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Entry markets:
Sweden and Norway



Similarities in system, difference in culture





Healthcare System – Sweden facts

Population

- Approximately 10.6 million inhabitants.

Organisation

- 21 regions responsible for financing, organising and delivering healthcare.
- 6 regional healthcare cooperation areas.
- 290 municipalities with responsibility for municipal healthcare.

Primary Healthcare

- Approximately 1,100–1,200 primary healthcare centres nationwide.
- Centres provide accessible first-line healthcare throughout the country.

Hospitals & Specialist Care

- Approximately 100 hospitals nationwide.
- Around 85 hospitals operated by regional authorities.
- 7 university hospitals providing highly specialised care, medical research and education.
- Services include general medicine, surgery and specialist care.



Healthcare System – Sweden facts

Private Healthcare

- Private healthcare providers operate alongside the public healthcare system.
- Many private providers deliver publicly funded services through regional agreements.
- Private health insurance is available as a supplementary option.

Assistive Technology & Medical Devices

- Regions and municipalities are responsible for providing assistive devices and technical aids.
- Responsibilities and procurement structures vary between regions and municipalities.



Facts University hospitals

Sweden – University Hospitals & Organ Transplantation

Seven University Hospitals
Sweden has seven university hospitals that provide highly specialised care, research and education.

Four Transplantation Centres
Organ transplantation is performed at four university hospitals in Sweden.

Transplantation by organ

Kidney
Uppsala, Karolinska (Huddinge), Sahlgrenska, Skåne (Malmö)

Heart
Sahlgrenska, Skåne (Lund)

Lung
Sahlgrenska, Skåne (Lund)



The Seven University Hospitals

Uppsala University Hospital
- Kidney transplantation

Karolinska University Hospital (Huddinge, Stockholm)
- Kidney, liver and pancreas transplantation

Sahlgrenska University Hospital (Gothenburg)
- Heart, lung, kidney, liver and other organ transplantation

Skåne University Hospital (Lund and Malmö)
- Heart and lung transplantation (Lund)
- Kidney transplantation (Malmö)

University Hospital of Umeå
- University hospital (no organ transplantation)

Linköping University Hospital
- University hospital (no organ transplantation)

Örebro University Hospital
- University hospital (no organ transplantation)

Performs organ transplantation (4 hospitals)

University hospital (7 in total)

Sweden – Municipal Healthcare Overview

290 Municipalities

Responsible for local social services, elderly care and designated healthcare services.

Work alongside the 21 regions in delivering Sweden's decentralised healthcare system.

Universal Healthcare Coverage

Sweden provides universal, tax-funded healthcare coverage for its residents.

The Ädel Reform (1992)

Transferred significant responsibility for long-term elderly care and certain healthcare services from the regions to municipalities.

Key Municipal Responsibilities

- Elderly care and long-term care.
- Home healthcare and nursing services.
- Special needs and assisted living facilities.
- Residential care for people with disabilities.
- Rehabilitation and assistive devices within municipal healthcare.
- School healthcare services.



Key Healthcare Professionals

Occupational Therapists (OTs)

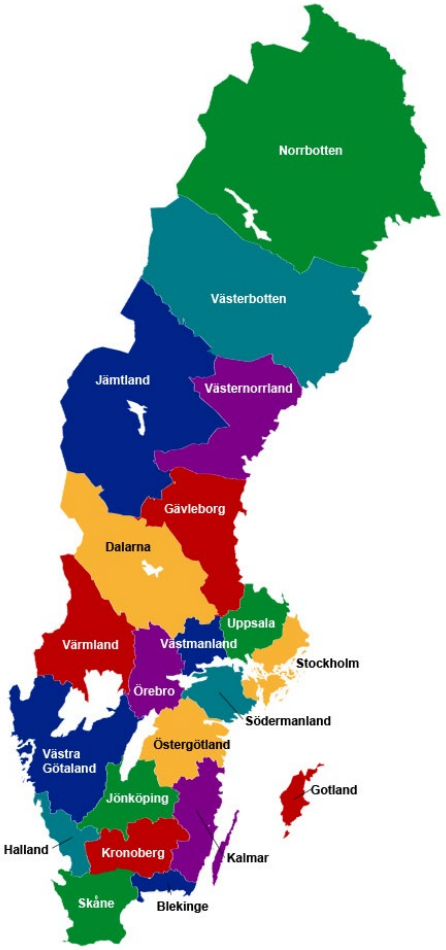
- Assess needs and prescribe assistive devices, including mobility and daily living aids.

Physiotherapists (PTs)

- Assess mobility and rehabilitation needs and may prescribe mobility aids such as walkers and rollators.

Assistive Technology Coordinators & Consultants

- Support assessment, selection, adaptation and the providing of technical aids.



Key Healthcare Professionals

Processes & Responsibilities

- Assistive devices and home adaptations are handled through separate assessment and administrative processes.
- Municipalities are responsible for providing designated assistive devices and home healthcare services.
- Responsibilities and procedures vary between municipalities and regions.

Procurement

- Each municipality manages its own procurement processes.
- Purchasing may take place through individual tenders or joint procurement agreements.
- Framework agreements are commonly used for assistive devices and medical equipment.



Sweden – Regional Hospitals & Procurement
Procurement & Budgets

- Each of Sweden's 21 regions is responsible for its own hospital procurement and tender processes.
- Hospitals and regional healthcare organisations manage budgets for capital equipment, hospital furniture, medical technology and healthcare products.
- Procurement is often coordinated through regional purchasing organisations and framework agreements.

Hospital Development & Investments

- Extensive renovation and modernisation of existing hospitals.
- Construction of new hospital facilities to meet future healthcare demands and technological developments.
- Each region is responsible for its own hospital development and long-term investment plans.
- Major investments aim to create more specialised, efficient and integrated healthcare facilities.

Innovation & Development

- Hospitals provide test beds and clinical environments for new technologies and innovations.
- Opportunities for collaboration between hospitals, technology providers, universities and research institutions.
- Growing demand for innovative medical equipment, digital healthcare solutions and advanced hospital infrastructure.



Regulatory Requirements

CE Marking

Compliance with the EU Medical Device Regulation (MDR 2017/745).
In-vitro diagnostic medical devices are covered separately by IVDR 2017/746.

Quality Management & ISO Standards

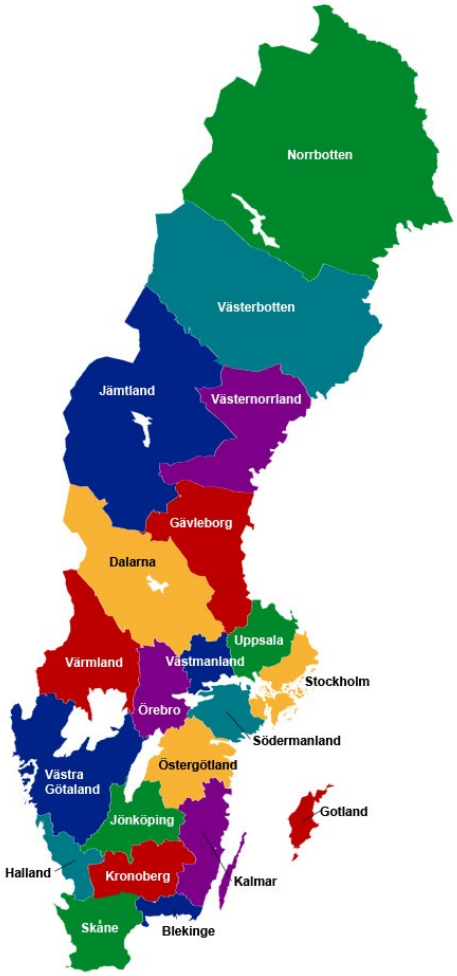
ISO 13485 – Quality Management System for Medical Device Manufacturers.
ISO 9001 – General Quality Management System.
ISO 14001 – Environmental Management System.

An ISO 13485-certified QMS is widely recognised in the medical device industry. Equivalent compliant quality management systems may be acceptable, depending on regulatory requirements.

Swedish Regulatory Authority
Swedish Medical Products Agency (Läkemedelsverket)
https://www.lakemedelsverket.se/en

Local Market Presence & Clinical Validation

- Local clinical evaluation and testing experience are an advantage.
- Swedish hospital references and documented clinical performance strengthen market credibility.
- Collaboration with Swedish healthcare providers can support product validation and market entry.



Tender platforms- Sweden

https://www.opic.com/upphandlingar/

Healthcare furniture, healthcare equipment, medical etc.

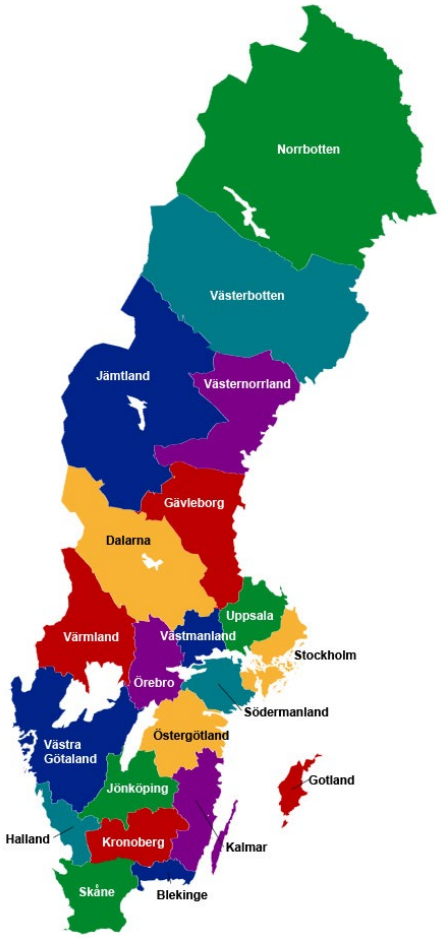
https://www.e-avrop.com/e-Upphandling/Default.aspx

Many municipalities and regions are using E-avrop

www.Byggfakta.se

www.sverigebygger.se

Both are reliable sources for information on upcoming hospital projects.



Procurement/tender process

Each region forecasts their expenses **1–3 years** prior to the expected delivery date.

The average length of public procurement contracts for healthcare is **(2+2) 4 years.**

The decision/budget-maker is most frequently the **hospital management.**

Most county councils/regions create **procurement units** with advisory and steering groups, including a wide range of stakeholders from product users, medical personnel to technicians.

Clinicians are key decision-makers in the selection of a manufacturer.

The procurement process, including the preparatory phase, can take between **6 months – 1 year.**

Each hospital decides which funds to allocate for **innovative products.**

Sustainability criteria are gaining in importance.

There is an increasing focus on **optimizing the breadth of products,** reducing total costs and having fewer suppliers and invoice flows.

Sweden – Market Opportunities & Networking

Market Opportunities

- Build strong relationships with Occupational Therapists (OTs), Physiotherapists (PTs) and other assistive technology prescribers.
- Create awareness of your company, products and core values.
- Understand the Swedish public procurement process and tender requirements.
- Approximately 80% of purchases are made through tenders, while 20% may be purchased outside formal tender processes.



Key Industry Events & Platforms

Leva & Fungera – https://levafungera.se
Vitalis – https://vitalis.nu
Swedish Medtech – https://www.swedishmedtech.se
SFVH – Courses & Conferences – https://sfvh.se/kurser-och-konferenser

Key Opportunity: Build relationships with decision-makers, prescribers and end users to increase brand awareness, identify market needs and create future business opportunities.

Facts – Norway

Healthcare System

Population: **5.17 million**

Municipalities are responsible for providing healthcare to the population.

Hospitals are responsible for specialist care.



Opportunities – Norway

Healthcare System

KIS – Kommune, Institusjon og Sykehus
Municipality, Institution and Hospital

NAV – The Norwegian Labour and Welfare Administration
Administers a third of the national budget through schemes including sickness and cash-for-care benefit.

https://www.nav.no/samarbeidspartner/om-hjelpemidler

All Norwegian citizens are enrolled in the reimbursement system.



When Can LOU Be Avoided?

Direct Procurement & Legal Exceptions

Direct procurement or procurement without prior advertising may be possible under specific conditions:

Unique Products: Where only one supplier can meet the requirements due to technical reasons or exclusive rights, and no reasonable alternative exists.

Low Contract Value: Purchases below the direct procurement threshold of **SEK 700,000** (approximately EUR 62,000), excluding VAT, under LOU.

Innovation & Testing: Certain research and development activities or innovation projects may qualify for specific exemptions or alternative procurement procedures.

Direct Agreements: Contracts may be signed without a full tender process when the applicable legal conditions are met.

Important: Each case must be assessed individually and documented in accordance with LOU.

How to Develop Business in the Hospital Segment – Sweden & Norway

1. Build Clinical Relationships
Approach end users, particularly clinicians and healthcare professionals, to introduce your products and demonstrate their benefits.
Build relationships with key users, prescribers and clinical decision-makers.

2. Increase Market Visibility
Attend exhibitions, seminars, conferences and specialist events.
Create awareness of your company, products and values.

3. Develop Product Ambassadors
Identify and engage clinical ambassadors who understand your products.
Encourage satisfied users to share their experiences and demonstrate product value.

4. Understand Public Procurement
Learn the procurement processes and requirements in each market.
Engage in early market dialogue to help identify needs and communicate product benefits.
Contribute with relevant, objective input to functional requirements and technical specifications.

5. Position Your Products for Procurement
Ensure your products meet relevant regulatory, clinical and technical requirements.
Demonstrate measurable benefits, quality and total cost of ownership.

Key Requirements & Purchasing Priorities

Delivery & Product Knowledge

- Reliable and competitive delivery times are increasingly important.
- Suppliers with strong product knowledge, technical expertise and responsive support are highly valued.

Patient Safety & Risk Prevention

- Products designed to minimise human error and improve patient safety.
- Smart safety features, such as colour-coded needles, help reduce the risk of mistakes.
- Solutions that prevent injuries to both patients and healthcare staff.

Sustainability

- Growing focus on environmental sustainability throughout the product lifecycle.
- Preference for products and suppliers with measurable environmental benefits.

Efficiency & Cost Reduction

- Solutions that streamline clinical workflows and improve operational efficiency.
- Products that reduce unnecessary procedures, errors and time-consuming tasks.
- Preventing injuries and complications to reduce associated healthcare costs.

What characterizes the purchasing processes in the different countries?



Sweden:
- Longer lead times
- Consensus decision-Longer purchase process
- Afraid of making bad decisions.
- Hard to change implemented routines

What characterizes the purchasing processes in the different countries?



Norway

- Faster decision than in Sweden.
- Doctors in hospitals have easier to make decisions.
- Rikshospitalet Oslo. KEY customer.

Entering a conservative market and conservative branch

Important to highlight the benefits, how your new technology actually adds value to the users. What do customers win, avoid and gain from using your solution or product.

Review the possibility of signing agreements with distributors already working in the segment.

Be patient and don’t be afraid to push decisions.