Aarhus University Hospital. Click [here](#) for more info.

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

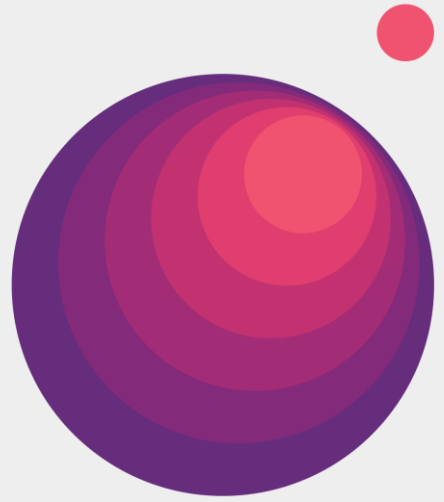
- **Preventive solution:** As in other European countries, it is more difficult to get reimbursed for preventive solutions than for non-preventive solutions. This is particularly the case if there is limited evidence of the clinical effectiveness of the preventive solution.
 - Spending on prevention is relatively low in DK 2.4%, compared to Europe (2.8%) ec.europa.eu/Eurostat
- **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



Norway
Health Tech