

PPRI Pharma Profile

Sweden 2023

PPRI Pharma Profile Sweden

Update: 2023

PPRI Representatives

The Swedish Dental and Pharmaceutical Benefits Agency: Gunilla Rönholm and Peter Skiöld

Authors

Dental and Pharmaceutical Benefits Agency: Carl Björvang, Johan Pontén, Gunilla Rönholm, Peter Skiöld

Disclaimer

The data provided in this document by the members of the PPRI network and other authors represent the current situation. The data have no legally binding value and are meant especially for the information of PPRI network members who are committed to sharing information on pharmaceutical pricing and reimbursement.

Reference number: 00265/2023

Summary

The purpose of this report is to provide an overview of the Swedish healthcare system with focus on pricing and reimbursement of pharmaceuticals in Sweden.

National health coverage for all residents is provided by the regions

The national health service covers all residents. The Swedish system is highly decentralised with three independent governmental levels; the national government, the regions and the municipalities, on a regional and local level – and they are all involved in healthcare. The regions have the main responsibility for providing healthcare.

Health services are mainly funded by taxes

The regions are responsible for the funding of health services and pharmaceuticals. This is a part of their overall responsibility for providing healthcare and they levy taxes to finance their duties. The regions also generate income through state subsidies and user fees.

Patients pay a limited part of the actual cost for visits and treatments

Patients pay a fee when visiting a healthcare service centre and when treated in a hospital. The maximum annual amount is dependent on the region in question, often around 1 200 SEK (€~109). This includes pharmaceutical treatment. Patients pay a co-payment of maximum 2 600 SEK (€~240) per year for out-patient pharmaceuticals included in the benefits scheme. Costs for pharmaceuticals in the benefits scheme are mainly covered by a government grant.

Non-reimbursed medicines and prescription free medicines (OTC) are generally not subsidized. Hence, the price of such pharmaceuticals is unregulated.

All healthcare decisions are based on a national ethical platform

Decisions on pricing and reimbursement of pharmaceuticals need to be in-line with the ethical platform, which is legislated and applies to all prioritising of publicly funded health care in Sweden. The three principles: the human value principle, the need and solidarity principle and the cost-effectiveness principle.

Pricing and reimbursement of new pharmaceuticals in the out-patient sector

The Board of Pharmaceutical Benefits decides simultaneously on pricing and reimbursement for products included in the benefits scheme. The decision is based on clinical evidence and health economic documentation provided by the pharmaceutical companies. In preparation for the decisions, TLV reviews this information and may ask for additional material. Provided the first two principles of the ethical platform are fulfilled, the application is granted if TLV finds that the health economic analysis shows that the requested price is justified on the basis of the value that the pharmaceutical delivers. This is often described as Value Based Pricing of pharmaceuticals. The reimbursement decision depends on several factors, where one may be the existence of a managed entry agreement between the regions and the phar-

maceutical company. TLV is also providing economic assessments of pharmaceuticals used in the specialized in-patient care. These assessments are used by the regions in making recommendations on preferred treatment of choice.

Competition results in lower costs for out-patient pharmaceuticals

Pharmaceuticals with competition, mainly generics, are subject to substitution at the pharmacy. The preferred product is selected through a monthly auction. Competition between manufacturers result in significant price decreases that generate cost-savings.

Regions procure medicines for hospital use

Public procurement of medicines used in hospitals is carried out by the regions. These have lists of preferred medicines and those are supposed to be first choice, when possible. Hospital pharmacies are expected to dispense and stock other pharmaceuticals as well, if there is a demand for them.

Challenges and future developments

The government have initiated several measures to ensure safe and functional provisions of pharmaceuticals in the face of war or other crisis. This includes the establishment of a network of readiness pharmacies which should have an increased ability to continue supplying medicines in a case of disrupted supply lines. The government is also prioritising environmentally sustainably and long-term affordability in the provision of pharmaceuticals. To this end, studies have been initiated into how companies can be compensated for sustainable production practises and how managed entry agreements and other tools can be used to limit cost-burden of new pharmaceuticals to the healthcare system.

Acknowledgements

The Swedish Dental and Pharmaceutical Benefits Agency (TLV) is grateful for contributions from Mikael Svensson and Therese Löfbom at the Swedish Association of Local Authorities and Regions (SALAR). We are also grateful for the help from Caroline Sundström at the Swedish Medical Products Agency (SMPA), Annika Forsen and Pia Venäläinen at the Swedish eHealth Agency (EHM), Marianne Svensson at the Swedish Agency for Health and Care Services Analysis, Eva-Lena Aspetorp at Region Värmland, Petra Hallén at Region Kalmar, Lena Gustafsson at Region Västra Götaland, Helén Merckell at Region Örebro County and Maria Landgren at Region Skåne.

We, the authors, also want to thank our colleagues at TLV who have helped us with this document. Your competence in the various areas of the profile have been key to the accuracy of the information in here.

Introduction

PPRI Pharma Profiles: national reporting systems on pharmaceutical pricing and reimbursement

The need for accurate and up-to-date country information has been broadly acknowledged. Information about specific issues of a country is of key importance for decision makers and researchers, even if their needs with regard to the level of detail may vary.

Within the framework of the PPRI (Pharmaceutical Pricing and Reimbursement Information) research project (2005 – beginning of 2008), the project consortium, consisting of the Austrian National Public Health Institute (Gesundheit Österreich GmbH) and the World Health Organization (WHO) developed the so-called “PPRI Pharma Profiles” as a tool for understanding, collecting and analysing pharmaceutical pricing and reimbursement information. A key principle of the PPRI Pharma Profiles is that the Profiles are written by national country experts, usually staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance institutions) represented in the PPRI network and that they are critically reviewed by project consortium members.

Between 2005 and 2020, 35 PPRI Pharma Profiles, 19 PHIS Hospital Reports, 9 PPRI / PHIS Pharma Profiles and 3 PPRI Pharma Briefs were produced. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at https://ppri.goeg.at/ppri_country_information.

The PPRI Pharma Profile 2021 is designed to comprise up-to-date information as of 2021 (or latest available year) about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates and glossaries

All PPRI Pharma Profiles are based on a template which provides a homogenous outline for reporting.

Editorial guidelines provide advice to authors and reviewers and aim to increase the readability of the profiles. Readers can expect a universal approach with regard to citations, data presentations, spelling etc. across the PPRI Pharma Profiles.

To achieve clarity for authors, reviewers and readers and thus to create a common understanding of the concepts and terms used, a glossary was developed in the early times of the PPRI project. It has been regularly updated since. The most updated version of the Glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at the WHO Collaborating Centre's website at <https://ppri.goeg.at/ppri-glossary>. Authors of the PPRI Pharma Profiles are requested to adhere to the Glossary.

PPRI and WHO Collaborating Centre

Pharmaceutical Pricing and Reimbursement Information (PPRI) was originally a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It was performed from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 90 institutions: These are public authorities and third-party payers from 52 countries (mainly European countries, including all 27 EU Member States) as well as European and international institutions such as European Commission services and agencies, Organisation for Economic Co-operation and Development (OECD), World Health Organisation (WHO, HQ and Regional Office for Europe) and World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including updates of country-specific information. The PPRI secretariat is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG). The Department has also been nominated as a WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

Table of content

Acknowledgements.....	VI
Introduction.....	7
List of tables	12
List of figures	14
List of abbreviations	15
1 Health care system	18
1.1 Population and age structure	18
1.2 Organisation of the health care system.....	19
1.2.1 Organisation of out- and in-patient health care	21
1.3 Health expenditure.....	23
1.4 Sources of funding.....	24
2 Pharmaceutical system	27
2.1 Organisation of the pharmaceutical system.....	27
2.1.1 Regulatory framework	27
2.1.2 Authorities	29
2.2 Availability of and access to medicines.....	35
2.2.1 New chemical entities.....	35
2.2.2 National Pharmaceutical Strategy	36
2.2.3 Processing times	37
2.3 Development of the pharmaceutical sales.....	37
2.4 Pharmaceutical consumption	39
2.5 Generics.....	40
2.6 Top 10 medicines	40
2.7 Market players	42
2.8 Pharmaceutical expenditure.....	43

2.9	Sources of funding	44
3	Pricing, reimbursement and volume control in the out-patient sector	45
3.1	Organisation of the out-patient sector	45
3.2	Pricing of medicines	45
3.2.1	Pricing policies	46
3.2.2	Pricing Procedures	47
3.2.3	Specific pricing policies	55
3.2.4	Discounts / rebates	55
3.2.5	Remuneration of wholesalers and community pharmacies	56
3.2.6	Taxes	58
3.3	Reimbursement of medicines	58
3.3.1	Specific reimbursement schemes	59
3.3.2	Reimbursement procedure	60
3.3.3	Reference price system	60
3.3.4	Private pharmaceutical expenses	60
3.4	Volume control	62
3.4.1	Generic substitution	63
3.4.2	Biosimilar substitution	64
3.4.3	INN prescribing	65
3.4.4	Other generic and biosimilar promotion	65
3.4.5	Claw-backs and paybacks	66
3.4.6	Managed-entry agreements	67
3.5	Evaluation	67
3.5.1	Prescription monitoring	68
3.5.2	Pharmaceutical consumption monitoring	68
3.5.3	Decision making tools	70
4	Pricing, reimbursement and volume control in the in-patient sector	71
4.1	Organisation of the in-patient sector	71
4.2	Pricing and purchasing policies	72

Sweden

4.3	Procurement	73
4.4	Reimbursement	74
4.4.1	Hospital pharmaceutical formularies	75
4.4.2	Pharmaceutical and Therapeutic Committees	75
4.5	Volume Control in the in-patient sector	76
4.5.1	Monitoring	76
4.5.2	Decision-making tools	77
4.5.3	Evaluation of measures	79
4.5.4	Reports and results	79
4.5.5	Interface management	80
5	Developments	84
6	Bibliography	86
6.1	Literature	86
6.2	Legislation	92
6.3	Web links	93

List of tables

Table 1.1: Sweden – Demographic indicators 2010, 2015, 2018, 2020 and 2021	18
Table 1.2: Sweden – Health expenditure 2010, 2015, 2018, 2020 and 2021	24
Table 2.1: Sweden – Authorities in the regulatory framework of the pharmaceutical system, 2021	30
Table 2.2: Sweden – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2022	33
Table 2.3: Sweden – Annual prescriptions in the out-patient sector 2010, 2015, 2018, 2020, 2021 and 2022	35
Table 2.4: Sweden – Number of new molecular entities, 2010-2021	35
Table 2.5: Sweden – Annual pharmaceutical consumption 2010, 2015, 2018, 2020, 2021 and 2022	39
Table 2.6: Sweden – Development of the generic shares in volume and value, 2010, 2020 and 2022	40
Table 2.7: Sweden – Top 10 active ingredients in value and volume in the out-patient sector, 2022 ..	41
Table 2.8: Sweden – Top 10 active ingredients in value and volume in the in-patient sector, 2022	41
Table 2.9: Sweden – Retailers of medicines 2010, 2015, 2018, 2020 and 2021	43
Table 2.10: Sweden – Total pharmaceutical expenditure 2010, 2015, 2018, 2020 and 2021.	44
Table 3.1: Sweden – Ways of pricing of medicines at manufacturer level, 2021	47
Table 3.2: Sweden – Pricing policies, 2022	48
Table 3.3: Sweden – Regulation of wholesale and pharmacy remuneration, 2022	56
Table 3.4: Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals without competition	57
Table 3.5: Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals with generic competition (Product-of-the month)	57
Table 3.6: Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals ostomy products.	57
Table 3.7: Formula for calculating pharmacy sales price including retail margin for medical devices and medical device consumables.	58
Table 3.8: Sweden – Out-of-pocket payments for medicines, 2023	62
Table 3.9: Substitution at the pharmacy, how it is managed at the pharmacy and the patient's costs	64
Table 3.10: Examples of information material regarding generic substitution	66
Table 4.1: Most important changes in the out-patient and in-patient sectors from 2010 onwards	82

List of figures

Figure 2.1:	Sweden – Flowchart of the pharmaceutical system, 2021	28
Figure 2.2:	Organisation of the national pharmaceutical strategy	36
Figure 2.3:	The pharmaceuticals market in 2021, by segment	38
Figure 3.1:	Review of pricing and reimbursement status	50
Figure 3.2:	Price- and volume change for pharmaceuticals with competition after 2003.....	52
Figure 3.3:	Price change for pharmaceuticals with competition (depending on the number of competitors)	53
Figure 3.4:	Generic price linkage: price ceiling for interchangeable products with generic competition.....	54
Figure 3.5:	Co-payment for pharmaceuticals.....	61
Figure 4.1:	The organisation of health care services	72
Figure 4.2:	Process for managed introduction of new pharmaceuticals.....	79

List of abbreviations

AB	Aktiebolag (Joint-stock company)
ATC	Anatomic therapeutic chemical classification
ATMP	Advanced therapy medicinal products
CBL	Centre for Improved Pharmaceutical Usage
DDD	Defined daily doses
EEA	European Economic Area
EHM	Swedish eHealth Agency (E-hälsomyndigheten)
EMA	European Medical Agency
EU	European Union
FGL	The association for generics and biosimilars (Föreningen för Generiska läkemedel och Biosimilarer)
Fohm	Public Health Agency of Sweden (Folkhälsomyndigheten)
GDP	Gross domestic product
HE	Health expenditure
HIV	Human Immunodeficiency Virus
HTA	Health technology assessment
INN	International Non-proprietary Name
IRP	International Reference Pricing
IVO	The Health and Social Care Inspectorate
LIF	The association for the researched-based pharmaceutical industry (Läkemedelsindustriföreningen)
LMA	Lag om mottagande av asylsökande med flera
LSS	Lagen om stöd och service till vissa funktionshindrade

PPRI Pharma Profile 2022

Sweden

LV	Läkemedelsverket (see SMPA)
NCU	National currency unit
NPM	Non-prescription medicine(s)
NPR	National Patient Register
NPS	National Pharmaceutical Strategy
NT-rådet	The New Therapies Council
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-counter pharmaceutical
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPP	Pharmacy purchasing price
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
SALAR	The Swedish Association of Local Authorities and Regions (see SKR)
SBU	Swedish Agency for Health Technology Assessment and Assessment of Social Services (Statens beredning för medicinsk och social utvärdering)
SCB	Statistics Sweden
SEK	Swedish Krona
SFS	Swedish Code of Statutes (Svensk författningssamling)
SKR	Sveriges kommuner och regioner (see SALAR)
SMPA	Swedish Medical Products Agency (see LV)
SOU	Statens Offentliga Utredningar
THE	Total health expenditure

Sweden

TLV	The Swedish Dental and Pharmaceutical Benefits Agency (Tandvårds- och Läke- medelsförmånsverket)
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WHO	World Health Organisation

1 Health care system

This chapter gives a brief introduction to the demographic situation in Sweden as well as to the organisation to the health care system, sources of funding and health expenditure.

1.1 Population and age structure

The population of Sweden reached 10 million in 2017 and has continued to increase. The population density is approximately 23.2 inhabitants per km². The population is geographically unevenly distributed. The major urban areas are located along the southern coastline, especially in the Stockholm, Gothenburg and Malmö areas. The inland and northern parts of Sweden are more scarcely populated. Recent population growth is driven by both a birth surplus and the fact that the immigration is higher than emigration.

Table 1.1:
Sweden – Demographic indicators 2010, 2015, 2018, 2020 and 2021

Demography	2010	2015	2018	2020	2021
Total population	9 415 570	9 851 017	10 230 185	10 379 295	10 452 326
Population aged 0–14	1 564 959	1 717 143	1 819 729	1 837 798	1 839 103
Population aged 15–64	6 113 365	6 186 647	6 374 745	6 453 411	6 494 457
Population aged > 64	1 737 246	1 947 227	2 035 711	2 088 086	2 118 766
Life expectancy at birth ¹	81.45	82.09	82.47	82.39	82.97
Life expectancy at age 65 ²	84.62	85.13	85.35	85.18	85.71

Source: SCB.

¹ Calculated as 'life expectancy of males' * 'proportion of males' + 'life expectancy of females' * 'proportion of females'

² Calculated as ('remaining life expectancy of males at 65' * 'proportion of males at 65' + 'remaining life expectancy of females at 65' * 'proportion of females at 65')

The average life expectancy has been increasing steadily and is still increasing at the same time as the difference in average life expectancy between men and women is decreasing. There is now a larger difference in life expectancy between people with different levels of education than between men and women. In 2021 the average life expectancy was 81.2 years for men and 84.8 years for women. The percentage of the population aged above 64 years has grown faster than the population aged between 15 and 64 since year 2010. In 2021, 20.3 per cent of the country's population was 65 or older.¹ The

¹ SCB (2022) Medellivslängden i Sverige.

proportion of older individuals is expected to increase continuously because of the ageing of the post-war generations. The increase means that more people are likely to develop chronic diseases generally associated with increased age. This development entails one of the greatest challenges for the health care system. A study of potential scenarios of future needs for health care have shown that the cost of health care could increase by approximately 30 per cent between 2010 and 2050. The cost of elderly care is expected to increase by 70 per cent. Also, the number of persons with severe health problems is expected to increase by 45 per cent between 2010 and 2050.²

In 2021, 74 percent of the Swedish population self-assessed that they had good or very good health. Men indicate better health than women and a larger proportion of individuals with higher education say that they have good health compared to those with lower education.³ Educational background is an increasingly important marker of health in Sweden. In 2020, at the age of 30, both males and females with a higher education background had a roughly 6 years longer life-expectancy than their counterparts with only a lower-secondary education. A growing proportion of the population has secondary or tertiary education. Women generally have a higher educational level than men, and the gender gap increases. There is a clear and general correlation between higher education and better health.⁴

The Covid-19 pandemic had extensive impacts on the health of the Swedish population. More than 22 000 people died due from the virus infection itself.⁵ Beyond this, the pandemic caused much non-emergency care to be delayed, creating a backlog in untreated healthcare needs.⁶

1.2 Organisation of the health care system

The Swedish health care system covers all residents. It has developed gradually in the context of a welfare policy where equality and fairness are highly regarded. This is reflected in the organisational and legal framework on which it is structured.

Swedish healthcare is a National Health Service system. The most important law regulating the provision of healthcare is the Health and Medical Services Act (2017:30). The law not only incorporates equal access to services based on need, it also emphasises a vision of equal health for all. The healthcare system provides coverage for all residents of Sweden, regardless of nationality.

² Vårdanalys (2014) VIP i Vården?, p.21.

³ Folkhälsomyndigheten (2022) Folkhälsans utveckling: Årsrapport 2022, p.20.

⁴ Folkhälsomyndigheten (2022) Folkhälsans utveckling: Årsrapport 2022, p.19.

⁵ Folkhälsomyndigheten (2023) Bekräftade fall av covid-19 i Sverige.

⁶ Socialstyrelsen (2022) Pandemin har fortsatt stor påverkan på vården.

Sweden

Important acts that form the basis for the Swedish health care system:

- The Health and Medical Services Act / Hälso- och sjukvårdslagen (2017:30)
- The Medicinal Products Act / Läkemedelslagen (2015:315)
- The Act on Sales of Medicinal Products / Lagen (2009:366) om handel med läkemedel
- The Act on Sales of Certain Prescription Free Products / Lagen (2009:730) om handel med vissa receptfria läkemedel
- The Act on Pharmaceutical Benefits / Lagen (2002:160) om läkemedelsförmåner m.m.
- The Act on Patients' Security / Patientsäkerhetslagen (2010:659)
- The Pharmacy Data Act / Apoteksdatalagen (2009:367).
- The Act on National Medicines' List / Lagen (2018:1212) om nationell läkemedelslista
- The Health Data Registry Act / Lagen (1998:543) om hälsodataregister
- The Patient Act / Patientlagen (2014:821)
- The Patient Data Act / Patientdatalagen (2008:355)
- The Communicable Diseases Act / Smittskyddslagen (2004:168)
- The Dentistry Act / Tandvårdslagen (1985:125)
- The Act on Aesthetic Surgical Treatments and Aesthetic Injection Treatment/ Lagen (2021:363) om estetiska kirurgiska ingrepp och estetiska injektionsbehandlingar
- The Public Procurement Act / Lagen (2016:1145) om offentlig upphandling

The Swedish system is highly decentralised with three independent governmental levels; the national government, the regions and the municipalities – all involved in healthcare.

Overall responsibility for the healthcare sector rests, at the national level, with the Ministry of Health and Social Affairs (Socialdepartementet). The National Board of Health and Welfare (Socialstyrelsen), a public authority, has a supervisory function over the regions, acting as the government's central advisory and supervisory agency for health and social services. The Ministry of Health and the National Board of Health and Welfare collaborate with other central governmental bodies; the Medical Products Agency (Läkemedelsverket, SMPA), the Swedish Agency for Health Technology Assessment and Assessment of Social Services (Statens beredning för medicinsk och social utvärdering, SBU), the Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket, TLV) and the Public Health Agency of Sweden (Folkhälsomyndigheten, Fohm), among others.

There are 21 regions that are responsible for healthcare provision to the citizens. The regions are grouped into six health care regions to facilitate cooperation regarding specialised medical care. The regions own and operate many healthcare facilities, such as hospitals and primary care centres. There are also a few private hospitals, and the number of private physicians and health centres varies substantially between regions. The 290 municipalities are responsible for providing nursing-home care, social services and housing needs for the elderly.

The principles of resource-allocation vary among the regions. Most regions have decentralised a large part of the financial responsibility to healthcare districts, through decentralised budgets. Activities such as psychiatry, geriatrics and emergency services are normally financed through centralised budgets.

1.2.1 Organisation of out- and in-patient health care

Primary care, or out-patient health care, is provided at 1 170 primary care units throughout the country of which 44 per cent are privately owned.⁷ The primary care units provide the population's basic medical treatment, including care, preventive care and rehabilitation that does not require a hospitals' medical and technical resources.

Since 2010, residents may register with any public or private health care provider accredited by the local region. Individuals register with a primary care unit/practice and, if they so choose, a specific general practitioner. Those who opt not to register with a primary care unit or with one in another region than they live in are not guaranteed care within a mandated timeframe. Nevertheless, individuals may also make visits to practices where they are not registered. (The Health and Medical Services Act (2017:30))

University and regional hospitals provide services for conditions requiring hospital treatment. There are seven university hospitals, about 20 region hospitals and more than 40 local hospitals.⁸ The average number of available in-patient-care beds was 21 200 in 2020 which corresponds to 2.0 per 1 000 inhabitants.⁹

The 21 regions are grouped into six health care regions to facilitate cooperation and to maintain a high level of advanced medical care. Highly specialised care, requiring the most advanced technical equipment, is concentrated at university hospitals to achieve higher quality and greater efficiency, and to create opportunities for research and development. Acute care hospitals (seven university hospitals and 59 other hospitals) provide full emergency services.¹⁰ Most hospitals are public, but regions may also have contract with private hospitals. There are six larger private hospitals in the country, of which three are non-profit.

During the Covid-19 pandemic there was a decrease in primary care visits per person. This is estimated to have caused a significant backlog in treatment, as well as a lower degree of surveillance for chronic and life-threatening diseases. This, in addition to the treatment of post-covid symptoms, is expected to lead to an increase in health care demands in the years to come. However, the pandemic also led to a surge in individuals applying for health profession educations.¹¹

⁷ SKR (2021) Statistik om hälso- och sjukvård samt regional utveckling, 2020, p.30.

⁸ SOU (2021:71) Riksstressen i hälso- och sjukvården – stärkt statlig styrning för hållbar vårdinfrastruktur, p.76.

⁹ SKR (2021) Statistik om hälso- och sjukvård samt regional utveckling, 2020, p.25.

¹⁰ SOU (2021:71) Riksstressen i hälso- och sjukvården – stärkt statlig styrning för hållbar vårdinfrastruktur, p.158.

¹¹ Socialstyrelsen (2022) Tillståndet och utvecklingen inom hälso- och sjukvård och tandvård: Lägesrapport 2022, p.38-40.

However, this increase in demand for health care education has yet to materialise into an increased labour supply, as courses take several years to complete. The availability of physicians employed in health care, in relation to the population, rose in the early 2000's but remained steady between 2016 and 2019.^{12,13} With the increasing age and health care demands of the Swedish population, there is an increasing need for health care professionals. As such, despite the increase in the number of physicians over the 2000–2016 period, all 21 regions reported a lack of specialist physicians.¹⁴

Over time, it has become more common for regions to buy services from private health care providers. In 2020, 19 per cent of health care was financed by the regions but carried out by private health care providers.¹⁵ For this private run, public funded health care, patients are covered by the same regulations and fees that apply to public care facilities.¹⁶ (See section 3.3.4 and 4.4 for private pharmaceutical expenses).

In recent years there has been a restructuring of highly specialised health care within Sweden, to increase specialisations within different hospitals and thereby improve patient outcomes. In 2016, a government commissioned inquiry, found that at least 500 deaths could be avoided every year with a better organisation of highly specialised care.¹⁷ In accordance with the suggestions of this inquiry, a new system was created, with the Board of Health and Welfare as the coordinating body.

For this system, a group of experts evaluated which health care areas needed increased concentration of specialisation, and how many such centres each area would need. Then, through a bidding process and a political review board, specialisation centres were appointed. These centres are supposed to be active indefinitely, though the Board of Health and Welfare conducts ongoing review of the centres and also evaluates the need for new areas of increased specialisation in accordance with the advances of medical practises.¹⁸

¹² Socialstyrelsen (2019) Bedömning av tillgång och efterfrågan på legitimerad personal i hälso- och sjukvård samt tandvård: Nationella planeringsstödet 2019, p.104.

¹³ Socialstyrelsen (2022) Bedömning av tillgång och efterfrågan på legitimerad personal i hälso- och sjukvård samt tandvård: Nationella planeringsstödet 2022, p.29.

¹⁴ Socialstyrelsen (2022) Bedömning av tillgång och efterfrågan på legitimerad personal i hälso- och sjukvård samt tandvård: Nationella planeringsstödet 2022, p.38.

¹⁵ SCB (2022) Finansiärer och utförare inom vård, skola och omsorg 2020: Privata företag utförde 17 procent av verksamheten inom vård, skola och omsorg 2020.

¹⁶ 1177 (2022) Patientavgifter och högkostnadsskydd.

¹⁷ SOU (2015:98) Träning ger färdighet: Koncentrera vården för patientens bästa.

¹⁸ Socialstyrelsen (2022) Nationell högspecialiserad vård.

Increase in number of pharmacies since the end of the government monopoly

The pharmacy market was restructured in 2009 and the government-controlled pharmacy monopoly ceased to exist in June 2009. Since then, the number of pharmacies has continuously increased (see Table 2.9).

In Sweden, there are two protected professional titles that together correspond to the term pharmacist in international statistics. Dispensing pharmacist/dispenser (receptarie) requires a three-year university degree, and pharmacist (apotekare) requires a five-year university degree. In 2021, there were 58 licensed dispensers and 62 licensed pharmacists per 100 000 inhabitants.¹⁹

1.3 Health expenditure

Sweden is a highly industrialised country. The economy is export-orientated and well diversified. The gross domestic product increased by 53 per cent between 2010 and 2021, from SEK 3 574 billion to 5 452 billion. At the same time, total health expenditure has increased by 110%, which translates to an increase of approximately SEK 31 500 to 59 700 (€~2 920 – 5 880) per capita.

¹⁹ Socialstyrelsen (2022) Statistik om legitimerad hälso- och sjukvårdspersonal 2021 samt arbetsmarknadsstatus 2020, p.1.

Sweden

Table 1.2:

Sweden – Health expenditure 2010, 2015, 2018, 2020 and 2021

Health expenditure in NCU = SEK	2010	2015	2018	2020	2021
GDP (in million SEK)	3 573 581	4 260 470	4 828 306	5 038 538	5 451 813
THE	297 322	460 301	528 265	579 281	623 633
– <i>thereof public HE</i>	82.5%	84.0%	84.8%	85.9%	85.6%
– <i>thereof private HE</i>	17.5%	16.0%	15.2%	14.1%	14.4%
HE in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.
– <i>thereof public</i>	n.a.	n.a.	n.a.	n.a.	n.a.
– <i>thereof private</i>	n.a.	n.a.	n.a.	n.a.	n.a.
HE in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.
– <i>thereof public</i>	n.a.	n.a.	n.a.	n.a.	n.a.
– <i>thereof private</i>	n.a.	n.a.	n.a.	n.a.	n.a.
<i>Exchange rate (NCU per €)</i>	9.54	9.36	10.26	10.49	10.15

GDP = gross domestic product, HE = health expenditure, NCU = national currency unit, THE = total health expenditure, SEK = Swedish Krona

Source: SCB, OECD, Sveriges Riksbank

1.4 Sources of funding

The Swedish health care system is primarily funded by taxes, but there is no specific health tax. The local authorities have the right to levy taxes and to determine the tax rate. Principal health policy objectives and frameworks are determined at the national level, but the actual provision of services is ensured by the regions and municipalities. It is the regions and municipalities who are the health care providers and who have direct responsibility for health care, not the state. The organisation of health care services and responsibilities are linked to three sources of funding.

Taxes covers costs for pharmaceuticals used in hospitals

The regions are solely responsible for the funding of in-patient pharmaceutical expenditure. This is a part of their overall responsibility for providing healthcare and they levy taxes to finance these duties. The regions also generate income through government grants and user fees.

Government grant covers costs for out-patient medicines

Costs for out-patient pharmaceuticals are formally financed by the regions. They receive a grant from the government to cover these costs (the Pharmaceutical Benefits Scheme). The government and SALAR negotiate agreements concerning the amount and the conditions of the grant. Lately, this negotiation has been a yearly activity.

In 2015 the regions received SEK 21.8 billion²⁰ in grants from the government, and in 2022 this had increased to SEK 34.4 billion.²¹ These agreements include a risk-sharing component where the regions and the state equally share the cost of the difference between the actual costs and the fixed subsidy exceeding +/– 3 percent.²²

Patient payments and costs for non-reimbursed medicines, over-the-counter (OTC) and traded goods

The patient fee for a hospital stay is maximum SEK 110 (€~10) per day. Patient fees for primary care vary between SEK 100 and 300 (€~9–27) depending on the region. For specialist, the fee ranges between SEK 200 and 400 (€~18–36). After a patient has paid a total of between SEK 1150 and 1 200 (€~105 and €~109), depending on the region, in the course of a year, medical consultations within 12 months of the first consultation are free of charge.²³ There is a similar ceiling for prescription medication, where no one pays more than SEK 2 600 (€~240) in a 12-month period.²⁴ (See section 3.3.4 and 4.4 for private pharmaceutical expenses).

If TLV has not already regulated a price, prescription pharmaceuticals not included in the benefits scheme are unregulated and subject to free pricing. The same applies for non-prescription pharmaceuticals sold in pharmacies and other retail settings. The cost for these pharmaceuticals does not count towards the patient's prescription medication ceiling. Meanwhile, the regions cover the full costs for infectious disease medicines prescribed under the Swedish Communicable Diseases Act (2004:255) and there is no co-payment for the patient.²⁵

Social insurance

Social insurance is financed through a combination of employer and employee contributions and through taxes. Social insurance provides financial security in the event of illness and disability, to the elderly and to families with children. It does not cover health care or unemployment, which are each covered by

²⁰ SKL (2015) Statens bidrag till regionerna för kostnader för läkemedelsförmånerna m.m. för år 2015, p.3.

²¹ SKR (2022) Statens bidrag till regionerna för kostnader för läkemedelsförmånerna m.m. 2022, p.4

²² SKR (2022) Statens bidrag till regionerna för kostnader för läkemedelsförmånerna m.m. 2022, p.4

²³ SKR (2022) Patientavgifter i hälso- och sjukvården i alla regioner 2022. Note that these prices and ceiling applied in 2022.

²⁴ TLV (2022) Så fungerar högkostnadsskyddet.

²⁵ Swedish Communicable Diseases Act (2004:255) 9 b §

Sweden

separate systems. Social insurance is individually based and includes both income-related benefits and basic protection in the form of universal benefits and benefits depending on need.²⁶

Health insurance

Government health insurance is an insurance against loss of income in the event of illness. The employer provides sick pay for the first 14-day period, except for a deduction corresponding to 20% of the first week of illness. After this period, health benefit is paid by the Swedish Social Insurance Agency. This agency is also responsible for compensation during the first two weeks of the sickness period for those who are not entitled to sick pay. A doctor's certificate is required from the eighth day of sickness. In certain cases, employers or the Swedish Social Insurance Agency may require a doctor's certificate from an employee from the first day of sickness absence.²⁷

Private health insurance in Sweden is divided into two groups. The first, and most common group, is a complementary insurance against loss of income or life quality in case of illness or debility. The second, smaller but more rapidly growing group, is an insurance that provides discounted access to the private, non-government funded, health care sector. Since private primary care providers can provide speedier primary care and are perceived as more willing to refer patients to specialised care, whether private or public, these insurances have been marketed as a way to 'pay your way past the queue'. A recent government investigation has looked into this issue and made recommendations to prevent private health insurances from creating wealth-based segregation within the Swedish health care system.²⁸

If you are insured in Sweden and study or stay in another European Union (EU) or European Economic Area (EEA) country, or Switzerland, for some other reason, you are entitled to necessary health care on the same financial terms as any other inhabitant of the country.²⁹ The European health insurance card does not pay for private health care or for an ambulance flight or other special transport back to Sweden.

²⁶ Regeringen (2016) Social Insurance in Sweden.

²⁷ Försäkringskassan (2022) Intyg för sjukpenning.

²⁸ SOU (2021:180) Reglering av privata sjukvårdsförsäkringar – ökad kunskap och kontroll.

²⁹ 1177 (2022) Vård i Sverige om du kommer från ett annat land.

2 Pharmaceutical system

This chapter provides a description of the pharmaceutical system; its organisation, regulatory framework and authorities, availability and access to medicines, pharmaceutical expenditure and consumption, the market players and the funding of the system for the out-patient and the in-patient sectors.

2.1 Organisation of the pharmaceutical system

The following section will outline the structures of the pharmaceutical system in Sweden. First, the general regulatory framework will be provided. After this, the functions of some of the key actors will be presented.

2.1.1 Regulatory framework

The Swedish Parliament (Riksdagen) and the Swedish Government (Regeringen) has adopted a set of acts which govern the pharmaceutical sector. The Ministry of Health and Social Affairs (Socialdepartementet) has the overall responsibility for health issues.³⁰ The Ministry is responsible for submitting legislative proposals regarding changes to the healthcare and social systems, that later are decided by the Swedish Parliament. Each ministry is responsible for several government agencies tasked with applying the laws and carrying out the activities decided on by the parliament and the government. The government can also issue ordinances, for example to specify how various laws such should be enacted or to guide the work of government agencies.

Sweden joined the European Union in 1995 and has since harmonised its legislation regarding authorisation of pharmaceuticals etc. with the European Union. The legislative framework for the production, registration and distribution of pharmaceuticals is the Medicinal Products Act (Läkemedelslagen 2015:315). This is complemented by the Medicinal Products Ordinance (SFS 2015:458) and by numerous other provisions.

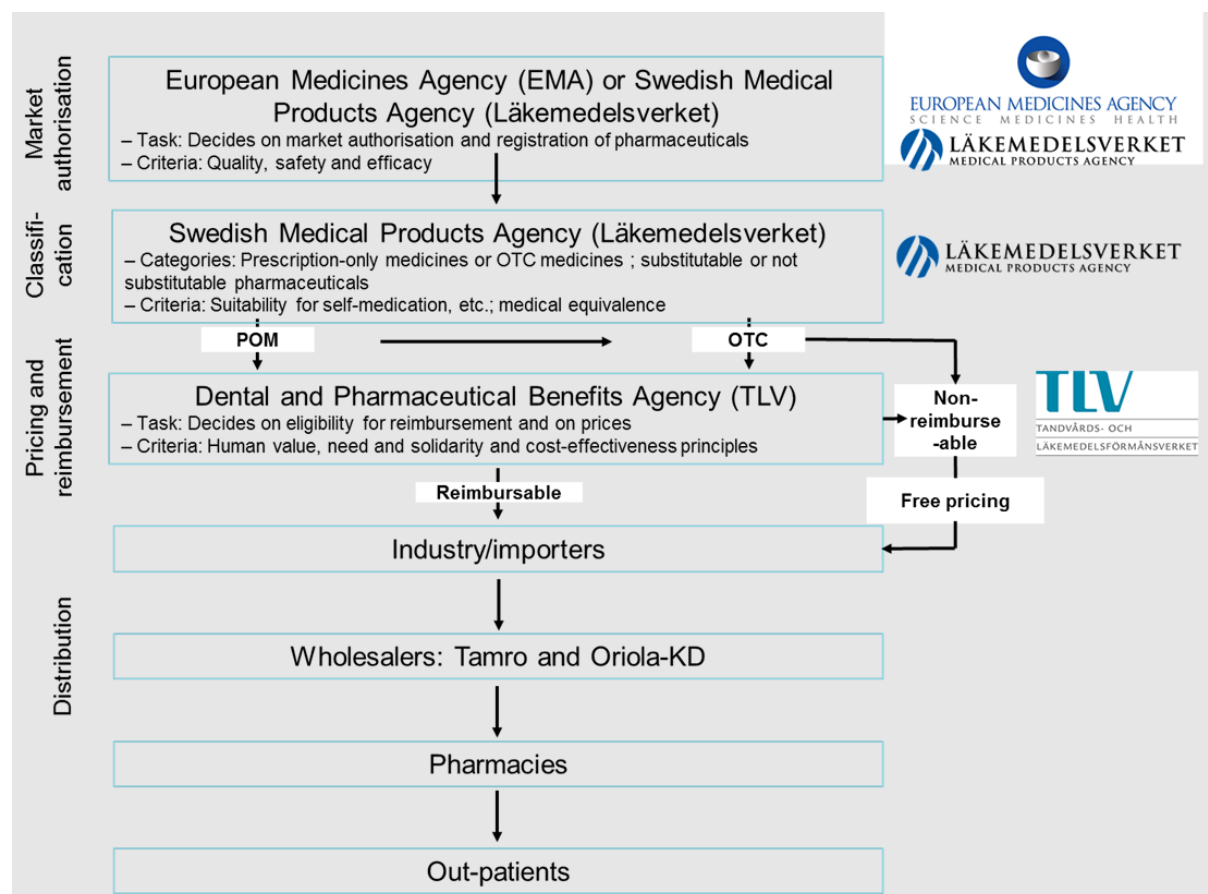
The Act on Pharmaceutical Benefits etc. (Lag (2002:160) om läkemedelsförmåner m.m.) builds the overall legal framework for the pricing and reimbursement of pharmaceuticals. In addition to this the government has passed an ordinance on Pharmaceutical Benefits etc. (SFS 2002:687). TLV has issued provisions which provide rules on the application of the legal framework and has also published general guidelines

³⁰ Regeringen (2022) Socialdepartementet.

Sweden

for economic evaluations submitted with applications for the inclusion of a medicine in the Pharmaceutical Benefits Scheme and for price increases of pharmaceuticals.³¹

Figure 2.1:
Sweden – Flowchart of the pharmaceutical system, 2022



Source: TLV.

³¹ Tandvårds- och läkemedelsförmånsverkets allmänna råd (TLVAR 2003:2) om ekonomiska utvärderingar; Läkemedelsförmånsnämndens allmänna råd (2006:1) om grunder för prishöjningar på läkemedel.

2.1.2 Authorities

SMPA assures the safety of pharmaceutical treatments

The SMPA is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and sale of pharmaceuticals and other medicinal products. It also provides recommendations for medical treatment in various therapeutic areas. In these treatment recommendations, the option of pharmaceutical treatment is considered in regard to other measures such as changes in lifestyle or surgery. SMPA is a governmental agency under The Ministry of Health and Social Affairs and the agency is primarily financed by fees from pharmaceutical producers and distributors.

According to the SMPA's annual report for 2021, the agency is responsible for supervising a market involving 128 national manufactures of pharmaceuticals (and a large number of international manufacturers), 249 companies with a license to distribute pharmaceuticals, 499 marketing authorisation holders in Sweden with pharmacovigilance system, 1 446 community pharmacies, 5 232 registered retailers for selling OTC in non-pharmacies.³²

TLV decides on reimbursement and prices of pharmaceuticals and medical devices

TLV is a governmental agency under The Ministry of Health and Social Affairs responsible for pricing and reimbursement decisions on medicines used in out-patient care. Decisions on pricing and reimbursement of new medicines are made by a separate expert board within the agency; The Pharmaceutical Benefits Board. The board is appointed by the government and consists of seven members. The members have a background in the regions, universities/health economic expert centres and user groups/patient organisations. The Director General of TLV makes decisions that are not the responsibility of the board. For example, the Director General makes all decisions on price increases and decreases of medicines.

The eHealth agency manages e-prescriptions and sales data

The Swedish eHealth Agency (EHM) is managing electronic prescriptions. The agency is also responsible for collecting and supplying statistics about pharmaceutical sales from pharmacies, retailers and distributors. Anyone selling pharmaceuticals in Sweden is obligated by law to provide regular reports of their sales to EHM.

The agency is mandated to investigate how it can add to already existing pharmaceutical statistics with additional data to further increase quality and added value. Comprehensive national pharmaceutical statistics enables analysis and monitoring of pharmaceutical use.

³² Läkemedelsverket (2022) Läkemedelsverkets årsredovisning 2021, p. 38.

Sweden

Table 2.1:

Sweden – Authorities in the regulatory framework of the pharmaceutical system, 2021

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Socialdepartementet	The Ministry of Health and Social Affairs	Regulatory body.	Overall planning and legislative authority. The Ministry of Health and Social Affairs is responsible for issues concerning the welfare of society.
Läkemedelsverket (LV)	The Swedish Medical Products Agency (SMPA)	Governmental agency under the Ministry of Health and Social Affairs.	In charge of market authorisation, classification, vigilance and monitoring of clinical trials.
Tandvårds- och läkemedelsförmånsverket (TLV)	The Dental and Pharmaceutical Benefits Agency (TLV)	Governmental agency under the Ministry of Health and Social Affairs. The Decisions on pricing and reimbursement of new medicines are made by a separate expert board within the agency; The Pharmaceutical Benefits Board.	Responsible for pricing and reimbursement decision, including reviewing health technology assessments (HTA). TLV's remit is also to determine retail margins for pharmaceuticals subsidised by the state for all pharmacies in Sweden, regulate the substitution of medicines at the pharmacies and supervise certain areas of the pharmaceutical market.
E-hälsomyndigheten (EHM)	The Swedish eHealth Agency	Governmental agency under the Ministry of Health and Social Affairs.	The agency leads and coordinate the government's e-health initiatives. Managing electronic prescriptions in Sweden. Gather and supply statistics about pharmaceutical sales from pharmacies, retailers and distributors.
Socialstyrelsen (SoS)	The National Board of Health and Welfare	Governmental agency under the Ministry of Health and Social Affairs.	Has supervisory function over the regions, is in charge of guidelines for care and treatment of serious chronic illness and follows up and evaluates the services provided.

Sweden

Statens beredning för medicinsk utvärdering (SBU)	The Council on Technology Assessment in Healthcare	Governmental agency under the Ministry of Health and Social Affairs.	A HTA organisation responsible for assessing healthcare technology from medical, economic, ethical and social standpoints.
Inspektionen för vård och omsorg (IVO)	The Health and Social Care Inspectorate (IVO)	Governmental agency under the Ministry of Health and Social Affairs responsible for supervising health care, social services and activities under the Act concerning Support and Service for Persons with Certain Functional Impairments (LSS).	IVO's supervision remit covers the processing of complaints concerning, for example, the reporting of irregularities in health care and social care (called lex Sarah and lex Maria reports) and the municipal obligation to report non-enforced decisions.
Myndigheten för vård- och omsorgsanalys (Vårdanalys)	The Swedish Agency for Health and Care Services Analysis	Governmental agency under the Ministry of Health and Social Affairs with the mission to strengthen the position of patients and users through analysing health care and social care services from the perspective of patients and citizens.	The agency analyses how health and care services work, as well as reviewing how effective Governmental commitments and activities are in the area.
Folkhälsomyndigheten (Fohm)	The Public Health Agency of Sweden	Governmental agency under the Ministry of Health and Social Affairs.	The agency has a national responsibility for public health issues and works to ensure good public health. The agency also works to ensure that the population is protected against communicable diseases and other health threats.
Regionerna	The regions	21 regional self-governing local authorities. The regions have together with the 290 municipalities formed an interest organisation – The Swedish Association of Local Authorities and Regions (SKR/SALAR).	Providers of healthcare. Procures medicines used in hospitals. The regions' Pharmaceutical Committees produce, for example, lists of medicines recommended as the first-choice treatment for a range of common diseases. The Pharmaceutical Benefits Group for Regions, with representatives both from the regions and SALAR, deliberates with TLV in

Sweden

			pricing and reimbursement cases.
--	--	--	----------------------------------

Source: TLV

The regions provide healthcare to the public

The 21 regions are self-governing local authorities that provide healthcare in Sweden. Most of their activities are financed by taxes which they have a right to levy. However, to finance the costs for medicines in out-patient care the region are subsidised by the state. It is the regions that are responsible for financing in the both in- and out-patient care.

In each region there is at least one Pharmaceutical and Therapeutic Committee. The committees support physicians in their choice of treatment through publishing annual lists of pharmaceuticals recommended to be used as the first choice for a range of common diseases and through various types of training and development initiatives. (See section 4.4.2).

The regions have a right to deliberate with TLV before the Pharmaceutical Benefits Board makes its decisions on the introduction of new pharmaceuticals into the subsidy system. The regions can also initiate price adjustment reviews. In addition, the regions have appointed a group of experts called The New Therapies Council (NT-rådet), that make recommendations primarily on the use of new in-patient medicines.

Sweden

Table 2.2:

Sweden – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2022

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Market authorisation and Vigilance	The Medicinal Products Act / Läkemedelslagen (2015:315) The Act on Sales of Medicinal Products / Lag (2009:366) om handel med läkemedel	In- and out-patient sector	The Swedish Medical Products Agency, SMPA; (Läkemedelsverket, LV).	Responsible for market authorisation, classification, vigilance and monitoring of clinical trials. Also in charge of issuing permits and supervision of pharmacies.	The association for the researched-based pharmaceutical industry (LIF) and the association for generics and biosimilars (FGL), the pharmacy associations, as well as health care professionals and patient organisations.
Purchasing	The Public Procurement Act / Lag om offentlig upphandling (2016:1145) The Health and Medical Services Act / Hälso- och sjukvårdslag (2017:30)	In-patient sector	The Regions (Regionerna)	Providing health care and procurement of medicines.	Patients and patient organisations.

PPRI Pharma Profile 2022

Sweden

Pricing and Reimbursement	The Act on Pharmaceutical Benefits / Lag (2002:160) om läkemedelsförmåner m.m.	Out-patient sector	The Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket, TLV).	Responsible for pricing and reimbursement of medicines and devices. Monitor and supervise some areas of the pharmacy market.	All of the above
Promotion	The Medicinal Products Act / Läkemedelslagen (2015:315)	In- and out-patient sector	The Swedish Medical Products Agency, SMPA; (Läkemedelsverket, LV).	Marketing and advertising are regulated in the Medicines Act and in the SMPA's regulation on the advertising on medicinal products.	
Distribution	The Act on Sales of Medicinal Products / Lag (2009:366) om handel med läkemedel	In- and out-patient sector	Tamro and Oriola KD, both privately owned distributors.	Distributing medicines to pharmacies and hospitals.	Pharmaceutical companies and pharmacy associations.

Source: TLV, Socialstyrelsen, SMPA

2.2 Availability of and access to medicines

Each year, more products are authorised than withdrawn or delisted. However, during 2020, the number of approved pharmaceutical products in Sweden decreased by 2, to 14 859.³³ In 2021, the upward trend continued, with an additional net 234 products approved and a total number of approved products of 15 093, according to the SMPA.³⁴

Table 2.3:

Sweden – Annual prescriptions in the out-patient sector 2010, 2015, 2018, 2020, 2021 and 2022

Prescriptions	2010	2015	2018	2020	2021	2022 ¹
No. of prescriptions (in millions)	89.39	96.43	102.07	106.14	107.49	111.18
Prescriptions in value (in NCU = MSEK)	25 569	28 365	33 636	36 991	37 526	39 932

¹ Preliminary statistics

No. of prescriptions = number of packages prescribed.

Prescription in value = public and private expenditures on prescribed medicines.

Source: EHM.

2.2.1 New chemical entities

As can be seen below, the number of molecular entities available on the Swedish pharmaceuticals market increased throughout 2010–2021. The increase was higher in the early part of the period.

Table 2.4:

Sweden – Number of new molecular entities, 2010–2021

New molecular entities	2010 – 2015	2016 – 2021
Number of new molecular entities ¹	124	104

¹ Net increase in molecular entities available.

Source: EHM

³³ Läkemedelsverket/ The Medical Products Agency (2021) Läkemedelsverkets årsredovisning 2020, p.22.

³⁴ Läkemedelsverket/ The Medical Products Agency (2022) Läkemedelsverkets årsredovisning 2021, p.22.

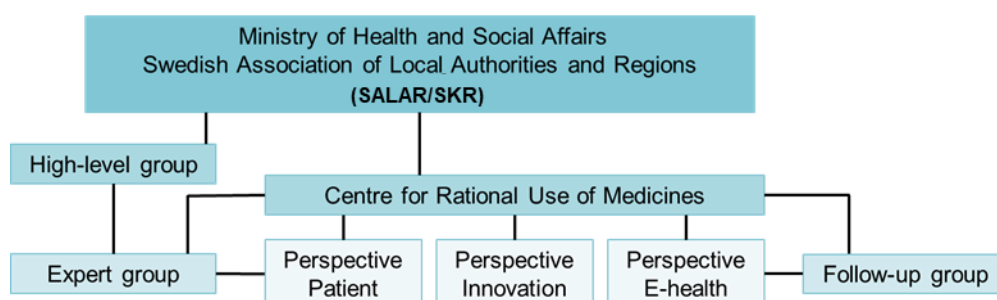
2.2.2 National Pharmaceutical Strategy

The provision of pharmaceuticals in Sweden is dependent on the collaboration of numerous government agencies, care providers and distribution chain participants. To coordinate the work of these actors towards a set of common goals and aims, the Swedish government and SALAR, together with a number of key organisations, have constructed a national pharmaceutical strategy (NPS). Its long-term vision for pharmaceutical provision in Sweden is centred around three goals³⁵:

1. Effective and safe use of medicines
2. Available medicines and equal use
3. Socio-economic and environmentally sustainable use of medicines.

The Centre for Improved Pharmaceutical Usage (CBL), an office within SMPA, is responsible for organising the work around the NPS. The core work is centred around activities and focus areas. Activities are events and processes that aim towards implementing changes dependent on coordinated actions from several actors within the pharmaceutical provision sphere. Focus areas are topics that are to be especially targeted during limited time spans, to either carry out a range of activities or prepare for future activities within that area. For the 2020–2022 period, there were three focus area related to challenges of; access to and availability of medicines, follow-up of use of medicines, and evaluation of knowledge and evidence.³⁶

Figure 2.2:
Organisation of the national pharmaceutical strategy



Source: TLV

³⁵ Läkemedelsverket (2021) The National Pharmaceutical Strategy.

³⁶ For more information on the NPS, see Socialdepartementet (2020) Nationell läkemedelsstrategi 2020–2022.

2.2.3 Processing times

TLV is responsible for pricing and reimbursement of pharmaceuticals included in the reimbursement scheme.

The processing of pricing and reimbursement applications for new medicines is not allowed to exceed 180 days, according to the EU Transparency Directive. In 2021, no case exceeded the time limit. However, in recent years, the average processing time for new original pharmaceuticals has increased. In 2021 TLV announced decisions, on average, within 128 days for new original pharmaceuticals (this may be compared to 121 days in 2020 and 115 days in 2019).³⁷

The processing time for new substances is longer than other types of applications since they require a more extensive assessment than for example new pharmaceutical formulations or new package sizes where the substance is already included in the pharmaceutical benefits scheme.

Despite processing times having risen over the last years, fast processing times still enable early access to some pharmaceuticals. This has included Ilumetri (Tildrakizumab) for patients where TNF inhibitors have not yielded sufficient effect, where a decision was made within 98 days. Another example is Jardiance (Empagliflozin), for patients with heart failure and reduced ejection fraction, which was processed in 90 days.

2.3 Development of the pharmaceutical sales

The Swedish pharmaceutical market can be divided into different segments as follows:

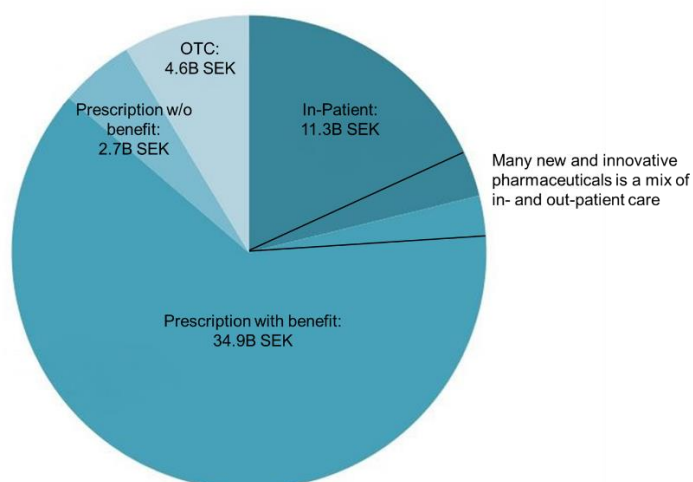
- Pharmaceuticals for the out-patient sector
 - included in the benefits scheme
 - not included in the benefits scheme
- Pharmaceuticals for the in-patient sector
- Prescription free medicines (OTC)

In 2021, the cost of medicines in the benefit scheme amounted to approximately SEK 34.9 billion including patient own payments. In addition, prescription pharmaceuticals not included in the benefits scheme amounted to SEK 2.7 billion:

³⁷ TLV (2022) Årsredovisning 2021, p.12.

Sweden

Figure 2.3:
The pharmaceuticals market in 2021, by segment



Note: depending on definition of total market and market segmentation, the shares of respective segment differ.

Out of the pharmaceutical sales, 4.85 billion SEK are parallel imports. Out of these 4.29 billion SEK are among prescriptions with benefit, 0.36 Billion SEK are among prescriptions without benefits and 0.2 billion SEK in the in-patient sector. As such, it is significantly more common in the prescription market, about 13.3% by value, compared to the in-patient market, around 1.7% by value.

Source: TLV

2.3.1 Prescriptions in the out-patient sector

Prescription of a pharmaceutical product is the most common treatment method in the Swedish healthcare system. Almost two-thirds (65 %) of the population used at least one prescribed pharmaceutical in 2021. This level has remained almost unchanged for several years. The most common group of pharmaceuticals is antihypertensive products, followed by painkillers, antibiotics, anti-allergy products and antidepressants.³⁸

The prescription of antibiotics has declined for all ages since 2006. The greatest reduction is found among children from 0 to 4 years old. There are considerable differences between the two age groups in which the prescription of antibiotics is highest, children from 0 to 4 years and the elderly 75+. While the prescriptions per population in these groups was almost the same in 2006, the prescriptions in the

³⁸ Socialstyrelsen (2022) Statistics on Pharmaceuticals, p.1.

Sweden

0–4 year-olds decreased by more than 2/3 while it only decreased by roughly 1/3 for the 75 years and older, resulting in that prescriptions for the latter group was double of that of the former in 2021.³⁹

2.4 Pharmaceutical consumption

As seen in the table below, the consumption of pharmaceuticals has increased in Sweden over the 2010–2021 period. This trend is consistent over both the in- and out-patient sectors and in terms of both packages and defined daily doses (DDD), except for a slight decrease in packages in the in-patient sector during 2020 and 2021. This trend even holds when accounting for the population increase during 2010–2021, as seen in Table 1.1, with an increase in per capita consumption from 617 DDD in 2010 to 678 DDD in 2021.

Packages and DDD are both measures used in pharmaceutical consumption data in Sweden, used for different analytical purposes. For more information on the statistic management of consumption, see 3.5.1 and 3.5.2.

Table 2.5:
Sweden – Annual pharmaceutical consumption 2010, 2015, 2018, 2020, 2021 and 2022

Consumption	2010	2015	2018	2020	2021	2022 ¹
Total pharmaceutical consumption ²						
In packages ³	162.57	168.40	181.67	189.27	191.06	203.74
In DDD ⁴	5 811.00	6 090.31	6 521.52	6 981.21	7 085.28	7 377.76
Pharmaceutical consumption in the in-patient sector						
In packages	12.10	12.92	12.98	12.73	12.77	13.03
In DDD	136.41	134.87	137.14	136.61	139.91	144.87
Pharmaceutical consumption in the out-patient sector						
In packages	89.39	96.43	102.07	106.14	107.49	111.18
In DDD	5 101.89	5 402.30	5 759.33	6 164.45	6 255.05	6 481.93

¹ Preliminary statistics

² Includes in-patient, out-patient and over the counter human pharmaceuticals

³ Millions of packages

⁴ Millions of DDD

Source: EHM

³⁹ Swedres–Svarm (2021) Sales of antibiotics and occurrence of resistance in Sweden, p. 23.

2.5 Generics

For the system for generics within the Swedish out-patient sector, see 3.2.2.4 and 3.4.1. In the in-patient sector, each region has its own recommendations and procedures for generic substitution, as advised by their Pharmaceutical and Therapeutic Committee.

As can be seen in the table below, there is a significant discrepancy between the volume and value measurements of generics within both the out- and in-patient sectors. This indicates that both the product-of-the-month system used in the out-patient sector and the public procurement procedures used for the in-patient sector are efficient at reducing costs without hampering access.

Table 2.6:
Sweden – Development of the generic shares in volume and value, 2010, 2020 and 2022

Generic share	Volume ¹			Value ²		
	2010	2020	2022	2010	2020	2022
Shares in % of total market (in-patient/ out-patient)	n.a.	53	56	n.a.	17	17
Shares in % of total out-patient market	26	56	59	10	21	20
Shares in % of out-patient re-imbursement market	27	58	62	11	22	22
Shares in % of out-patient off-patent market	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Shares in % of the in-patient market	n.a.	30	29	n.a.	4	4

¹ Expressed in number of packages

² Expressed in expenditure

Source: EHM

2.6 Top 10 medicines

The following lists show the most utilised and the most expensive pharmaceuticals in the Swedish market during 2021, divided in out- and in-patient sectors. Note that the consumption rank is based on DDD and the expenditure rank is based on pharmacy sales prices:

Sweden

Table 2.7:

Sweden – Top 10 active ingredients in value and volume in the out-patient sector, 2022

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure	
1	C10AA05	Atorvastatin	1	B01AF02	Apixaban
2	B03BB01	Folic acid	2	A10BJ06	Semaglutide
3	C08CA01	Amlodipine	3	N06BA12	Lisdexamfetamine
4	C09CA06	Candesartan	4	L04AB04	Adalimumab
5	A02BC01	Omeprazole	5	B02BD02	Coagulation Factor VIII
6	C09AA02	Enalapril	6	L02BB04	Enzalutamide
7	B01AC06	Acetylsalicylic acid	8	R03AK07	Formoterol and Budesonide
8	C09CA01	Losartan	8	L04AC05	Ustekinumab
9	N06AB06	Sertraline	9	A10BK03	Empagliflozin
10	B03BA01	Cyanocobalamin	10	B01AF01	Rivaroxaban

Source: EHM

Table 2.8:

Sweden – Top 10 active ingredients in value and volume in the in-patient sector, 2022

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the in-patient sector, ranked with regard to expenditure	
1	M05BX04	Denosumab	1	L01FC01	Daratumumab
2	L04AB02	Infliximab	2	L01FF02	Pembrolizumab
3	N02BE01	Paracetamol	3	J06BA02	Human immunoglobulin
4	H02AB01	Betamethasone	4	L01FF01	Nivolumab
5	B03BB01	Folic acid	5	S01LA05	Aflibercept
6	C03CA01	Forusemide	6	L04AA33	Vedolizumab
7	B01AB04	Dalteparin	7	N07XX12	Patisiran
8	A02BC01	Omeprazole	8	L04AA23	Natalizumab
9	C10AA05	Atorvastatin	9	L04AB02	Infliximab
10	B03AA07	Ferrous sulfate	10	L01FX04	Ipilimumab

Source: EHM

There are a few observations that are worthy of note in the above tables. One of the is that, apart from apixaban and the formoterol and budesonide combination, all of the top-ranking out-patient substances in terms of expenditure are related to specialists care rather than generalised practitioners.

2.7 Market players

In Sweden there are five pharmacy chains with national coverage, all with internet services, three dedicated internet pharmacies and a small number of independent physical pharmacies. Within hospital pharmacy there are two national chains as well as a few a small number of pharmacies run by the regions themselves. The distribution market is also dominated by two companies. Beyond this, registered supermarkets and convenience stores around the country are allowed to sell a selection of non-prescription medicines (NPM).

For prescription pharmaceuticals, dispensation is limited to licensed community and internet pharmacies. These can, in turn, use pharmacy agents to deliver pre-controlled and -packaged pharmaceutical deliveries. For NPMs, the SMPA regulates the selection of products that can be sent by non-pharmacies.

The pharmacy market, defined as community and internet pharmacies open to the public, is mature but is still growing in terms of revenue and gross margin. The last years the market has been characterised by an increased market share for internet pharmacies. The mature market resulted in a joint venture between two of the pharmacy chains towards the end of 2022. The number of physical pharmacies declined marginally in 2021 but has since been stable in total. The availability to the public is considered to be stable.

Sweden

Table 2.9:

Sweden – Retailers of medicines 2010, 2015, 2018, 2020 and 2021

Retailers	2010	2015	2018	2020	2021
No. of community pharmacies	1121	1358	1421	1433	1411
– <i>Thereof:</i> <i>No. of private pharmacies¹</i>	776	986	1027	1031	820
– <i>Thereof:</i> <i>No. of public pharmacies</i>	345	372	394	402	391
No. of hospital pharmacies (only for in-patients) ²	n.a.	31	40	34	26
No. of dispensing doctors	0	0	0	0	0
No. of other POM disp., <i>please specify</i>	n.a.	22	23	10	10
Total no. of POM dispensaries	1121	1311	1484	1477	1447
No. of internet pharmacies	n.a.	9	9	9	9
No. of NPM disp., like drugstores	6690	5566	5397	5374	5232

Disp. = dispensaries, No. = number, NPM = non-prescription medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients (Glossary on pharmaceutical terms of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies available at <http://ppri.goeg.at>).

¹ Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

² Hospital pharmacies dispensing to out-patients are not included in this figure (according to the Glossary on pharmaceutical terms of the Vienna WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies available at <http://ppri.goeg.at>).

Data as of 1 January

Source: Sveriges Apoteksörening, Apoteket AB, Läkemedelsverket

2.8 Pharmaceutical expenditure

As seen in the table below, the total pharmaceutical expenditure has increased significantly in Sweden over the 2010–2021 period. However, when compared to the GDP of Sweden, seen in Table 1.2 the expenditures have been rather steady, at slightly below 1% of GDP. Beyond this, it is noticeable that the

Sweden

private share of expenditure reduced during the 2018–2021 period. To which degree this is a Covid-effect remains to be seen.

Table 2.10:

Sweden – Total pharmaceutical expenditure 2010, 2015, 2018, 2020 and 2021.

Pharmaceutical expenditure	2010	2015	2018	2020	2021	2022 ¹
TPE in NCU = SEK (M) ²	35 575	39 703	46 662	51 310	52 688	56 891
– <i>thereof public</i> ³	25 639	26 667	32 616	38 297	39 747	42 917
– <i>thereof private</i> ⁴	9 936	13 036	14 046	13 014	12 940	13 974
PE in the out-patient ⁵	25 569	28 365	33 636	36 991	37 526	39 932
– <i>thereof public</i>	18 767	18 830	23 456	27 823	28 490	30 298
– <i>thereof private</i>	6 802	9 535	10 180	9 168	9 036	9 635
PE in the in-patient	6 872	7 836	9 160	10 473	11 258	12 620
– <i>thereof public</i> ⁶	6 872	7 836	9 160	10 473	11 258	12 620
– <i>thereof private</i> ⁷	0	0	0	0	0	0

NCU = national currency unit, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure

Data as of 31 December

¹ Preliminary statistics

² Refers to human pharmaceuticals sold at pharmacies or used in hospitals, not medical durables or nature medicines.

³ Includes payments through the subsidy system and in-patient pharmaceuticals.

⁴ All expenditures except those paid by public.

⁵ Only prescription medicine.

⁶ Patients pay for visits but not for medicines per se.

⁷ Does not include private practices, such as aesthetics clinics.

Source: EHM

2.9 Sources of funding

See 1.4.

3 Pricing, reimbursement and volume control in the out-patient sector

This section covers a description of the organisation of the pricing system and policies. It describes also the organisation of the reimbursement system, the reimbursement schemes, reference price system, private pharmaceutical expenses and the volume control mechanisms in the out-patient sector as of 2023.

For a pharmaceutical to be covered by the reimbursement scheme the company concerned applies to the Dental and Pharmaceutical Benefits Agency (TLV). In the application the company states the price they apply for, and health economic documentation is enclosed. TLV's decisions need to be consistent with the so-called ethical platform, which is legislated and applies to all prioritising of publicly funded health care. The three principles in the platform are: the human value principle, the need and solidarity principle and the cost-effectiveness principle (described more extensively below). Provided that the first two principles are fulfilled, the application is granted if TLV finds that the health economic analysis shows that the requested price is justified on the basis of the value the pharmaceutical delivers in terms of improved health and cost savings, i.e. it is cost-effective. The reimbursement decision is thus based on value, which is often described in terms of Sweden applying Value Based Pricing of pharmaceuticals.

Sweden is more or less alone in conducting full value-based pricing system which widens the analysis from a health care perspective to also include effects outside the health care sector.⁴⁰ This means that the country has a relatively high willingness to pay per health unit gained.

3.1 Organisation of the out-patient sector

See 2.1 as well as Flowchart of the pharmaceutical system (Figure 2.1) and Legal basis and actors (authorities and market players) of the pharmaceutical system (Table 2.2).

3.2 Pricing of medicines

In Sweden, pharmaceuticals in the benefits scheme that are used in the out-patient sector may be divided in two segments:

⁴⁰ Vogler S. (2022) Payer policies to support innovation and access to medicines in the WHO European Region: Oslo Medicines Initiative technical report, p.15.

-
- pharmaceuticals without competition, mainly patented protected products incl. biosimilar products
 - pharmaceuticals with competition, within the system for substitution at the pharmacy, product-of-the-month

3.2.1 Pricing policies

The policies for pricing pharmaceuticals and other medical products used in the out-patient sector depends on several factors. Generally, prices for pharmaceuticals and other products financed by the public are both regulated and transparent (i.e. pharmacy purchase and pharmacy retail price).

The Pharmaceutical Benefits Board decides on price and reimbursement

TLV is the agency in charge of deciding whether a pharmaceutical product should be eligible for reimbursement and included in the Swedish benefits scheme. The decision is made by the Pharmaceutical Benefits Board (Nämnden för läkemedelsförmåner). The board makes joint reimbursement and pricing decisions for new applications: original brand products, new dosage forms of medicines already granted reimbursement status, new licensed medicinal products, and new generic medicinal products. The board consists of seven members representing the regions, universities and patient organisations.

The eligibility criteria for reimbursement are laid out in the Act on Pharmaceutical Benefits and can be summarised mainly in three principles (SFS 2002:160):

- ***The human value principle***; underlines the respect for equality of all human beings and the integrity of every individual. It is not allowed to discriminate on the basis of sex, race, age et cetera, when making reimbursement decisions.
- ***The need and solidarity principle***; states that those in greatest need take precedence when it comes to reimbursing pharmaceuticals. In other words, patients with more severe diseases are prioritised over patients with less severe conditions.
- ***The cost-effectiveness principle***; states that the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective.

All of the above-mentioned criteria for reimbursement eligibility should be considered and balanced against each other by TLV. In accordance with the EU's Transparency Directive the board is to announce its decisions on pricing and reimbursement within 180 days after the application is complete.⁴¹ (See section 2.2.3).

Sweden runs a positive list indicating which medicines are reimbursed for out-patient use. All products in the benefits scheme are reimbursed at 100 per cent, meaning that the full amount of the cost for the product is included in the patients high-cost threshold (see section 3.3.4 for patient's co-payment). There is currently no negative list in place.

⁴¹ TLV (2022) Årsredovisning 2021, p.12.

Sweden

Table 3.1:

Sweden – Ways of pricing of medicines at manufacturer level⁴², 2021

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicine		
	POM	NPM	Reim-bursable	Non-reimbursable	Generics	Parallel imported	Biosimilars
Free pricing	Yes ¹	Yes	No	Yes	Yes ²	See (Non) reimbursement market	Yes
Statutory pricing	No	No	Yes ³	No	Yes ³	See (Non) reimbursement market	No
Price negotiations	Yes ⁴	No	Yes ⁴	No	No	See (Non) reimbursement market	No
Tendering	No	No	No	No	No	See (Non) reimbursement market	No
Others – specify: Auction	No	No	Yes ⁵	No	Yes ⁵	See (Non) reimbursement market	No

POM = prescription-only medicine(s), NPM = non-prescription medicine(s)

1: For non-reimbursable POM

2: For non-reimbursable generics

3: Ceiling for bids within auction system for reimbursable generics

4: For reimbursable POM

5: Monthly auction-like system for reimbursable generics, see 3.2.2.4 and 3.4.1.

Source: TLV

3.2.2 Pricing Procedures

The Swedish pricing policies rely on value-based pricing, managed entry agreements and auctions for various product types for out-patient as well as public procurement for in-patient use. The following section will outline the details of these procedures and when they are applied. First, the following table provides an overview of the pricing models used, and not used, by the Swedish health care system:

⁴² In Sweden, manufacturer and wholesaler levels are treated as one, since there are no traditional wholesalers, see Table 3.3.

Sweden

Table 3.2:
Sweden – Pricing policies, 2022

Pricing policies	In use: yes / no	Price type ¹	Scope ²
External price referenc- ing	No		
Internal price referencing	No*	* Except some products subject to generic substitution in the product-of-the-month system. See section 3.4.1.	
Cost-plus pricing	No		
Indirect profit control	No		
Managed-entry agree- ments:	Yes	MEA may exist between the regions and pharmaceutical companies. MEAs do however not affect the list price, but may affect the cost of treatment for the regions.	
Others, specify: Value based pricing	Yes	Pharmacy purchasing price (PPP) and pharmacy retail price (PRP). Reimbursement is 100 % of PRP.	Products in the benefits scheme without competition from generics.

¹ Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

² Scope = a pricing policy does not always refer to all medicines: e.g. a pricing policy could only refer to reimbursable medicines, whereas for NPM there is free pricing.

Source: TLV

3.2.2.1 Value-based pricing in a product-oriented, *not indication-based, system*

The pharmaceutical company submits an application to TLV including supporting documentation as to the clinical effect and the cost-effectiveness of the product. The application is assessed based on the criteria's above (see 3.2.1).

The reimbursement system is mainly product-oriented, meaning that pharmaceuticals are usually granted reimbursement status for all indications. It is however possible that a pharmaceutical is granted reimbursement for a limited area of use or indication or only to a specified patient group.

3.2.2.2 Pricing and reimbursement processes are combined

Sweden

Medical assessors, health economists and legal counsellors at TLV review the clinical evidence and health economic documentation provided by the pharmaceutical companies. The reimbursement and pricing processes are done simultaneously resulting in a joint reimbursement and pricing decision. The reimbursement decision depends on several factors, where one may be the existence of a managed entry agreement between the regions and the pharmaceutical company.

The Pharmaceutical Benefits Board will reject the application for reimbursement if the price is too high or the product does not fulfil the decision criteria, e.g. cost-effectiveness. The company may then decide if it should apply again at another price.

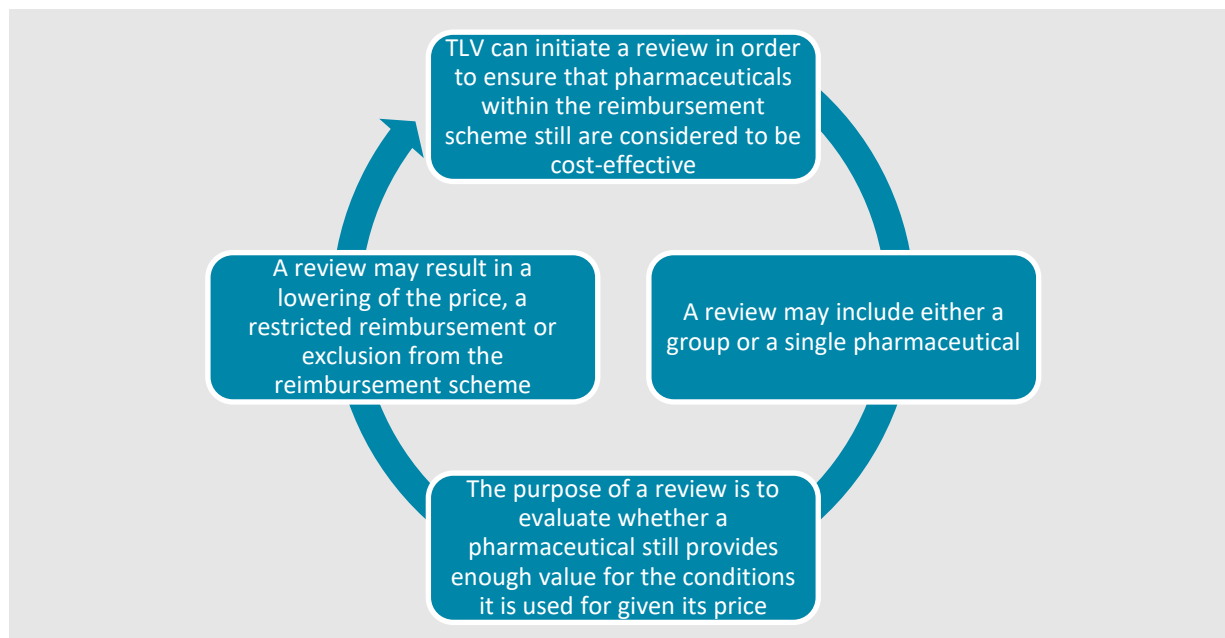
Acting on the initiative of a sponsor or manufacturer of a specific medicinal product included in the scheme, TLV can decide on a price increase and price decrease respectively. TLV also decides on parallel-imported medicinal products, new dosage strengths and package sizes for medicines already granted reimbursement status. Furthermore, acting on its own initiative, TLV can remove a medicinal product from the benefits scheme. The Director-General of TLV is responsible for these decisions.

A decision whether or not to approve an application for a price increase is to be announced within 90 days after the application is complete. If many applications are submitted near in time to each other, the processing time can be extended for a single 60-day period. If a decision is not made within that time frame, then the requested price is accepted.

TLV is also part of the Nordic FINOSE collaboration together with the Finnish Medicines Agency (Fimea) and the Norwegian Medicines Agency (NoMA). Within this framework, pharmaceutical companies can file joint applications to all three countries, allowing the agencies to cooperate on the evaluations and write joint assessment reports. The collaboration leads to sharing of resources and knowledge between the countries. The collaboration also promotes consensus in evidence requirements and HTA methodologies. The FINOSE assessments reports can be used as a basis for joint Nordic price negotiations with the pharmaceutical companies.

Another tool of TLV's disposal is the possibility to initiate a review of a pharmaceutical's pricing and reimbursement status. The following figure illustrates the review-process.

Figure 3.1:
Review of pricing and reimbursement status



Prices are set at the pharmacy purchase price-level. Manufacturers sell the products directly to the pharmacies, operating without wholesalers. They instead purchase distribution services from distribution companies. The pharmacy retail price corresponds to the pharmacy purchase price plus a pharmacy mark-up, which is decided by TLV (see section 3.2.5).

In general, all pharmaceuticals, also including OTC-classified medicines, may be reimbursed, provided that the conditions stipulated in the Act on Pharmaceutical Benefits, etc., are fulfilled. However, OTC pharmaceuticals for antidotal smoking treatment and natural remedies are explicitly excluded from reimbursement.

A special pricing procedure is applied for pharmaceuticals older than 15 years that have no (or weak) generic competition, (see section 3.2.2.4). However, International Reference Pricing (IRP) is not applied in Sweden.

3.2.2.3 Managed entry agreements – a tool for early and equal access

Since 2014, a managed entry agreement⁴³ (MEA) between the regions and a pharmaceutical company may be one of several factors considered when TLV decide on price and reimbursement status. New

⁴³ A managed entry agreement can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use or limit their budget impact.

pharmaceuticals are introduced earlier, and some pharmaceuticals are sometimes associated with uncertainties regarding their use and effectiveness in everyday clinical practice. Risk-sharing via managed entry agreements is an increasingly important tool to manage uncertainties and reduce costs to reasonable levels. Such agreements may ensure cost effectiveness and may also dampen the increasing costs for new pharmaceuticals. Discussions between regions, pharmaceutical companies and TLV can thus enable the use of such pharmaceuticals, even when there is significant uncertainty about their medical effect and its cost-effectiveness.⁴⁴

Managed entry agreements between regions and pharmaceutical companies also have potential as powerful tools to create competition and stimulate price dynamics within established therapeutic areas where, for various reasons, competition and price pressure has not arisen. One example is biologicals, where price competition rarely arises despite the market entry of biosimilars. An example of this is how, in 2016, due to managed entry agreements, competition emerged in the area of TNF-alpha inhibitors as a result of the introduction of a biosimilar.

As of January 2022, there are managed entry agreements in seven therapeutic groups, plus a few ungrouped pharmaceuticals, totally encompassing 47 products. This is down markedly from the 62 products covered during all or part of 2021.⁴⁵ However, it is in line with the 2018 count of 46 products.⁴⁶

Analysis by TLV show that these MEAs produce significant savings for Swedish health care. In 2015, the year after the current MEA system was introduced, total savings were estimated at 259 million SEK, rising to 722 million in 2016, 947 million in 2017 and 2 774 million in 2018.⁴⁷ Since 2018, the yearly savings have remained more stable, with 3 084 million SEK in 2019, 2 823 million in 2020 and 2 705 million in 2021.⁴⁸

3.2.2.4 An auction-based system for products with competition

For off-patent products, generic substitution is mandatory between medically equivalent pharmaceuticals. The pharmacy is obligated to dispense the least expensive pharmaceutical product included in the benefits scheme that is available on the market – regardless of what product is prescribed, as long as SMPA have deemed the given products as substitutable. The physician and the pharmacist may prohibit substitution on medical grounds only.

⁴⁴ TLV (2022) Besparingar från sidoöverenskommelser 2021: Slutavstämning Mars 2022, p.7.

⁴⁵ TLV (2022) Besparingar från sidoöverenskommelser 2021: Slutavstämning Mars 2022, p.5–7.

⁴⁶ TLV (2019) Besparingar från sidoöverenskommelser helåret 2018: Slutavstämning, mars 2019, p.5.

⁴⁷ TLV (2019) Besparingar från sidoöverenskommelser helåret 2018: Slutavstämning, mars 2019, p.8.

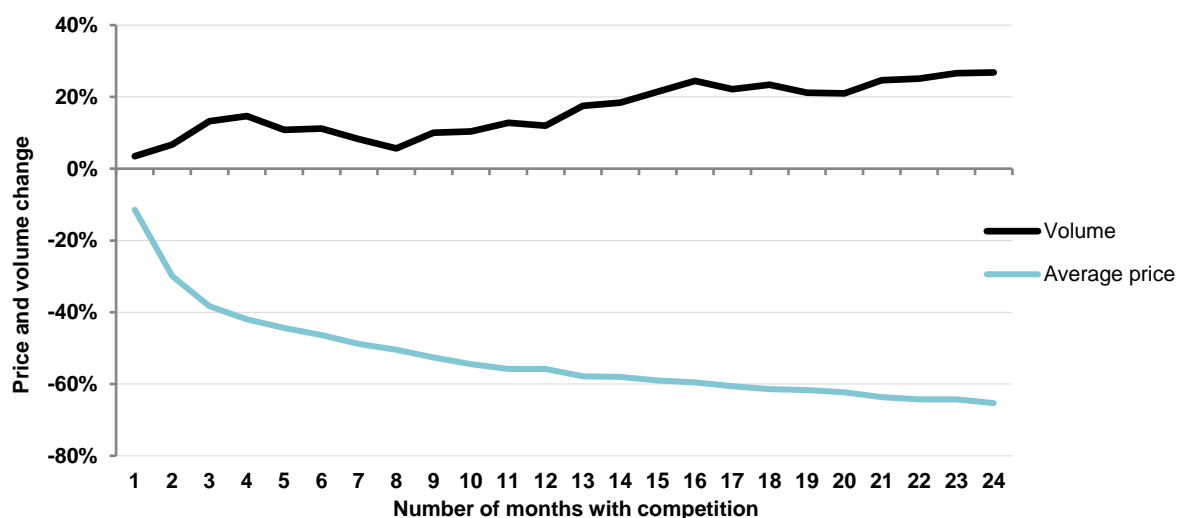
⁴⁸ TLV (2022) Besparingar från sidoöverenskommelser 2021: Slutavstämning Mars 2022, p.8.

Sweden

The preferred product is appointed through an auction-like system. Each month, the off-patent pharmaceutical product with the lowest listed price is approached to be the product-of-the-month. To be given this designation, the pharmaceutical company must ensure availability of the pharmaceutical during the entire price period and that the expiring date of the product meets the minimum requirements. The pharmacies are then obliged to obtain and dispense the product of the month. TLV also appoints two back-up products that pharmacies can switch to if it is not possible to obtain the cheapest alternative.⁴⁹

The purpose of the substitution system of pharmaceuticals in pharmacies is to keep the society's cost down for pharmaceuticals whose patent protection has expired. Competition between manufacturers have resulted in significant price reductions on pharmaceuticals. Already after three months, the price has fallen on average by 40 percent and after two years the price has fallen further, to 35 percent of the price before competition arose. As the price falls, volumes increase, which means that more patients get access to effective treatment. Also, financial resources are made available for other care since the decrease in price is larger than the increase in volume.

Figure 3.2:
Price- and volume change for pharmaceuticals with competition after 2003



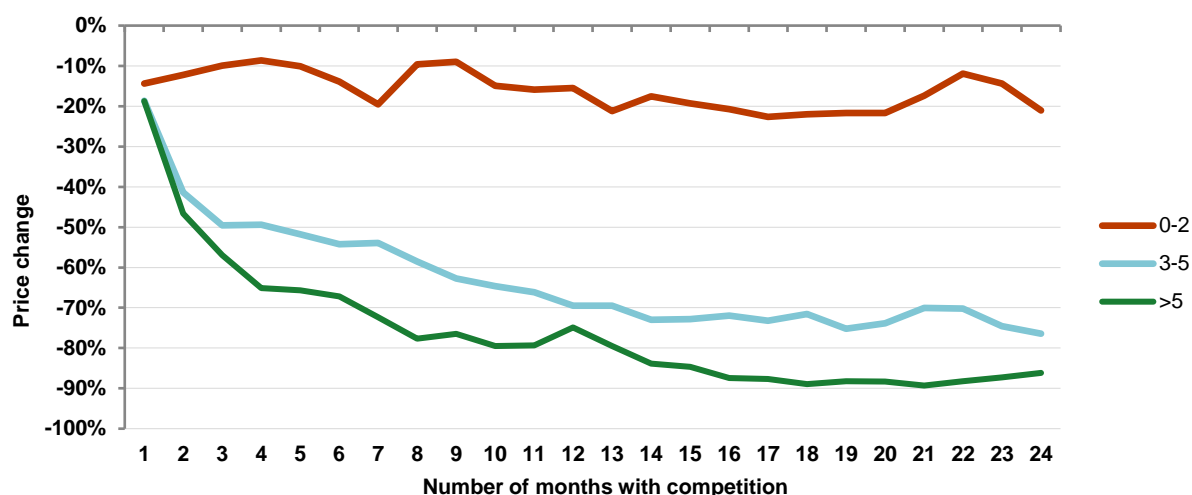
Source: TLV.

⁴⁹ Though not a formal auction, as it relies on the pharmaceutical companies applying to change their own listed price in order to compete, the incentives for them to do so means that the system practically functions as an auction-based system.

Sweden

There is a difference in how the price develops depending on the number of active competitors active in a certain exchange group. Exchange groups with several competitors have a higher price reduction compared to groups with fewer competitors.

Figure 3.3:
Price change for pharmaceuticals with competition (depending on the number of competitors)



Source: TLV.

The figure above does not exclude other factors that could affect prices. This means that the price trend may be affected by other factors than by the number of competitors. However, there does seem to be a clear linkage between the number of competitors and the price trend in an exchange group.

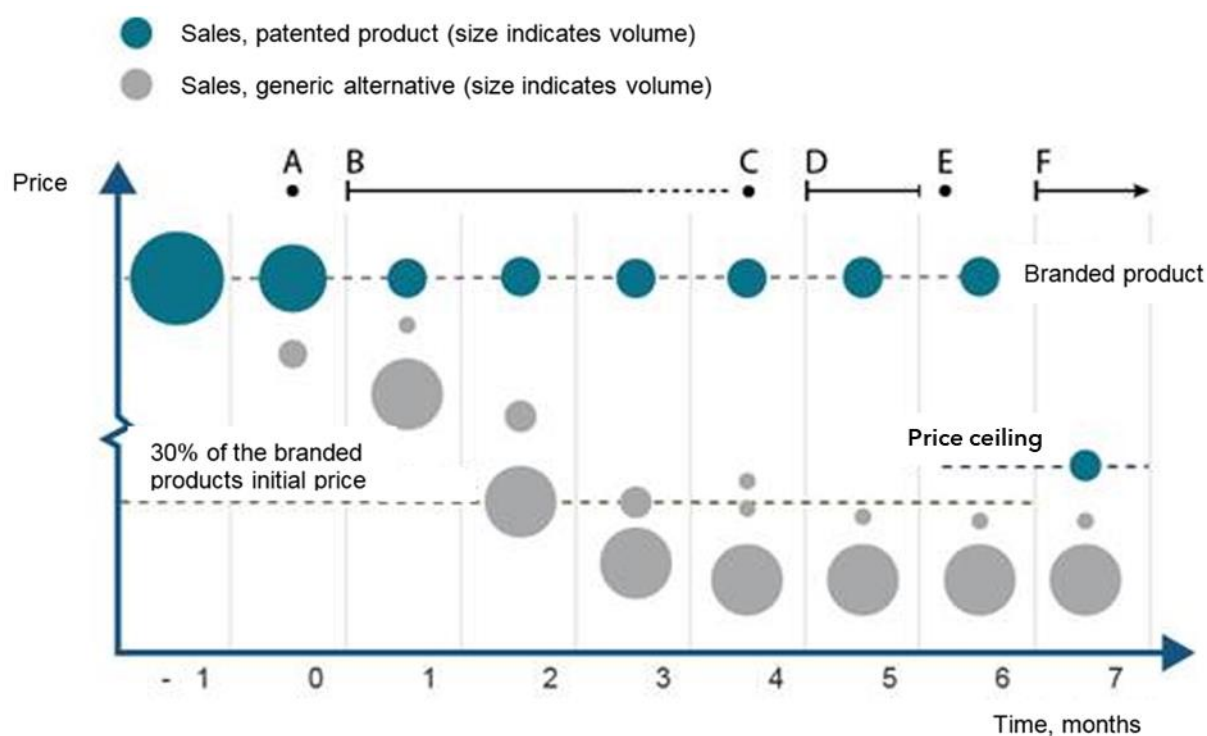
Generic substitution leads to lower prices, and afterwards significant price differences between generic substitutes can arise. In this situation TLV will lower the maximum accepted selling price within the benefits scheme by setting a lower ceiling price for substitutable pharmaceuticals (most relevant for the branded original product that has lost its patent protection). Each month, TLV analyses prices and sales volumes in order to find groups where the criteria for setting a ceiling price are met. When the prices of a group of substitutable pharmaceuticals have dropped by at least 70 per cent of the price that the pharmaceuticals had before generic competition arose, and when generic competition has been ongoing for at least six months, TLV sets a ceiling price. The new fixed ceiling price is 35 percent of the price that the pharmaceuticals had before generic competition arose.⁵⁰

⁵⁰ TLV (2022) Takpriser.

Sweden

Setting the ceiling price in this way thus reduces the differences in price between substitutable pharmaceuticals within the benefits scheme, but it also has the effect of further lowering costs in addition to the cost-lowering effect of generic substitution itself.⁵¹ However, since the ceiling is set at fixed SEK values, it does not take inflation pressures into account and risks forcing companies to withdraw their products from the Swedish market due to lack of profitability. As such, TLV is currently reviewing how to make the ceiling more long-term sustainable in case of sustained high-level inflation.

Figure 3.4:
Generic price linkage: price ceiling for interchangeable products with generic competition



Note:

Point A: First generic enters the market.

Period B: Competition leads to lower prices.

Point C: The price of the cheapest generics is below 30 percent of the original product (before generic competition), hence the criteria's for so called a preliminary roof price is met.

Point/period D: TLV establish an official final roof price. The companies then have to apply for a price below 35 percent of the original product or withdraw their product from the reimbursement scheme.

Point E: TLV decides on new prices.

Point/period: The new prices come into force and the new roof price is established.

Source: TLV.

⁵¹ TLV (2016) Det svenska periodens vara-systemet: En analys av prisdynamiken på marknaden för utbytbara läkemedel, p.17, 24.

Some older pharmaceuticals have no, or only weak, generic competition. This may, for example, be due to the fact that a generic pharmaceutical may not be regarded substitutable to the original medicine, or that the pharmaceutical is a so-called biological pharmaceutical. In 2014, a price reduction of reimbursed pharmaceuticals that were older than 15 years, and that had no or only weak competition, was introduced. The price reduction is equivalent to 7.5% and applies to any pharmaceutical product with the same active substance and delivery format, even only one of the products in that given group has reached 15 years of age. The location of new product groups to be lowered occurs twice a year and once the price of a product group has been lowered that group will not be lowered again.⁵² For example, in 2021, the price cuts under this 15-year rule was carried out on two occasions, in June and December, and involved a total of 341 pharmaceuticals packages (substance, package size, dosage form and strength-level).⁵³

3.2.2.5 Other pricing procedures

Cost-plus pricing, profit control procedures and tendering procedures are not used in the out-patient sector in Sweden.

3.2.3 Specific pricing policies

High-cost medicines

Value based pricing is the procedure for pricing and reimbursement for all products in the benefits scheme used in the out-patient sector. There is no separate definition of high-cost medicine.

Generic price link

Regarding generic price linkage between synthetic originals and generics, see section 3.2.2.4. There is no price link between biological originals and biosimilars.

3.2.4 Discounts / rebates

There are no discounts or rebates on products included in the reimbursement scheme. MEA's may exist between the regions and pharmaceutical companies for out-patient pharmaceuticals in the benefits scheme. MEAs do however not affect the list price, but may, due to risk-sharing agreements, affect the cost of treatment for the regions.

⁵² TLV (2022) Prissänkning enligt 15-årsregeln.

⁵³ TLV (2022) Årsredovisning 2021, p.22.

Sweden

3.2.5 Remuneration of wholesalers and community pharmacies

In Sweden, the distribution of pharmaceutical products is managed by distributors. Manufacturers buy their services directly for all product types. Hence, there are no traditional wholesalers in the Swedish pharmaceuticals market.

The remuneration of pharmacies is depending on if a pharmaceutical product is part of the subsidy system or not. For those products that are not in the system, free pricing is applied in all stages of the distribution chain. Products in the subsidy system are regulated. The regulated price applies to the price at which the pharmacies buy the products. The pharmacies then have fixed sales margins on their sales of subsidised products, as seen in Table 3.4 to Table 3.7.

Table 3.3:

Sweden – Regulation of wholesale and pharmacy remuneration, 2022

Wholesale remuneration			Pharmacy remuneration		
Regulation	Content	Scope	Regulation	Content	Scope
<i>No, use of wholesalers. Manufacturers use distribution companies, whose pricing is unregulated.</i>	<i>Manufactures and distributors negotiate the distribution service prices.</i>	<i>All products.</i>	<i>Yes, regulation of the pharmacy mark-up.</i>	<i>Regressive mark-up up to a ceiling.</i>	<i>All prescription medicines that are included in the benefits scheme.</i> <i>For medicines not included in the benefits scheme, trade goods, and OTC, there is no regulation regarding the retail margin. Pharmacies are allowed to freely set the price as well as the retail margin for those products.</i>

Source: TLV. Note, this remuneration scheme only applies to pharmaceuticals in the subsidy system. For OTCs and non-subsidised pharmaceuticals, free pricing is applied.

The changed regulation only applies to pharmaceutical packages. That means that the retail margin for ostomy products, medical devices and medical device consumables was unaffected by the change.

The following is a summary of the retail margins set by TLV.⁵⁴

⁵⁴ TLV (2022) Apotekens marginaler.

Sweden

Table 3.4:

Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals without competition.

Pharmacy purchasing price, (PPP) SEK	Pharmacy retail price (PRP), SEK
≤ 75	$PPP \times 1.20 + 30.50$
> 75–300	$PPP \times 1.03 + 43.25$
> 300–50 000	$PPP \times 1.02 + 46.25$
> 50 000	$PPP + 1\,046.25$

Source: TLV.

Table 3.5:

Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals with generic competition (Product-of-the month)

Pharmacy purchasing price, (PPP) SEK	Pharmacy retail price (PRP), SEK
≤ 75	$PPP \times 1.20 + 30.50 + 12.75$
> 75–300	$PPP \times 1.03 + 43.25 + 12.75$
> 300–50 000	$PPP \times 1.02 + 46.25 + 12.75$
> 50 000	$PPP + 1\,046.25 + 12.75$

Source: TLV.

Table 3.6:

Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals ostomy products.

Pharmacy purchasing price, (PPP) SEK	Pharmacy retail price (PRP), SEK
≤ 47.35	$PPP \times 1.362 + 4$
> 47.35–4 500	$PPP \times 1.108 + 16$
> 4 500	$PPP + 502 + 0.01 \times (PPP - 4\,500)$

Source: TLV.

Sweden

Table 3.7:

Formula for calculating pharmacy sales price including retail margin for medical devices and medical device consumables.

Pharmacy purchasing price, (PPP) SEK	Pharmacy retail price (PRP) SEK
≤ 47.35	$PPP \times 1.402 + 3.36$
$> 47.35 - 4\,500$	$PPP \times 1.106 + 17.36$
$> 4\,500$	$PPP + 494.36 + 0.01 \times (PPP - 4\,500)$

Source: TLV.

Value-added tax (VAT) is added by 25 per cent to ostomy product, medical devices and medical device consumables.

3.2.6 Taxes

The standard VAT rate is 25 percent and is applied to OTC-pharmaceuticals. The VAT of 25 percent is also applied to ostomy product, medical devices and medical device consumables. There is no VAT on prescribed pharmaceuticals, nor on OTC products collected using a prescription. As private companies, pharmacies pay the standard 20.6 percent corporate tax on profits.

3.3 Reimbursement of medicines

The reimbursement system is a national scheme and covers the whole country. In other words, all reimbursed pharmaceuticals are reimbursed in every region and the price is the same across the country. However, in every region there is at least one Pharmaceutical Committee which produces a list of medicines recommended as the first-choice treatment for a range of common diseases.

In general, all pharmaceuticals – including OTC pharmaceuticals – may be reimbursed and included in the benefits scheme, provided that the conditions stipulated in the Act on Pharmaceutical Benefits are fulfilled. However, it is important to note that most OTC medicines are not included in the reimbursement system. Pharmaceutical companies usually do not apply for reimbursement for OTC pharmaceuticals as medicines outside the benefits scheme are unregulated and subject to free pricing. Pricing of those product may also vary between pharmacies.

The current reimbursement system, with decreasing patient co-payments, has been in place since 1997. Before this, patients paid a fixed set of prices per prescription until they reached the maximum payment ceiling, after which all prescriptions for covered pharmaceuticals were fully subsidised. However, all pharmaceuticals that addressed conditions deemed as chronic were fully subsidised independent of the payment ceiling, leading to extensive debates over the definition of chronic conditions.

3.3.1 Specific reimbursement schemes

Pharmaceuticals prescribed to children under 18 years are since from January 2016 without co-payment for the patient, as long as the pharmaceutical is included in the benefits scheme. There is also a national policy that young adults (under 21 years) receive free contraceptives, included in the benefits scheme, without any out-of-pocket co-payment from January 2017.

Insulins is a group of medicines in the benefits scheme that is also without co-payment for the patient and thus subsidised at 100 per cent. Some medical devices needed for ostomy are also without co-payment for the patient.

Pharmaceuticals prescribed under Swedish Communicable Diseases Act (Smittskyddslagen) for preventing contamination of certain communicable diseases (e.g. hepatitis C and HIV), are subsidised at 100 per cent and is without co-payment for the patient. Also visiting clinics and testing for communicable diseases and is free of charge for the patient.⁵⁵ Pharmaceuticals prescribed for persons lacking perception of their own illness are also subsidised at 100 per cent and is without co-payment for the patient in most regions.⁵⁶

3.3.1.1 Asylum seekers, people with no papers and people in hiding

Adults seeking asylum, in hiding or without identification documents, are offered emergency medical care and dental care in Sweden, if needed. Persons under 18 years of age, are offered health and medical care on the same terms as other children living in the region where the person is seeking treatment.

Each time someone receives health care the person must provide name, date of birth and a telephone number and also show a 'Lag om mottagande av asylsökande med flera' (LMA) card or the receipt from the time of the asylum application. The LMA card is issued by the Swedish Migration Agency (Migrationsverket) at the time of application for asylum. The card is a temporary ID document that is valid during the asylum application process.

The following health care fees apply for adults (above 18 years): Appointments with a doctor at a health centre cost a maximum of SEK 50 (€~5). Medical care provided following a referral costs a maximum of SEK 50 (€~5). Appointments with a referral to a caregiver other than a doctor cost a maximum of SEK 25 (€~3). Hospital care is free of charge. Prescription medicines cost a maximum of SEK 50 (€~5). However, the asylum seeker pays full price for prescription pharmaceuticals not covered by the high-cost protection scheme and included in the benefits scheme, just the same as non-asylum seekers do. There is no charge for preventive paediatric, maternity, prenatal and childbirth care or abortions, nor for protective care against contagious diseases. Dental treatment provided by the Swedish Public Dental Service

⁵⁵ 1177 (2022) Patientavgifter och högkostnadsskydd.

⁵⁶ TLV (2015) Slutrapport om receptbelagda läkemedel utanför läkemedelsförmånerna, p.40.

(Folktandvården) costs a maximum of SEK 50 (€~5). A repeat appointment with a dentist costs a maximum of SEK 50 (€~5).⁵⁷

3.3.2 Reimbursement procedure

The pricing and reimbursement process is combined, see section 3.2.2.

In terms of communication with doctors and pharmacists, the main tool is the journal system, where prescribers can see if a given pharmaceutical product is included in the subsidy. Beyond this, the Pharmaceutical and Therapeutic Committees provide annual lists of covered and recommended pharmaceuticals (see 3.4). Beyond this, TLV provides newsletters featuring recent decisions and there are information physicians and pharmacists with special duties to keep their fellow professional up-to-date.

3.3.3 Reference price system

There is no reference price system. For information about the product-of the-month system for substitutable pharmaceuticals with generic competition, see section 3.2.2.4.

3.3.4 Private pharmaceutical expenses

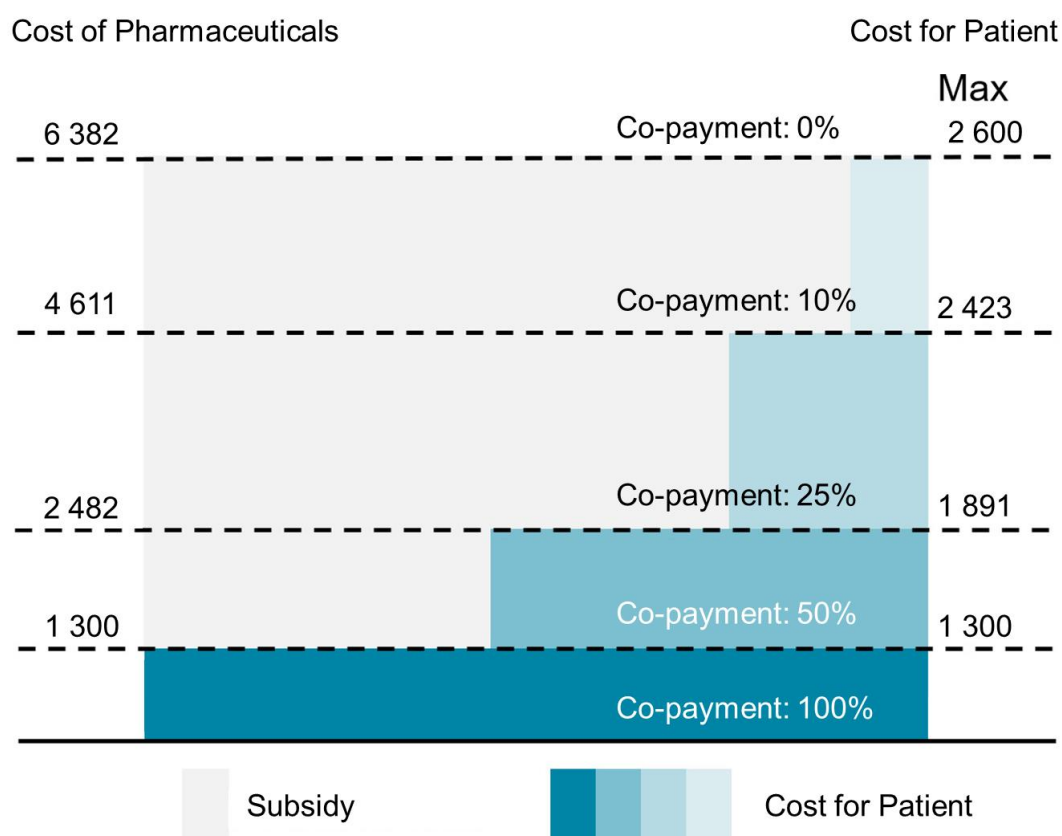
For pharmaceuticals included in the benefit scheme, the patient and the government share the costs of the pharmaceuticals. During a 12-month period, a patient pays the full amount of the pharmaceutical up to SEK 1 300 (€~110). After paying SEK 2 600 (€~220), the patient is fully subsidised. Between SEK 1 300 and 2 600, the patient is subsidised 50, 75 or 90 per cent, depending on the accumulated annual costs.⁵⁸ These levels are periodically updated in line with inflation.

⁵⁷ Migrationsverket (2022) Fees for health care.

⁵⁸ TLV (2022) Så fungerar högkostnadsskyddet.

Sweden

Figure 3.5:
Co-payment for pharmaceuticals



Source: TLV, EHM.

See section 3.3.1 for more information on specific reimbursement schemes for vulnerable groups; children under 18 years, young adults under 21 years regarding contraceptives, insulins, pharmaceuticals prescribed under the Swedish Communicable Diseases Act, and pharmaceuticals prescribed for persons lacking perception of their own illness. There is also specific regulations regarding cost and access to medicines for asylum seekers, people with no papers and people in hiding (see section 3.3.1.1).

Sweden

Table 3.8:
Sweden – Out-of-pocket payments for medicines, 2023

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	N.a.	–
Percentage payments	The patient pays the full amount of pharmaceuticals up to SEK 1 300 (€~120). Between SEK 1 300 and 2 600, the patient is subsidised 50 %, 75 % or 90 %. After paying SEK 2 600 (€~235), the patient is fully subsidized.	Pharmaceuticals prescribed for children under 18 years old, insulins, pharmaceuticals prescribed for preventing contamination of certain communicable diseases (i.e. HIV), and pharmaceuticals for persons lacking perception of their own state of illness, are always subsidised at 100 %.
Deductibles	SEK 2 600 / €~235	–
Reference price system	N.a.	–

Source: TLV

3.4 Volume control

Licensed physicians are free to prescribe any product of their choice to a patient under the condition that it is based on science and experience in clinical practise. Certain products may however be dispensed within the reimbursement scheme, only when prescribed by a specialist. Some healthcare professionals have a restricted right to prescribe medication, such as dentists, nurses with special training in pharmacology and pathology, as well as midwives.⁵⁹

Pharmaceutical and Therapeutic Committees support physicians and other healthcare professionals in their choice of product through publishing annual lists of pharmaceuticals recommended as the first-choice treatment for a range of common diseases and through various types of training and development initiatives. (See section 4.4.2 for more information about Pharmaceutical and Therapeutic Committees).

Since the prescription right is not limited by volume or cost controls, efforts are made to encourage voluntary volume control, usually in relation to specific groups of pharmaceutical products. One example of this is Strama, an organisation aimed at limiting unnecessary use of antibiotics.⁶⁰ Another is the TNF

⁵⁹ Socialstyrelsen (2022) Förskrivningsrätt.

⁶⁰ Strama (2022) Om Strama.

inhibitor app by TLV, which aims to enable practitioners and planners a better understanding of the economic impact of the prescription of various forms of TNF inhibitors.⁶¹

3.4.1 Generic substitution

Generic substitution of pharmaceuticals in pharmacies was introduced in October 2002, and was made mandatory through the product-of-the-month system in 2009. For products with competition, pharmacies are obliged to offer the equivalent medicine with the lowest price (per unit). However, they also receive a 12.75 SEK per package compensation for doing so, see 3.2.5.

The purpose of substitution is to limit society's as well as patient's costs. Savings that are achieved from substitution increase access to treatment for more people and help pay for new, and often expensive, products that become available.

The Medical Products Agency decides on which pharmaceuticals are interchangeable at a product level and publishes a list of groups of interchangeable products. The list is updated approximately eight times per year and provides key information for regulating substitution in the pharmacies.

The system for regulating which products that are to be substituted in all pharmacies is called the products-of-the-month. Each month, TLV informs which product in each package-size group that has the lowest retail price per unit and that should be dispensed at the pharmacies that month (if there are no medical reasons not to substitute the product). Hence, the substitutable pharmaceuticals with the lowest prices can vary, which means that pharmacies may offer different pharmaceuticals to a patient at different times. TLV also appoints two back-up products that pharmacies can substitute to if the cheapest product no longer is available.

In 2014, a system of active participation was introduced, where companies wishing to be part of the product-of-the-month competition have to actively sign of for this with TLV. By doing so, they also guarantee that they will be able to supply the entire Swedish market with enough supply of the given product throughout the month, with a possible fine if they failed to do so. The supplied products must also fulfill certain expiration date requirements. While this meant that the product-of-the-month was not always the cheapest on the market, it ensured that pharmacies would not have to switch to more expensive products in the middle of a month due to lack of stock, which had previously been an ongoing issue.

For more information on the product-of-the-month system, see 3.2.2.4.

⁶¹ TLV (2022) Välkommen till webbapplikation för TNF-hämmare.

Table 3.9:

Substitution at the pharmacy, how it is managed at the pharmacy and the patient's costs

How it is managed at the pharmacy	Patient's cost
Change to the product of the month (normal case) The product of the month is dispensed.	The cost is included the high-cost protection in the benefits scheme.
The prescriber opposes the substitution due to medical reasons. The prescribed product is dispensed.	The cost is included the high-cost protection in the benefits scheme.
The dispensing pharmacist opposes the substitution. The prescribed product is dispensed.	The cost is included the high-cost protection in the benefits scheme
The patient opposes the substitution and would like the prescribed pharmaceutical dispensed.	The cost is the difference between the prescribed pharmaceutical and the product of the month and is not included the high-cost protection in the benefits scheme. The remaining cost is included in the high-cost protection.
The patient neither want's the prescribed pharmaceutical or the product of the month, but rather a different substitutable pharmaceutical.	The patient pays the full cost of the pharmaceutical. The cost is not included in the high-cost protection.

Source: TLV.

3.4.2 Biosimilar substitution

Biosimilars are not assessed by the Swedish Medical Products Agency as substitutable on a pharmacy level in Sweden. Instead, they are treated as their own separate substances and are not included in the product-of-the-month system that applies for generic substitution. However, each prescribing doctor is able to switch from a biologic originator to a biosimilar as they see fit.

Historically, doctors have been hesitant to make biosimilar substitutions due to fears of patient safety. As such, biosimilars have been mainly used for new patients rather than for ongoing treatments. However, the SMPA recommends that limited substitution can be made during an ongoing treatment, but that repeated switches should be avoided.⁶²

SMPA has recently received a government assignment to study the possibility to introduce biosimilar substitution in out-patient care and facilitation of switching in in-patient. The assignment is to result in a report by April 2024.⁶³

⁶² Läkemedelsverket (2017) Godkännande och uppföljning av biosimilarer: Information om biosimilarer från Läkemedelsverket, p.17.

⁶³ Socialdepartementet (2022) Regleringsbrev för budgetåret 2023 avseende Läkemedelsverket.

3.4.3 INN prescribing




It is currently not permitted to prescribe using the generic name/International Non-proprietary Name (INN) only. Instead, prescribers must indicate a brand name of either an original or a generic product. Since 2018, EHM has conducted a study about how to introduce INN prescription in Sweden, as part of a government assignment to develop the National Medication List. The current suggestion for a technical solution is to use the interchangeable product groups determined by the SMPA, which means that the prescription would determine substance, strength and dose form but not a specific product by name. The implementation date of INN prescription has yet to be scheduled.

3.4.4 Other generic and biosimilar promotion

Pharmacies receive an extra SEK 12.75 (€~1.15) in retail margin when dispensing a product with competition from generics, i.e. within the Product-of-the-month system.

TLV and SMPA have produced information material regarding generic substitution specifically targeted at patients, prescribers and pharmacists. The material comprises of a patient folder, posters, fact sheets and other in-depth material to pharmacists and prescribers. All the material has been developed in consultation with patient organisations, pensioners' associations, regions, and other pharmacy associations. The information is based on current regulations and guidelines, research findings and other studies and reports as well as interviews.

Table 3.10:
Examples of information material regarding generic substitution

	Link
Information to patients in eight languages 	<p>Swedish: www.tlv.se/download-load/18.467926b615d084471ac33470/1510316350249/Folder_patienter_A5.pdf</p> <p>Arabic: www.tlv.se/download/18.467926b615d084471ac33141/1510316386743/Patientfolder_2014_arabiska.pdf</p> <p>Bosnian / Croatian / Serbian: www.tlv.se/download-load/18.467926b615d084471ac33148/1510316386772/Patientfolder_2014_bosniska_kroatiska_serbiska.pdf</p> <p>English: www.tlv.se/download/18.467926b615d084471ac33146/1510316386789/Patientfolder_2014_engelska.pdf</p> <p>French: www.tlv.se/download/18.467926b615d084471ac33145/1510316386805/Patientfolder_2014_franska.pdf</p> <p>Persian: www.tlv.se/download/18.467926b615d084471ac33215/1510316387101/Patientfolder_2014_persiska.pdf</p> <p>Somalian: www.tlv.se/download/18.467926b615d084471ac33213/1510316387119/Patientfolder_2014_somaliska.pdf</p> <p>Sorani: www.tlv.se/download/18.467926b615d084471ac33139/1510316386835/Patientfolder_2014_sorani.pdf</p> <p>Spanish: www.tlv.se/download/18.467926b615d084471ac3313f/1510316386942/Patientfolder_2014_spanska.pdf</p>
Information to pharmacists 	<p>www.tlv.se/apotek/generiskt-utbyte/informationsmaterial-om-det-generiska-utbytet.html</p> <p>www.tlv.se/apotek/stod-for-apotekspersonal.html</p>
Information to prescribers 	<p>www.tlv.se/apotek/generiskt-utbyte/informationsmaterial-om-det-generiska-utbytet.html</p>

Source: TLV.

3.4.5 Claw-backs and paybacks

Claw-backs are not used for out-patient pharmaceuticals.

3.4.6 Managed-entry agreements

See section 3.2.2.3.

3.5 Evaluation

The pharmaceutical market is under constant evaluation both by government commissions and various agencies. The regions are also continuously evaluating aspects of the market regarding financial, medical and other aspects.

TLV, for example, regularly monitors a number of pharmaceuticals related expenditures. One example is the outcome of the agreement between the government and LIF regarding the 7.5 per cent price cut on products older than 15 years. It also monitors the effects of re-evaluations, when TLV initiates reviews of subsidised medicines to see if they should still be covered. Together, the total savings from these activities was calculated to 1.39 billion SEK between 2014 and 2021.⁶⁴ Other ongoing expenditures monitoring for example the continuous evaluation of MEAs with various pharmaceutical companies⁶⁵ (for more, see section 3.2.2.3) and the annual international price comparison, where the development of pharmaceutical prices in Sweden are compared with those in a set of other European countries.⁶⁶

Beyond these continuous monitoring and evaluation, the Swedish government at times initiate reviews of specific areas or with specific intents. For the current assignments see section 5. To assist in the Swedish value-based pricing assessments, TLV publishes pharmaco-economic guidelines for companies applying for their product to be included in the subsidy system.⁶⁷

It is SMPA that monitors shortages of pharmaceutical products in Sweden. Since 2019, the shortage-levels have varied substantially, especially with a Covid-19 effect in early 2020. The monitoring includes pharmaceutical product category, through Anatomic therapeutic chemical classification (ATC)-codes, reasons for shortage, time from notice of upcoming shortage to actual shortage as well as the availability

⁶⁴ TLV (2022) Uppföljning av läkemedelskostnader: Juni 2022, p.56.

⁶⁵ TLV (2022) Prognos av besparingar från sidoöverenskommelser helåret 2022: Prognos 2, december 2022.

⁶⁶ TLV (2022) Internationell prisjämförelse 2021: En analys av svenska läkemedelspriser i förhållande till 19 andra europeiska länder.

⁶⁷ TLV (2021) Handbok för företag vid ansökan om subvention och pris för läkemedel.

of alternative treatments for the shortage product. Noticeable is that cases of shortage are due to production capacity or consumption spike issues, that notice before shortage is short and that most but not all shortage products can be replaced by other treatments.⁶⁸

3.5.1 Prescription monitoring

The National Board of Health and Welfare is commissioned by the government to provide evidence-based guidelines for the care and treatment of patients. The guidelines are agreed upon in collaboration with other actors, such as the SBU, SMPA and TLV. The overall goal is to contribute to the effective use of health care resources, allocated on the basis of need and governed by open and transparent decisions on priorities. The guidelines include recommendations for decisions on priority setting and provide national support to assist health care providers in establishing disease-management programmes. Three versions of the guidelines should normally be published: one for health care decision-makers, one for health care personnel, and one for patients and their relatives.⁶⁹

In 2021, EHM introduced the National Medication List. This enables various healthcare providers to monitor the prescribed and collected pharmaceuticals of any given patient. This is meant to increase patient safety.⁷⁰ Although the list has already been introduced, it is still in a process of being fully integrated into the health care system, which requires both technical and structural changes.⁷¹

3.5.2 Pharmaceutical consumption monitoring

The National Board of Health and Welfare registers data on pharmaceutical consumption at the level of the individual patient. The register can be linked to other health data, such as the patient register linking pharmaceutical use to different diagnoses.⁷² Data from the register is used in the process of national guidelines for health care and open comparisons to identify indicators of the quality of pharmaceuticals.⁷³

The pharmaceutical register contains all the dispensed prescriptions at the pharmacies as well as information on dispensed medical devices and medical consumables, such as ostomy products and foods for nutritional use by children under 16 years. The number of entries in the register is just over 100 million per year.

⁶⁸ Läkemedelsverket (2022) Statistik om restsituationer.

⁶⁹ Anell A., Glenngård A.H. & Merkur S. (2012) Sweden: Health system review. Health Systems in Transition, p. 36.

⁷⁰ E-Hälsomyndigheten (2022) Nationella läkemedelslistan.

⁷¹ E-Hälsomyndigheten (2022) Övergången till Nationella läkemedelslistan.

⁷² Only diagnoses from in-patient and specialised out-patient care are registered in the patient register. Diagnoses from the primary care are not registered.

⁷³ Socialstyrelsen/National Board of Health and Welfare (2017) Läkemedelsregistret.

The register contains information about:

- patient (sex, age, registered residence)
- pharmaceutical product (for example, ATC code, name, strength, package size)
- prescription (for example, the prescribed amount, the date of the prescription and the date when the goods are taken out)
- costs (region cost and customer fee)
- characteristics of the workplace where the prescription was made (for example, business orientation) and which professional and specialist prescribers have.

The purpose of the medicines register is to improve patient safety in the pharmaceutical field. The register is used by researchers, journalists, investigators, regional authorities and representatives of the pharmaceutical industry. Increased knowledge about different medicines' effects and safety may ultimately be of benefit to individual patients.

The register is subjected to extensive privacy protection. It is subject to the limitations set out in the the Act on National Medicines' List / Lagen (2018:1212) om nationell läkemedelslista and the Health Data Registry Act / Lagen (1998:543) om hälsodataregister. It also covers only out-patient pharmaceutical products and not products used in in-patient care.

Several government agencies are involved in analysing the developments in pharmaceutical sales and consumption. Though not looking directly at consumption, TLV continuously monitors several related factors, such as the cost developments for pharmaceutical products⁷⁴, developments on the pharmacy market⁷⁵ as well as the price of Swedish pharmaceuticals in an international perspective⁷⁶. Other agencies have analysed specific topics and policies related to pharmaceutical consumption at given timepoints, such as the Swedish Agency for Health and Care Services Analysis who reviewed the managed entry structures in 2016⁷⁷ and the Swedish National Audit Office who looked at the Swedish pharmaceuticals' subsidies in 2021⁷⁸ and pharmaceutical markets in 2022⁷⁹.

⁷⁴ TLV (2022) Uppföljning av läkemedelskostnader.

⁷⁵ TLV (2022) 2022 års uppföljning av apoteksmarknadens utveckling.

⁷⁶ TLV (2022) Internationell prisjämförelse 2021: En analys av svenska läkemedelspriser i förhållande till 19 andra europeiska länder.

⁷⁷ Vårdanalys (2016) Utvärdering av ordnat införande av nya läkemedel.

⁷⁸ Riksrevisionen (RiR 2021:14) Mesta möjliga hälsa för skattepengarna – statens subventionering av läkemedel.

⁷⁹ Riksrevisionen (RiR 2022:11) Statens tillsyn över apotek och partihandel med läkemedel.

3.5.3 Decision making tools

See section 3.2.2 for more information about TLV's review of information provided by pharmaceutical companies.

See section 4.5.5 for information about horizon scanning activities.

As a government agency, TLV is subject to periodic reviews by the Swedish National Audit Office. The latest such reviews were in 2021 and 2022. The 2021 review focused on the subsidy system and recommended, among other things, that TLV should improve how it takes the societal economic perspective into account in decisions and its framework for assessing the severity of various diseases and condition.⁸⁰ The 2022 review focused on the pharmaceutical market and recommended, among other things, that the government provides TLV with improved access to data collected by EHM and improve the agency's ability to issue sanction fees for companies that do not comply with regulations.⁸¹

⁸⁰ Riksrevisionen (RiR 2021:14) Mesta möjliga hälsa för skattepengarna – statens subventionering av läkemedel, p.69.

⁸¹ Riksrevisionen (RiR 2022:11) Statens tillsyn över apotek och partihandel med läkemedel, p.71.

4 Pricing, reimbursement and volume control in the in-patient sector

Health care is regulated at a national level, but actual provisions of services are decentralised to regional and local levels. The regions are responsible for providing specialised care within their area. The framework for hospital pricing and reimbursement of practitioners applies equally to both public hospitals and those private hospitals contracted by the regions.⁸²

It is the responsibility of the regions to plan and provide for health care based on needs. Since a large majority of the in-patient care is publicly provided, there is no licensing authority. Certain highly specialised care (tertiary care) is coordinated on a national level where a few regions provide the medical care for the whole country, not just for the population of their own area. (For more this, see 1.2.1)

4.1 Organisation of the in-patient sector

The regions are responsible for purchasing pharmaceuticals for the hospitals in their respective area. Purchasing procedures are regulated in the Public Procurement Act (2016:1145). The legal framework for hospital pricing, reimbursement and monitoring stipulated on a national level applies both to public and private hospitals.

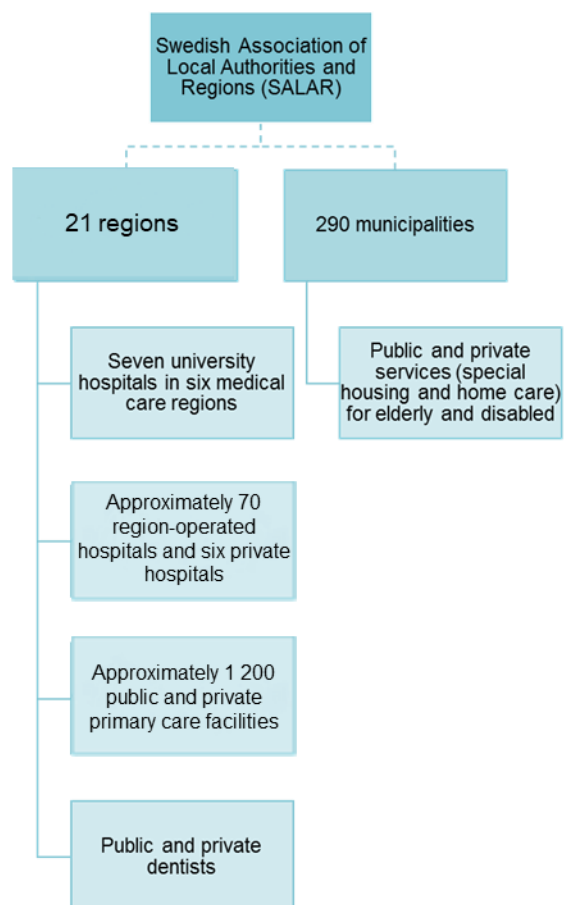
The market for providing hospital pharmacy services is subject to competition, though two service providers are dominant, Apoteket AB, and Apoex AB. An increasing number of smaller regions have chosen to run hospital pharmacies in their own organisations.

In other cases, the hospital pharmacy service is purchased in public procurement either as a complete service or in parts, like distribution to the hospital, distribution to the respective wards, dosage and dispensing, et cetera.

⁸² Socialstyrelsen (2022) About the Swedish healthcare system.

Sweden

Figure 4.1:
The organisation of health care services



Source: Anell A., Glenngård A.H., Merkur S. (2012). Note: SALAR is a membership organisation that assists and coordinates voluntary actions by the regions and municipalities.

4.2 Pricing and purchasing policies

Public procurement of pharmaceuticals used in hospitals is carried out by the regions. The Pharmaceutical and Therapeutics Committees are involved in the procurement process. Preparation of documentation for procurement is to a large extent based on statistics of previous purchases, as well as on an assessment of at what ATC-code level it is possible to formulate the procurement call. See section 4.4.2 for more information on Pharmaceuticals and Therapeutics Committees.

There are no national prices for pharmaceuticals used in hospitals. If the same product is reimbursed for out-patient use, this acts as an informal reference price. Other times, the regions use MEAs to reduce the prices of pharmaceuticals.⁸³

It is the region that procures pharmaceuticals (exceeding a certain threshold value) from the pharmaceutical company. Pharmaceuticals used in smaller volumes are bought from hospital pharmacies. The purchaser at the hospital is responsible for the order. The hospital price for these pharmaceuticals is equivalent to the pharmacy retail price.

Pharmaceuticals are exempt from VAT, although for OTC-products the standard rate of 25 percent applies. As most of hospitals are public, they are also exempt from paying VAT, even on products that otherwise would carry VAT.

4.3 Procurement

The regions are responsible for purchasing of pharmaceuticals for the needs of the hospitals in their respective area. In practice, purchasing is to an increasing degree coordinated among the regions forming one of the six health care regions. In some cases, other informal groupings of regions can make joint procurements. Also, national procurement takes place in some circumstances. The participating regions give power of attorney to the purchasing region and will later individually make an allocation decision.

The decision concerning which medicines should be primarily used in the in-patient sector is made at two levels. At the regional level, it is the region (or a group of regions) that decide(s) which pharmaceuticals to procure, and on the local level each hospital decides the structure for requesting medicines. At the region level, there is a procurement body managing the legal and administrative aspects of the process and, in most regions, deciding which tenders to accept. The pharmaceutical committees play an important advisory role in the procurement process. (For more on these committees, see 4.4.2)

The Public Procurement Act details the procedure of procurement of medicines for in-patient use. All purchases with a value above a certain threshold must be publicly procured. Since 2008 the processes of public procurement are monitored by the Swedish Competition Authority. The Public Procurement Act states that contracting authorities shall treat suppliers in an equal and non-discriminatory manner and shall conduct procurements in a transparent manner. Furthermore, the principles of mutual recognition and proportionality shall be observed in procurements. The applying supplier must include proof of economic standing and proof of technical and professional ability in the tender. The regions can also

⁸³ Janusinfo (2022) Avtal.

specify technical requirements or define required characteristics, for example medicine information about the product or information on fulfilling of environmental standards.⁸⁴

The decision to accept a tender is based on a set of criteria that the regions have laid down. Since most regions group together to get volumes large enough for discounts, the criteria tend to be uniform across the country. Usually, tenders are judged based on how well they serve their purpose, medically and pharmaceutically. In addition, there are often criteria on the ability to provide a secure delivery. The price is important, but the medical and often the pharmaceutical suitability are prioritised criteria.

SALAR operates Adda AB, a company that can make procurements for the regions and municipalities. However, pharmaceutical products are rarely purchased through Adda, except for vaccines for the national vaccination program, where municipalities are involved since some vaccines are given by school nurses.

4.4 Reimbursement

The provision of health care services is decentralised to region level, and it is financed mainly through region taxes. Both public and private hospitals on a contract with a region are reimbursed by that region for the pharmaceutical expenditure. However, pharmaceuticals used in in-patient care are not covered by the national benefits scheme.

There is no nation-wide reimbursement list for in-patient pharmaceuticals, since the regions decide on which treatments to use and finance them accordingly. However, the NT-council advises and coordinate the actions of the regions. (See 4.5.2 and 4.5.5 for more on the work of the NT-council)

Maximum fee for medical care amounts to €~110 per year

It is largely up to the regions and municipalities to set the fees that you pay for doctor's appointments and other healthcare services. In general, the fees charged by the various regions are quite similar. No co-payment is required for pharmaceuticals used during a hospital stay. (For more on patient fees, see 1.4)

Visits to maternity clinics are free of charge throughout the country. Several forms of screening are also free, such as mammography screening for women between 40 and 74 years old.⁸⁵ In all regions children under 18 years and, in most regions people under 20 years, do not have to pay any fee when visiting a health centre, youth clinic or other out-patient facilities. Both appointments and vaccinations provided by school health services are free of charge. Patients aged 85 years and older do not pay any fees in out-

⁸⁴ For more detail see Konkurrensverket (2022) The Public Procurement Act in brief and The Public Procurement Act (2016:1145).

⁸⁵ SFS (2016:659); SFS (2016:660); Socialstyrelsen (2022) Bröstcancer – screening med mammografi.

patient care, i.e. when visiting a care centre. Care and medication required for treatment of a disease that is a public health danger under the Communicable Diseases Act are free of charge.⁸⁶

Foreign citizens are entitled to emergency care

Persons from another EU or EEA country, or Switzerland, need a European Health Insurance Card to prove that the individual is entitled to emergency care at the ordinary fee. If you do not have a card, you may have to pay the entire cost.

If a person obtains non-emergency care and do not want to pay more than the fee, the individual must have a certificate indicating that the country of origin will pay the balance. Persons who do not have such a certificate, will be responsible for the entire cost.

If you come from most countries outside the EU, EEA and Switzerland, you will have to pay the entire cost of emergency or any other type of care.⁸⁷ As for asylum seekers, see 3.3.1.1 .

4.4.1 Hospital pharmaceutical formularies

Hospitals in the same region follow the same formularies. The Pharmaceutical and Therapeutics Committees and regional procurement are the main influencing factors on “drug of choice”. Some hospitals with different mission, especially university hospitals, could have somewhat different pharmaceuticals on their formularies. Several hospitals also have their own extempore production of pharmaceuticals such as radiopharmacology.

Computerised prescribing systems support compliance to the formularies. For some therapeutic areas there are national supporting systems. Oncology and pediatric are examples of such areas.

4.4.2 Pharmaceutical and Therapeutic Committees

All regions are obliged by law to have a Pharmaceutical and Therapeutics Committee.⁸⁸ A committee may have an advisory or a decision-making role. They may also form special sub-groups of experts, for instance for the care and treatment of elderly and their use of pharmaceuticals, working in interaction with the municipalities.

The committees support physicians in their choice of medicines through publishing an annual list of medicines recommended as the first-choice treatment for a range of common diseases and through various types of training and development initiatives. Sweden has treatment guidelines on the national

⁸⁶ SKR (2022) Patientavgifter i öppen hälso- och sjukvård år 2022; SFS (2004:168) 7.1–7.2.

⁸⁷ 1177 (2022) Patientavgifter och högstkostnadsskydd.

⁸⁸ Lag (1996:1157) om läkemedelskommittéer.

as well as the regional level, for many common diagnoses. There are no sanctions against physicians for not following the guidelines, as long as it is not malpractice. In relation to the in-patient care the role of the pharmaceutical committee is to advice and support the procurement body in the process of procuring medicines. The distribution of competence and responsibility between the procurement body and the pharmaceutical committee varies across the different regions.

Clinical recommendations are issued by pharmaceutical committees, the SMPA and the National Board of Health and Welfare. The formulary committees provide lists of recommended pharmaceutical treatments for out-patient care in each region, but often they are not compiled for in-patient care. The lists may be used by the hospital pharmacies as guidance (along with national guidelines and list of procured pharmaceuticals) to which pharmaceuticals to keep in stock.

4.5 Volume Control in the in-patient sector

The volume control for the in-patient sector in Sweden is carried out through a range of measures. Below follows an introduction of these measures, with a focus on monitoring systems, decision-making tools and interface-management.

4.5.1 Monitoring

The National Board of Health and Welfare manages the National Patient Register (NPR), which was established in 1964 and which became fully national in 1987, containing information on in-patient and out-patient care. Actors in both the out-patient and in-patient care have a responsibility to register patients' visits. The NPR contains patient, geographical, administrative and medical data, and the degree of coverage is generally very high.⁸⁹

Other registers at the Board of Health and Welfare include the pharmaceutical register, the mortality cause register and the cancer register. The registers are nationwide, cover the whole Swedish population and include data gathered over several decades. The data include a unique identification number for each registered person. Various laws apply to the registers, to ensure the protection of the rights of those listed. Patient databases located in every region contain information on individual identification numbers and include complete information about in-patient treatment and clinical investigations (X-rays, laboratory tests) and partial information about out-patient care.⁹⁰

The care provider can choose to let the hospital pharmacy collect more detailed information that connects the requesting clinic to the required medicine. Medicines prescribed in the out-patient sector and primary care can be traced back to the individual prescriber.

⁸⁹ Socialstyrelsen (2022) National Patient Register.

⁹⁰ For more on the registries, see Socialstyrelsen (2022) Registers.

Sweden

Certain diseases of particular interest are monitored in separate programs, the quality registers. A National Quality Registry contains individualised data concerning patient problems, medical interventions, and outcomes after treatment. It is annually monitored and approved for financial support by an Executive Committee with representatives from the state, the regions and the municipalities.⁹¹ Some examples are registries for diabetes, cancer (in 15 different registers) and approximately 80 other conditions.⁹² Each registry is rated according to a certification scale. The rating is dependent on several factors, such as the level of analyses, inclusion of relevant indicators, coordination with health services, use in research, data quality and reporting, coverage rate, technical solutions/tools, et cetera.⁹³

EHM provides the necessary infrastructure by collecting statistics on pharmaceuticals, their usage and prices, both from the in-patient sector and prescribed medicines used in the out-patient sector as well as medical devices and ostomy products. At the hospital level, the hospital pharmacies collect and report statistics to EHM. The data is used by the regions for their internal purposes and for research. Data is also available for different agencies and organisations.

For pharmaceutical shortages, SMPA is the monitoring agency. For more, see 3.5.

SBU conducts HTAs on various healthcare methods. However, their role is not to conduct ongoing monitoring but to investigate areas of particular importance. These areas are to be identified either by SBU or in collaboration with other government agencies.⁹⁴

Currently there is a movement towards increased use of healthcare data to evaluate the efficiency of various treatments. This is especially important in relation to advanced therapy medicinal products (ATMP)s and orphan pharmaceuticals. To this end, TLV has reviewed the changes necessary to the Swedish monitoring systems in order for them to provide real world data that is both of high quality and useful for HTAs.⁹⁵ The data sharing will also be assisted by upcoming EU-legislation on patient data and HTA.

4.5.2 Decision-making tools

All regions have agreed to collaborate on pricing, introduction and monitoring of new pharmaceuticals used in the in- and/or out-patient sector. For in-patient medicines, this national process for managed

⁹¹ SKR (2022) Quality Registries.

⁹² SKR (2022) Find a registry.

⁹³ SKR (2022) Certifiering.

⁹⁴ SFS (2007:1233) Förordning med instruktion för Statens beredning för medicinsk och social utvärdering.

⁹⁵ TLV (2022) Uppföljning med hjälp av alternativa datakällor med fokus på cancer.

Sweden

introduction includes horizon scanning, health economic assessment, joint negotiation, recommendation on use of the medicine, and monitoring of use on a national level.

Since 2015, the regions collaborate on managed introduction of new medicines. This includes joint negotiations on new in-patient medicines which are expected to have a large impact on health care and are subject to health economic evaluation by TLV and recommendations by the NT council.

The council for new therapies (NT-council) support health authorities in making informed decisions on the use of new and often high-priced drugs by assessing and providing recommendations on specific products. It is the regions that have given the NT-council this mandate. The overall objective is to achieve an equitable and cost-effective use of new products throughout the country, and that treatment can be initiated without unnecessary delay.

Each health care region has appointed a representative for the New Therapies Council. The Council is also supported by medical experts as well as experts in the field of health economics, ethics, oncology, horizon scanning et cetera are involved in the process.⁹⁶

An advantage of collaborating is that the regions get a stronger position by acting together, which is likely to improve the probability of getting lower prices and thus more cost-effective use for pharmaceuticals compared to if every region would act on their own.

⁹⁶ For information on managed introduction of new drug therapies, see Janusinfo (2022) Managed introduction – this is how it works.

Figure 4.2:
Process for managed introduction of new pharmaceuticals



Source: SALAR.

4.5.3 Evaluation of measures

See sections 4.5.2 and 4.5.5

4.5.4 Reports and results

See section 4.5.5.

In terms of auditing, the Swedish National Audit Office conducts audits of the national agencies involved in the in-patient pharmaceutical structures, see 3.5.3. The regions have their own internal and external auditors.⁹⁷

4.5.5 Interface management

Each region is obliged by law to have at least one Pharmaceutical and Therapeutics Committee. These are supposed to advise the health care system on pharmaceutical usage. They advise both the in- and out-patient sectors. As such, they act as an interface management function.

When making recommendations, the committees take extra care to consider treatments that span both in- and out-patient care. This is because pharmaceuticals can have significantly different prices in the two systems. As such, the economic assessment of the committees should take the combined cost of treatment into account. This has become increasingly important as efforts are made to limit the duration of hospital visits, which has meant that more care is conducted in patients' homes.

For individual patients, physicians and other health care professionals have access to the medical journals within the same region. This enables them to manage treatments.

4.5.5.1 Horizon Scanning

Horizon scanning is performed as a joint effort of four regions on behalf of all the Swedish regions, in collaboration with medical institutions, governmental agencies and SALAR.

The aim is to better prepare for the introduction of new pharmaceuticals and, before market authorisation, give a preliminary idea of their potential value and costs in the health care system and to plan for follow-up activities.

Horizon Scanning Program

All relevant new indications and pharmaceuticals are valued with regard to their medical potential and financial consequences in order to support prescribers and the health care system in issues regarding for example structural introduction and budgetary discussions. Information is gathered from different sources and then discussed with clinical experts several times a year based on pre-set criteria. The criteria are used to identify pharmaceuticals and considers for example innovativeness, need for new therapies, severe diseases, treatment of large patient groups and potential budget impact. The list is then reduced to a limited number of pharmaceuticals and indications with the most potential to affect

⁹⁷ These audit organisations, although governed by common codes and norms, can be structured in different ways. See for example Region Skåne (2022) Revision and Region Jämtland Härjedalen (2022) Regionens revisorer

 Sweden

the health care system. For the most prioritised substances, in-depth reports are written with the support of medical expertise. The reports are finalised around six months prior to market authorisation. They are not made publicly available, as they are based on preliminary data.⁹⁸

Sweden has joined the International Horizon Scanning Initiative and the horizon scanning process is currently undergoing development to adapt to this.

Output and on-going developments

The regions and the National Board of Health and Welfare make medicinal and budgetary forecasts based on for example current trends, at what stage in its life-cycle various pharmaceuticals are, expected launches of new products, patient experiences and treatment guidelines. The forecasts are publicly available in Swedish.⁹⁹

Health economic assessments of pharmaceuticals used in in-patient care

The government have commissioned TLV to conduct economic assessments of pharmaceuticals used in the specialised in-patient care.

The NT-council initiates the process by selecting products to be evaluated. TLV provides a report which includes a health economic assessment of the product at different price levels but does not make a recommendation. The NT-council then evaluates the assessment report, and provides recommendations to the regions. See section 4.5.2.

The assessments that TLV provides are made in collaboration with other organisations beside the NT-council, namely the Ministry of Health, pharmaceutical companies, LIF, medical and health economical experts, the National Board of Health and Welfare, SMPA and SBU.

Health-economic assessments of hospital products aim to contribute to:

- a better basis for clinical decisions and procurement of medicines
- greater transparency on drug cost and prices
- better use of existing resources for knowledge score by assessments made by a national authority and not by each individual region
- a more knowledge-driven and equitable use of medicines in the country

⁹⁸ Janusinfo (2022) Horizon scanning.

⁹⁹ See Socialstyrelsen (2022) Läkemedelsförsäljning i Sverige – analys och prognos 2021–2024 and for an example Region Skåne (2022) Prognossammanfattning läkemedelskostnader Region Skåne 2022–2023.

Sweden

- long-term cultural change regarding the perception of health economic information as well as open comparisons of therapy

TLV's role is not to make decisions on what pharmaceuticals should be used, but rather to provide information to support the NT-council in making recommendations at a national level. The NT-council evaluates the assessment report and determines the willingness to pay, guided by the ethical platform for prioritisation in health care.¹⁰⁰ When needed, negotiations are initiated to achieve cost-effectiveness. Following this the NT-council provides a recommendation on whether or not to use the medicine, which the regions are expected to follow. Each region makes the formal decision on use of the medicine and when applicable, signs the negotiated agreement.

In 2022, TLV made 14 health economic assessments for in-patient pharmaceuticals. Most of these pharmaceuticals were targeted at either Covid-19 or cancer. Other conditions targeted by these pharmaceuticals included systemic lupus erythematosus and sickle cell anaemia. Of special interest was that a few of the products were ATMPs, who posed increased challenges in their assessment processes.¹⁰¹

Table 4.1:

Most important changes in the out-patient and in-patient sectors from 2010 onwards

Year	Out-patient sector	In-patient sector
2010	The Act on Patients' Security (2010:659) – Increased flexibility for patients to register with health care providers	The Act on Patients' Security (2010:659)
2011		
2012		
2013	Introduction of support for pharmacies in sparsely populated areas	
2014	The Patient Act (2014:821) – A structure for MEAs between regions and pharmaceutical producers introduced – Price reduction introduced for off-patent pharmaceuticals without generic competition –	The Patient Act (2014:821) – A structure for MEAs between regions and pharmaceutical producers introduced

¹⁰⁰ Janusinfo (2022) NT-rådets bedömning av värdet av ett nytt läkemedel.

¹⁰¹ TLV (2022) Avslutade hälsoekonomiska bedömningar.

PPRI Pharma Profile 2022

Sweden

	Active participation introduced in the product-of-the-month system	
2015	The Medicinal Products Act (2015:315)	The Medicinal Products (2015:315) Establishment of regional collaboration on new medicines including the New Therapies Council.
2016	Pharmaceuticals in the benefit scheme prescribed to children under 18 years without co-payment for the patient. Divided dividend between the national governments and regions on prescription pharmaceuticals.	
2017	Health and Medical Services Act (2017:30) – Young adults (under 21 years) receive contraceptives included in the benefits scheme without any co-payment	Health and Medical Services Act (2017:30)
2018	The Act on National Medicines' List (2018:1212)	The Act on National Medicines' List (2018:1212) – New system for highly specialised care
2019		
2020		
2021	Introduction of the National Medication List	Introduction of the National Medication List
2022		
2023	Restructure of ceiling structure for the product-of-the-month system	
2024	Trial of environmental premium in the pharmaceutical benefit system – Emergency pharmacy system	
2025		

5 Developments

As we enter 2023 there are a number of developments within the Swedish pharmaceutical systems. Below is a presentation of some of the main areas of change. It will focus on the politically driven initiatives and be based around various assignments provided to the main pharmaceutical related agencies in the country given by the Swedish government.¹⁰²

In light of the Covid-19 pandemic and the war in Ukraine, efforts to ensure a functional pharmaceutical supply system even during war or crises have been given heightened priority. TLV, SMPA and EHM have a joint governmental assignment to propose a system for how a network of readiness pharmacies could be established, pharmacies that should have an increased ability to continue supplying medicines in a case of disrupted supply lines and other impairments to regular operations. SMPA also has assignments to improve information channels concerning potential lack of supply issues, to map the production capacity of pharmaceuticals in Sweden and to study how the security of dose dispensing capabilities at pharmacies can be enhanced.

While the Covid-19 pandemic is decreasing in severity, focus is shifting to evaluation of the long-term management of the virus. TLV has an assignment to make a health economic assessment of the pharmaceuticals used to treat Covid-19 patients. SMPA has an assignment to study how the monitoring of vaccine side-effects can be improved. Meanwhile, to address the consequences of the current war in Ukraine, SMPA is assigned to help the Swedish Civil Contingencies Agency support the Europe-wide effort to ensure steady supplies of pharmaceuticals to Ukraine.

Another key area to secure the ability in Sweden to provide modern health care in the future is to ensure a steady supply of functional antibiotics. TLV, SMPA and Fohm have a joint assignment to study how the supply of older, but still relevant, antibiotics can be strengthened, both by ensuring that at-risk antibiotics do not exit the Swedish market and by seeing how substances that have left the market can be brought back. In this context it is important to note that, as a low antibiotics resistance country, Sweden has a demand for substances that in many other parts of the world are no longer useful due to resistance development. Fohm and the Swedish Board of Agriculture also has a joint assignment to establish a coordination function and road map for the national work against antibiotics resistance.

The increased inflation in society, has also made an impact on the production costs of pharmaceuticals. TLV aims to ensure good access to pharmaceuticals and active competition in the product-of-the-month system, and continuously monitors the market. Hence, TLV has decided to conduct a review of the ceiling prices in the product-of-the-month system.

¹⁰² To see current assignments in their entirety, see EHM (2023) Regeringsuppdrag; LV (2023) Uppdrag; TLV (2023) Regeringsuppdrag.

Sweden

Simultaneously, as pharmaceutical costs are expected to increase in the coming year, there is a push to limit these increases in order to ensure the sustainability of Swedish health care provision. TLV is assigned to renegotiate the prices for pharmaceuticals covered in the subsidies and to improve the prognosis for how much savings can be made with MEAs. At the same time, environmental sustainability is also a priority, and TLV has been assigned to propose a model for how a pilot project for introducing an environmental premium in pharmaceutical procurement processes can be carried out.

In addition to sustaining current pharmaceutical provision, projects are also under way to facilitate and finance both improved services and new pharmaceutical products. When it comes to services, TLV has been tasked with developing a model for reimbursing pharmacies for providing additional services in relation to their dispensation of pharmaceuticals, such as information and assistance aimed at improving patient adherence to prescriptions. TLV is also assigned to find ways to improve access to pharmaceuticals targeting rare diseases and to improve the health economic models in relation to new ATMPs.

Another current priority is to improve health and pharmaceutical data provisions. TLV has been tasked with creating a list of published indicators of pharmacy performance in order to improve customer choice and spur competition in the sector. In addition, TLV has been assigned to explore the possibility of using alternative data sources for health economic analysis, with a special focus on cancer treatments. EHM has also been assigned to study how a national quality register for health care providers can be established. In addition to this, TLV is active in EUnetHTA21 and as such involved in and preparing for the future EU HTA system under the HTA Regulation.

Finally, steps are being taken to improve prescription practices. In terms of flexibility, EHM has been assigned to construct a system for digital prescriptions that enables the utilisation of prescriptions across the EU. In terms of prescription, EHM is tasked with producing a proposal for how INN prescriptions can be enabled in Sweden.

6 Bibliography

6.1 Literature

1177 (2022) *Patientavgifter och högkostnadsskydd*. Available at: www.1177.se/Stockholm/sa-fungerar-varden/kostnader-och-ersattningar/patientavgifter.

1177 (2022) *Vård i Sverige om du kommer från ett annat land*. Available at: <https://www.1177.se/Stockholm/sa-fungerar-varden/vard-om-du-kommer-fran-ett-annat-land/vard-av-personer-fran-annat-land>.

Anell A., Glenngård A.H. & Merkur S. (2012) 'Sweden: Health system review', *Health Systems in Transition*. Available at: <https://apps.who.int/iris/bitstream/handle/10665/330318/HiT-14-5-2012-eng.pdf>.

E-Hälsomyndigheten (2022) *Nationella läkemedelslistan*. Available at: <https://www.ehalsomyndigheten.se/yrkesverksam/nationella-lakemedelslistan>.

E-Hälsomyndigheten (2022) *Övergången till Nationella läkemedelslistan*. Available at: <https://www.ehalsomyndigheten.se/yrkesverksam/nationella-lakemedelslistan/overgangen-till-nationella-lakemedelslistan>.

E-Hälsomyndigheten (2023) *Regeringsuppdrag*. Available at: <https://www.ehalsomyndigheten.se/om-oss/regeringsuppdrag>

Folkhälsomyndigheten (2022) *Folkhälsans utveckling: Årsrapport 2022*. Available at: <https://www.folkhalsomyndigheten.se/contentassets/c8374b60c7174b2592ba7f76f52c3165/folkhalsans-utveckling-arsrapport-2022.pdf>.

Folkhälsomyndigheten (2023) *Bekräftade fall av covid-19 i Sverige*. Available at: <https://www.folkhalsomyndigheten.se/smittskydd-beredskap/utbrott/aktuella-utbrott/covid-19/statistik-och-analyser/bekraftade-fall-i-sverige>.

Försäkringskassan (2022) *Intyg för sjukpenning*. Available at: <https://www.forsakringskassan.se/halso-och-sjukvarden/sjukdom-och-skada/intyg-for-sjukpenning>.

Janusinfo (2022) *Avtal*. Available at: <https://janusinfo.se/nationelltinforandeavlake-medel/avtal.4.728c0e316219da813569b23.html>

Janusinfo (2022) *Horizon scanning*. Available at: <https://janusinfo.se/nationelltinforandeavlake-medel/managedintroductionthisishowitworks/inenglish/horizonscanning.5.4771ab7716298ed82ba97406.html>

Janusinfo (2022) *Managed introduction – this is how it works*. Available at: <https://janusinfo.se/nationelltinforandeavlakemedel/managedintroductionthisishow-itworks.4.6b32b8ec162bd970d6bb885.html>

Janusinfo (2022) *NT-rådets bedömning av värdet av ett nytt läkemedel*. Available at: <https://janusinfo.se/nationelltinforandeavlakemedel/saarbetarvi/ntradetsbedomningavvardetavettnyttlakemedel.4.558889c7169bd7723e69e0d.html>

Konkurrensverket (2022) *The Public Procurement Act in brief*. Available at: <https://www.konkurrensverket.se/en/public-procurement/laws-and-rules/the-swedish-public-procurement-act/>

Läkemedelsverket (2017) *Godkännande och uppföljning av biosimilarer: Information om biosimilarer från Läkemedelsverket*. Available at: https://www.tlv.se/download/18.36e5d52515ff45d25e39eb97/1512120479369/kunskapsunderlag_biosimilarer_lakemedelsverket.pdf

Läkemedelsverket (2021) *Läkemedelsverkets årsredovisning 2020*. Available at <https://www.lakemedelsverket.se/sv/om-lakemedelsverket/rapporter-och-publikationer/om-lakemedelsverket/arsredovisning-2020>.

Läkemedelsverket (2021) *The National Pharmaceutical Strategy*. Available at: <https://www.lakemedelsverket.se/en/the-national-pharmaceutical-strategy>

Läkemedelsverket (2022) *Läkemedelsverkets årsredovisning 2021*. Available at <https://www.lakemedelsverket.se/sv/om-lakemedelsverket/rapporter-och-publikationer/om-lakemedelsverket/arsredovisning-2021>.

Läkemedelsverket (2022) *Statistik om restsituationer*. Available at: <https://www.lakemedelsverket.se/sv/behandling-och-forskrivning/forskrivning/restsituationer/statistik-om-restsituationer>.

Läkemedelsverket (2023) *Uppdrag*. Available at: <https://www.lakemedelsverket.se/sv/om-lakemedelsverket/uppdrag>

Migrationsverket (2022) *Fees for health care*. Available at: <https://www.migrationsverket.se/English/Private-individuals/Protection-and-asylum-in-Sweden/While-you-are-waiting-for-a-decision/Health-care/Fees-for-health-care.html>

Regeringen (2016) *Social Insurance in Sweden*. Available at: https://www.government.se/globalassets/government/dokument/socialdepartementet/socialinsuranceinsweden_august-2016.pdf.

PPRI Pharma Profile 2022

Sweden

Regeringen (2022) *Socialdepartementet*. Available at: <https://www.regeringen.se/sveriges-regering/socialdepartementet>.

Region Jämtland Härjedalen (2022) *Regionens revisorer*. Available at: <https://www.regionjh.se/politikdemokrati/politiskorganisation/politiskaorgan/revision.4.25b4d7ab1555006925c1650f.html>

Region Skåne (2022) *Revision*. Available at: <https://www.skane.se/politik-och-demokrati/revision>

Region Skåne (2022) *Prognossammanfattning läkemedelskostnader Region Skåne 2022–2023*. Available at: <https://vardgivare.skane.se/siteassets/5.-uppfoljning/omraden/lakemedel/prognoser/prognossammanfattning-lakemedelskostnader-region-skane-2022-2023.pdf>

Riksrevisionen (RiR 2021:14) *Mesta möjliga hälsa för skattepengarna – statens subventionering av läkemedel*. Available at: <https://www.riksrevisionen.se/rapporter/granskningsrapporter/2021/mesta-mojliga-halsa-for-skattepengarna---statens-subventionering-av-lakemedel.html>

Riksrevisionen (RiR 2022:11) *Statens tillsyn över apotek och partihandel med läkemedel*. Available at: <https://www.riksrevisionen.se/rapporter/granskningsrapporter/2022/statens-tillsyn-over-apotek-och-partihandel-med-lakemedel.html>

SCB (2022) *Finansiärer och utförare inom vård, skola och omsorg 2020: Privata företag utförde 17 procent av verksamheten inom vård, skola och omsorg 2020*. Available at: <https://www.scb.se/hitta-statistik/statistik-efter-amne/offentlig-ekonomi/finansier-for-den-kommunala-sektorn/finansiarer-och-utforare-inom-varden-skolan-och-omsorgen/pong/statistiknyhet/finansiarer-och-utforare-inom-var-d-skola-och-omsorg-20202>.

SCB (2022) *Medellivslängden i Sverige*. Available at: <https://www.scb.se/hitta-statistik/sverige-i-siffror/manniskorna-i-sverige/medellivslangd-i-sverige>.

SKL (2015) *Statens bidrag till regionerna för kostnader för läkemedelsförmånerna m.m. för år 2015*. Available through info@skr.se

SKR (2021) *Statistik om hälso- och sjukvård samt regional utveckling, 2020*. Available at: <https://skr.se/download/18.4a782d2d17c01ffabdd51aa/1634305850273/Statistik-om-halso-och-sjukvard-samt-regional-utveckling-202009.pdf>.

SKR (2022) *Certifiering*. Available at: <https://skr.se/kvalitetsregister/drivaregister/utbildningomnationellakvalitetsregister/1omnationellakvalitetsregister/certifiering.44585.html>

SKR (2022) *Find a registry*. Available at: <https://skr.se/en/kvalitetsregister/hittaregister.54631.html>

SKR (2022) *Patientavgifter i hälso- och sjukvården i alla regioner 2022*. Available at: <https://skr.se/skr/halsasjukvard/ekonomiavgifter/patientavgifter.14668.html>.

SKR (2022) *Patientavgifter i öppen hälso- och sjukvård år 2022*. Available in: https://skr.se/download/18.7c1c4ddb17e3d28cf9bb91e3/1643354537330/Avgift_oppnvar_slutenvard_2022.pdf

SKR (2022) *Quality Registries*. Available at: <https://skr.se/en/kvalitetsregister/omnationellak-valitetsregister.52218.html>

SKR (2022) *Statens bidrag till regionerna för kostnader för läkemedelsförmåner m.m. 2022*, p.4. Available at: https://skr.se/download/18.3c9f9e1e17db3f33e525eeeb/1640262402155/Overenskom-melse_Statens_bidrag_lakemedelsformanerna_mm_2022.pdf.

Socialdepartementet (2020) *Nationell läkemedelsstrategi 2020–2022*. Available at: <https://www.lakemedelsverket.se/4a53ac/globalassets/dokument/nls/nls-2020-2022.pdf>

Socialdepartementet (2022) *Regleringsbrev för budgetåret 2023 avseende Läkemedelsverket*. Available at: <https://www.esv.se/statsliggaren/regleringsbrev/?rbid=23460>

Socialstyrelsen (2019) *Bedömning av tillgång och efterfrågan på legitimerad personal i hälso- och sjukvård samt tandvård: Nationella planeringsstödet 2019*. Available at: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2019-2-14.pdf>.

Socialstyrelsen (2022) *About the Swedish healthcare system*. Available at: <https://www.socialstyrelsen.se/en/about-us/healthcare-for-visitors-to-sweden/about-the-swedish-healthcare-system/>

Socialstyrelsen (2022) *Bedömning av tillgång och efterfrågan på legitimerad personal i hälso- och sjukvård samt tandvård: Nationella planeringsstödet 2022*. Available at: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2022-2-7759.pdf>.

Socialstyrelsen (2022) *Bröstcancer – screening med mammografi*. Available at: <https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/nationella-screeningprogram/slutliga-rekommendationer/brustcancer/>

Socialstyrelsen (2022) *Läkemedelsförsäljning i Sverige – analys och prognos 2021–2024*. Available at: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2021-4-7363.pdf>

Socialstyrelsen (2022) *National Patient Register*. Available at: <https://www.socialstyrelsen.se/en/statistics-and-data/registers/national-patient-register/>

Socialstyrelsen (2022) *Nationell högspecialiserad vård*. Available at: <https://www.socialstyrelsen.se/kunskapsstod-och-regler/regler-och-riktlinjer/nationell-hogspecialiserad-varld/>

Socialstyrelsen (2022) *Pandemin har fortsatt stor påverkan på vården*. Available at: <https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/pandemin-har-fortsatt-stor-paverkan-pa-varden>

PPRI Pharma Profile 2022

Sweden

Socialstyrelsen (2022) *Registers*. Available at <https://www.socialstyrelsen.se/en/statistics-and-data/registers/>

Socialstyrelsen (2022) *Statistics on Pharmaceuticals*. Available at: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2022-4-7843.pdf>

Socialstyrelsen (2022) *Statistik om legitimerad hälso- och sjukvårdspersonal 2021 samt arbetsmarknadsstatus 2020*. Available at: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/statistik/2022-9-8093.pdf>.

Socialstyrelsen (2022) *Tillståndet och utvecklingen inom hälso- och sjukvård och tandvård: Lägesrapport 2022*. Available at: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2022-3-7750.pdf>.

SOU (2015:98) *Träning ger färdighet: Koncentrera vården för patientens bästa*. Available at: https://www.regeringen.se/4aca81/contentassets/13c797c47802474db94fabac1b3d81c8/sou-2015_98.pdf

SOU (2021:71) *Riksintressen i hälso- och sjukvården – stärkt statlig styrning för hållbar vårdinfrastruktur*. Available at: https://www.regeringen.se/4a47a9/contentassets/1228dce1e5674e3b9308151cc56bb200/riksintressen-i-halso--och-sjukvarden-sou-2021_71.pdf

SOU (2021:180) *Reglering av privata sjukvårdsförsäkringar – ökad kunskap och kontroll*. Available at: https://www.regeringen.se/4a8649/contentassets/8976c2ea3e2d450ea4e512a8a43aaebf/sou-2021_-80.pdf.

Strama (2022) *Om Strama*. Available at: <https://strama.se/om-strama/>

Swedres-Svarm (2021) *Sales of antibiotics and occurrence of resistance in Sweden*. https://www.sva.se/media/8da965da486b11e/swedres_svarm_2021.pdf

TLV (2015) *Slutrapport om receptbelagda läkemedel utanför läkemedelsförmånerna*. Available at: https://www.tlv.se/download/18.7e3d365215ec824586445879/1510316353115/slutrapport_lakemedel_utanfor_formanerna.pdf

TLV (2016) *Det svenska periodens vara-systemet: En analys av prisdynamiken på marknaden för utbytbara läkemedel*. Available at: https://www.tlv.se/download/18.467926b615d084471ac34e18/1520414175582/Rapport_det_svenska_periodens_vara_systemet.pdf

TLV (2017) *Tandvårds- och läkemedelsförmånsverkets allmänna råd om ekonomiska utvärderingar.*

Available at: [https://www.tlv.se/download-load/18.467926b615d084471ac3230c/1510316374332/TLVAR_2017_1.pdf](https://www.tlv.se/download/load/18.467926b615d084471ac3230c/1510316374332/TLVAR_2017_1.pdf).

TLV (2019) *Besparingar från sidoöverenskommelser helåret 2018: Slutavstämning, mars 2019.* Available at:

https://www.tlv.se/download/18.7f64b8db1699a12cc6dde4b5/1553612949572/rapport_slutavstamning_besparingar_sidooverenskommelser_hel%C3%A5ret_2018.pdf

TLV (2021) *Handbok för företag vid ansökan om subvention och pris för läkemedel.* Available at:

https://www.tlv.se/download/18.3cea0a4c179ef9d61368a5d8/1624006663114/handbok_ver-sion3.9_foretag_vid_ansokan_om_subvention_och_pris.pdf.

TLV (2022) *2022 års uppföljning av apoteksmarknadens utveckling.* Available at:

[https://www.tlv.se/download-load/18.57c18261183d0830e0c49395/1666074141106/2022_ars_uppfoljning_av_apoteks-marknadens_utveckling.pdf](https://www.tlv.se/download/load/18.57c18261183d0830e0c49395/1666074141106/2022_ars_uppfoljning_av_apoteks-marknadens_utveckling.pdf)

TLV (2022) *Apotekens marginaler.* Available at: <https://www.tlv.se/apotek/apotekens-marginaler.html>.

TLV (2022) *Avslutade hälsoekonomiska bedömningar.* Available at: <https://www.tlv.se/regioner/lakemedel/kliniklakemedelsuppdraget/avslutade-halsoekonomiska-bedomningar.html?start=20220101-00000000-AM&end=20221231-23595999-PM>

TLV (2022) *Besparingar från sidoöverenskommelser 2021: Slutavstämning Mars 2022.* Available at:

https://www.tlv.se/download/18.9e9341817f9775950bee13/1647596132441/slutavstamning_sidooverenskommelser_2021_1526-2021.pdf

TLV (2022) *Internationell prisjämförelse 2021: En analys av svenska läkemedelspriser i förhållande till 19 andra europeiska länder.* Available at: https://www.tlv.se/download-load/18.1e8638ed17e9fe9208346faf/1643878446283/internationell_prisjamforelse_2021.pdf.

TLV (2022) *Om klinikläkemedelsuppdraget.* Available at: <https://www.tlv.se/regioner/lakemedel/kliniklakemedelsuppdraget/om-kliniklakemedelsuppdraget.html>

TLV (2022) *Prissänkning enligt 15-årsregeln.* Available at: <https://www.tlv.se/lakemedelsforetag/pris-sankning-enligt-15-arsregeln.html>.

TLV (2022) *Prognos av besparingar från sidoöverenskommelser helåret 2022: Prognos 2, december 2022.* Available at: https://www.tlv.se/download-load/18.62f8f955184b4082b21dcf54/1670932696907/prognos_202_av_besparingar_fran_sidooverenskommelser_helaret_2022_1948-2022.pdf

TLV (2022) *Så fungerar högkostnadsskyddet*. Available at: <https://www.tlv.se/lakemedelsforetag/hog-kostnadsskyddet/sa-fungerar-hogkostnadsskyddet.html>.

TLV (2022) *Takpriser*. Available at: <https://www.tlv.se/lakemedel/takpriser.html>.

TLV (2022) *Uppföljning av läkemedelskostnader: Juni 2022*. Available at: https://www.tlv.se/download/18.2d24f53418120eae3ffcbc35/1655360166123/rapport_uppfoljning_av_lakemedelskostnader_2022_1885-2022.pdf.

TLV (2022) *Uppföljning med hjälp av alternativa datakällor med fokus på cancer*. Available at: <https://www.tlv.se/publikationer/publikationer/2022-10-03-uppfoljning-med-hjalp-av-alternativa-datakallor-med-fokus-pa-cancer---oktober-2022.html>

TLV (2022) *Välkommen till webbapplikation för TNF-hämmare*. Available at: https://tlvanalys.shinyapps.io/TNF_hammare/

TLV (2022) *Årsredovisning 2021*. Available at: <https://www.tlv.se/publikationer/publikationer/2022-02-23-arsredovisning-2021.html>.

TLV (2023) *Regeringsuppdrag*. Available at: <https://www.tlv.se/om-tlv/regeringsuppdrag>

Vogler S. (2022) *Payer policies to support innovation and access to medicines in the WHO European Region: Oslo Medicines Initiative technical report*. Available at: <https://www.who.int/europe/publications/i/item/9789289058247>.

Vårdanalys (2014) *VIP i Vården?*. Available at: <https://www.vardanalys.se/rapporter/vip-i-varden>.

Vårdanalys (2016) *Utvärdering av ordnat införande av nya läkemedel*. Available at: <https://www.vardanalys.se/wp-content/uploads/2016/07/PM-2016-4-Utv%C3%A4rdering-av-ordnat-inf%C3%B6rande-av-nya-l%C3%A4kemedel.pdf>

6.2 Legislation

The following laws are relevant to the Swedish pharmaceutical system:

The Health and Medical Services Act / Hälso- och sjukvårdslagen (2017:30)

The Medicinal Products Act / Läkemedelslagen (2015:315)

The Act on Sales of Medicinal Products / Lagen (2009:366) om handel med läkemedel

The Act on Sales of Certain Prescription Free Products / Lagen (2009:730) om handel med vissa receptfria läkemedel

Sweden

The Act on Pharmaceutical Benefits / Lagen (2002:160) om läkemedelsförmåner m.m.

The Act on Patients' Security / Patientsäkerhetslagen (2010:659)

The Pharmacy Data Act / Apoteksdatalagen (2009:367).

The Act on National Medicines' List / Lagen (2018:1212) om nationell läkemedelslista

The Health Data Registry Act / Lagen (1998:543) om hälsodataregister

The Patient Act / Patientlagen (2014:821)

The Patient Data Act / Patientdatalagen (2008:355)

The Communicable Diseases Act / Smittskyddslagen (2004:168)

The Dentistry Act / Tandvårdslagen (1985:125)

The Act on Aesthetic Surgical Treatments and Aesthetic Injection Treatment/ Lagen (2021:363) om estetiska kirurgiska ingrepp och estetiska injektionsbehandlingar

The Public Procurement Act / Lagen (2016:1145) om offentlig upphandling Läkemedelsförmånsnämndens allmänna råd (2006:1) om grunder för prishöjningar på läkemedel.

The following are also a selection of ordinances and recommendations relevant to the Swedish pharmaceutical system:

Swedish Communicable Diseases Regulation (2004:255)

SFS (2016:659) om avgiftsfrihet för viss screening inom hälso- och sjukvården

SFS (2016:660) om avgiftsfrihet för screening för bröstcancer

Tandvårds- och läkemedelsförmånsverkets allmänna råd (TLVAR 2003:2) om ekonomiska utvärderingar.

SFS (2007:1233) Förordning med instruktion för Statens beredning för medicinsk och social utvärdering.

6.3 Web links

Organisations

EHM: www.ehalsomyndigheten.se/languages/english/welcome-to-the-swedish-ehealth-agency

Fohm: www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden

Janusinfo: <https://janusinfo.se/inenglish>

National Board of Health and Welfare: www.socialstyrelsen.se/en

SALAR: <https://skr.se/skr/englishpages>

SBU: www.sbu.se/en

SMPA: www.lakemedelsverket.se/en

TLV: www.tlv.se/in-english

Reports in English

TLV (2021) How should we assess and pay? Health-economic assessments and payment models for precision medicines and ATMPs. Available at: https://www.tlv.se/download/18.2f080b7e182629be22dd4e3c/1660743327830/rapport_rupm_atmp_eng.pdf

TLV (2021) Developed follow-ups with data from sources such as the National Service Platform. Available at: https://www.tlv.se/download/18.2a54744617f44b13a276c4b1/1646751924135/rep2105_rwd_report3_developed_follow-ups.pdf

TLV (2022) International price comparison 2021: An analysis of Swedish pharmaceutical prices in relation to 19 other European countries. Available at: https://www.tlv.se/download/18.9e9341817f9775950bd276/1647586496454/international_price_comparison_2021_107-2022.pdf