WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharma Profile

Sweden 2017

TLV
THE DENTAL AND PHARMACEUTICAL BENEFITS AGENCY

PPRI
Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Profile Sweden

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WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

BUNDESMINISTERIUM FÜR GESUNDHEIT

Summary

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

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

Health services are mainly funded by taxes
The county councils 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 county councils 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 1 100 SEK (€~116) and includes pharmaceutical treatment. Patients pay a co-payment of maximum 2 200 SEK (€~232) 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, prescription free medicines (OTC) and traded pharmacy goods are generally not subsidised, and therefore the prices for these product segments are 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 prioritizing 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 the preparation for the decisions, the Dental and pharmaceutical benefits agency, TLV, reviews this information and may request 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 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 county councils and the pharmaceutical company.

Competition results in lower costs for out-patient pharmaceuticals with competition

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

County councils procure medicines for hospital use

Public procurement of medicines used in hospitals is carried out by the county councils. The counties 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 it.

Also, TLV is providing economic assessments of pharmaceuticals used in the specialized in-patient care. These assessments are used by the county counties in making recommendations on preferred treatment of choice.

Challenges and future developments

The government have initiated several measures to achieve equal and early access as well as to ensure environmentally sustainable use and affordable pharmaceuticals. Actions have been taken in terms of collaborating on adaptive licensing of new medicines on a national level. Managed national introduction of new pharmaceuticals are monitored and evaluated. Registers provide key information for monitoring and research of pharmaceutical use in real life, and pilot studies are planned for the near future.

A special government commission of inquiry (SOU) is also to review the current system of financing, reimbursement and pricing of pharmaceuticals in Sweden. The final report is to be made public in December 2018.

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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 Public Health Institute (Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen) 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 was that the Profiles were 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 were critically reviewed by project consortium members.

PPRI Pharma Profiles, which primarily focused on the out-patient pharmaceutical sector, for 23 countries were published within the years 2007 to 2009. Even if the PPRI project officially ended at the beginning of the year 2008, the PPRI network members continued contributing by updating the PPRI Pharma Profiles.

As a further development, information on the in-patient sector was integrated: The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, including the Austrian Public Health Institute, the International Healthcare and Health Insurance Institute (IHHII) in Bulgaria and the Slovak Medicines Agency (SUKL), developed the PHIS Hospital Pharma report about medicines management in the hospital sector and the PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. The principle of involving national experts as authors remained the same. 19 PHIS Hospital Pharma reports and 5 PHIS Pharma Profiles were published. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at http://whocc.goeg.at/Publications/CountryReports.

Additionally, in order to allow information at a glance, posters about pharmaceutical systems and policies were produced. They are also available at the WHO Collaborating Centre's website at http://whocc.goeg.at/Publications/CountryPosters.

In order to support the production of the PPRI and PHIS Pharma Profiles, templates were matched and were made available to the authors. In the course of the years, the templates

for the comprehensive profiles (in 2015 the “PPRI/PHIS Pharma Profiles were renamed again to “PPRI Pharma Profiles”) were revised, further developed and updated.

The PPRI Pharma Profile 2017 is designed to comprise up-to-date information as of 2017 (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. The templates were developed in the PPRI and PHIS projects, were circulated for review and feed-back to the PPRI/PHIS network members, were tested by the authors of the profiles and afterwards revised by consortium members, taking into account the experiences made.

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 http://whocc.goeg.at/Glossary/About. Authors of the PPRI Pharma Profiles are requested to adhere to the Glossary.

PPRI, PHIS, 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 80 institutions: These are public authorities and third party payers from 46 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions such as European Commission services and agencies, OECD, 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 WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (see below).

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme's National Focal Points (NFP) and the Directorate General for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States (http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/EAHC_NFP_EUHealthProgramme_ImpactProjects.pdf).

Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected case study countries. Methodology tools, in particular with regard to terminology, indicators and reporting tools, were further developed based on work started in PPRI.

The Health Economics Department of the Austrian Public Health Institute (GÖG) was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and redesignated in 2014. The Centre continues methodology work started under the framework of the PPRI and PHIS projects: One of the Centre's explicit tasks is to develop the tool for for describing and analysing national pharmaceutical pricing and reimbursement systems ("Pharma Profiles"). WHO Collaborating Centre staff are also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the "PPRI Pharma Profiles" for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are thus offered open access to our findings and methodological tools developed. The PPRI and PHIS project websites are no longer maintained, all relevant PPRI and PHIS information was integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: http://whocc.goeg.at. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it includes published profiles, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

Since Sept. 2016 the Centre is located at the Pharmacoeconomics Department of the Austrian Public Health Institute (GÖG).

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List of abbreviations

ATC	Anatomic therapeutic chemical classification
DDD	Defined Daily Dose
EMA	European Medicines Agency
EU	European Union
FGL	Föreningen för generiska generiska läkemedel och biosimilarer / Association for Generic Medicines and Biosimilarer
INN	International Non-proprietary Name
GDP	Gross domestic product
HTA	Health technology assessment
HE	Health expenditure
LIF	Läkemedelsindustriföreningen / The Swedish Association of the Pharmaceutical Industry
LV	Läkemedelsverket (LV) / The Medical Products Agency (MPA)
NCU	National currency unit
NHS	National health service
NMEs	New molecular entities
Mio.	Million
n.a	Not available
n.apl.	Not applicable
OECD	Organisation for Economic Co-operation and Development
OTC	Over-the-counter medicine / Prescription free medicines
PHIS	Pharmaceutical Health Information System
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPP	Purchasing power parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price
SALAR	Sveriges kommuner och landsting (SKL) / The Swedish Association of Local Authorities and Regions (SALAR)
SBU	Statens Beredning för Medicinsk Utvärdering / Swedish Council on Technology Assessment in Healthcare

SEK	Svenska kronor / Swedish Crowns. Exchange rate 2016, SEK 9.47 = € 1
SFS	Svensk författningssamling / Swedish Code of Statutes
SOU	Statens Offentliga Utredningar / Reports of the Government's Commissions
THE	Total health expenditure
TLV	Tandvårds- och läkemedelsförmånsverket (TLV) / The Dental and Pharmaceutical Benefits Agency (TLV)
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 January 2017. The population density is approximately 21.9 inhabitants per km^2. The population is geographically unevenly distributed. The major urban areas are located along the coastline of southern country, especially in the Stockholm, Gothenburg and Malmö areas. The inland and the 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: Demographic indicators 2000, 2005, 2010–2016

Demography	2000	2005	2010	2011	2012	2013	2014	2015	2016
Total population	8 882 792	9 047 752	9 415 570	9 482 855	9 555 893	9 644 864	9 747 355	9 851 017	9 995 153
Population aged 0-14	1 630 798	1 560 776	1 564 959	1 584 270	1 611 859	1 646 101	1 682 033	1 717 143	1 760 994
Population aged 15-64	5 723 107	5 921 599	6 113 365	6 113 917	6 115 751	6 126 556	6 152 438	6 186 647	6 257 302
Population aged > 64	1 532 887	1 565 377	1 737 246	1 784 668	1 828 283	1 872 207	1 912 884	1 947 227	1 976 857
Life expectancy at birth	80.6	81.4	82.2	82.4	82.4	82.6	82.9		
Life expectancy at age 65	18.5	19.1	19.7	19.9	19.9	20.1	20.3	20.2	

Source: Statistics Sweden/ SCB:s statistikdatabas, 2017-03-08.

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 different levels of education than between men and women. In 2015 the average life expectancy was 80.3 years for men and 84.0 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 2000. In 2016, 19.8 per cent of the country's population was 65 or older. Proportionally Sweden has one of Europe's largest elderly populations.[1] The proportion 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

[1] Swedish Institute (2017), Health Care in Sweden.

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]

According to a self-assessment scale agreed at EU-level, more than 70 per cent of the Swedish population (aged 16-84) say they have good or very good health.[3] 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. At the age of 30, women with higher education are expected to have 5.1 years longer to live than women with only lower secondary education, and men with post-secondary education are expected to live 5.7 years longer than those with 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.

Mortality from cardiovascular diseases and cancer is declining overall, but differences between the various population groups based on level of education remain. People with less education are more likely to become ill as well as dying from cardiovascular disease and cancer, compared to those with higher education. Mental illness is increasing in the younger groups, while decreasing for the older parts of the population.

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 is highly regarded.

Swedish healthcare is a National Health Service system. The most important law regulating the provision of healthcare is the Health and Medical Services Act of 1982 (1982:763). 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.

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

- Health and Medical Services Act of 2017 / Hälso- och sjukvårdslag (2017:30)
- The Medicinal Products Act of 2015 / Läkemedelslag (2015:315)
- Act on sales of medicinal products / Lag (2009:366) om handel med läkemedel
- Act on sales of certain prescription free products / Lag (2009:730) om handel med vissa receptfria läkemedel.
- Act on Pharmaceutical Benefits of 2002 / Lag (2002:160) om läkemedelsförmåner m.m.
- Act on Patients' Security of 2010 / Patientsäkerhetslag (2010:659)

[2] Vårdanalys/The Swedish Agency for Health and Care Services Analysis, (2014) VIP i Vården? p. 21.
[3] Folkhälsomyndigheten/The Public Health Agency of Sweden, (2016) Folkhälsan i Sverige 2016, p. 11.

- Pharmacy data act / Apoteksdatalag (2009:367).
- Act on prescription registry's / Lagen (1996:1156) om receptregister.
- Act on medicines list / Lagen (2005:258) om läkemedelsförteckning
- Patient act / Patientlag (2014:821)
- Patient data act / Patientdatalag (2008:355)
- The Public Procurement Act / Lag (2016:1145) om offentlig upphandling

The Swedish system is highly decentralised with three independent governmental levels; the national government, the county councils/regions and the municipalities, on a regional and local level – and they are 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 county councils, 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, MPA), the Swedish Council on Technology Assessment in Healthcare (Statens Beredning för Medicinsk Utvärdering, known internationally by its Swedish acronym, SBU), the Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket, TLV) and the Public Health Agency of Sweden (Folkhälsomyndigheten), among others.

There are 21 regional authorities, county councils, that own and operate most of the healthcare facilities, such as hospitals and primary care centres. 10 county councils have been granted an increased responsibility for regional development by the government and are referred to also as regions. The county councils are grouped into six medical care regions to facilitate cooperation regarding specialised medical care. There are few private hospitals, and the number of private physicians and health centres varies widely between counties. 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 county councils. Most county councils have decentralised a large part of the financial responsibility to healthcare districts, through centralised 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 for 1 150 primary care units throughout the country of which 42 per cent are privately owned.[4] The primary care units provide the

[4] SKL/SALAR (2016), Statistik om hälso- och sjukvård samt regional utveckling 2015.

population's basic medical treatment, including care, preventive care and rehabilitation that does not require the hospitals' medical and technical resources.[5]

Since 2010, residents may register with any public or private provider accredited by the local county council. Individuals register with a primary care unit/practice rather than a general practitioner, even though the possibility to do so is stated in The Patient Act from 2015 (2014:821). In all county councils except Stockholm, registration with a practice is required. Nevertheless, individuals may also make visits to practices where they are not registered.[6]

County and regional hospitals provide services for conditions requiring hospital treatment. There are seven regional hospitals, also referred to as university hospitals, and about 70 hospitals at the county council level.[7] The average number of available in-patient-care beds was 23 900 in 2015 which corresponds to 2.4 per 1 000 inhabitants[8].

The 21 county councils are grouped into six health care regions to facilitate cooperation and to maintain a high level of advanced medical care. Highly specialized care, requiring the most advanced technical equipment, is concentrated at university hospitals to achieve higher quality and greater efficiency, and to create opportunities and research for development. Acute care hospitals (seven university hospitals and two-thirds of the 70 county council hospitals) provide full emergency services. Most hospitals are public, but county councils may also have contract with private hospitals. There are six larger private hospitals in the country, of which three are not for profit.[9]

In 2009 the average number of out-patient doctor visits in primary care and at hospitals per person was 2.8.[10] This number of visits to doctors has stabilised at this level and in 2015 the number of visits was 2.9 per capita. This is a minor decrease from 2014 (-0.3 %) coupled with an increase of visits to health care professionals other than medical doctors, (up 1.6 %). Slightly more than half of the visits occurred in primary care and the remainder in the out-patient hospital setting. However, the number of visits per person and year to primary care facilities remains low in a comparison to other countries in the study.[11]

[5] Definition according to the National Board of Health and Welfare based on article 5 in the Health and Medical Services Act of 1982.
[6] The Commonwealth Fund (2015) International Profiles of Health Care Systems.
[7] Anell A., Glenngård A.H., Merkur S. (2012) Health system review. Health Systems in Transition.
[8] SKL/SALAR (2016) Statistik om hälso- och sjukvård samt regional utveckling 2015.
[9] Anell A., Glenngård A.H., Merkur S. (2012) Health system review. Health Systems in Transition.
[10] Socialstyrelsen/ National Board of Health and Welfare, (2011) Lägesrapport 2011.
[11] Vårdanalys/ The Swedish Agency for Health and Care Services Analysis, (2015) Vården ur primärvårdläkarnas perspektiv – en jämförelse mellan Sverige och nio andra länder, p. 71.
More than 2, 900 Swedish primary care physicians have responded to the survey. Nine other countries participated in the survey: Australia, Canada, Germany, the Netherlands, New Zealand, Norway, Switzerland, the United Kingdom, and the USA.

Overall, the availability of physicians employed in health care, in relation to the population, has increased over time. Physicians employed in health care has increased by 2 per cent between 2012 and 2013 and by 10 per cent between 2008 and 2013.[12] Doctors within specialised health care have increased by nearly 2 per cent from 2012 to 2013, and by 7 per cent between 2008 and in 2013. The number of Swedish residents studying medicine in other countries continue to increase and doctors educated in other countries will continue to be an important recruitment base.[13]

Over time, it has become more common for county councils to buy services from private health care providers. In 2013, 12 per cent of health care was financed by county councils but carried out by private care providers. An agreement guarantees that patients are covered by the same regulations and fees that apply to municipal care facilities.[14] (See section 3.3.5 and 4.4 for private pharmaceutical expenses).

There is currently a discussion on measures towards concentrating highly specialised services even further. A government commissioned inquiry (SOU 2015:98) in 2016 proposed a solution for even more concentrated care.[15] The following is stated in the Inquiry report:

> *According to analyses performed by the Inquiry, there has been little consolidation of highly specialised care over the past 14 years. For example, 14.6 per cent of complicated operations in 2000 were performed at hospitals with a caseload of fewer than 20 per year. The 2013 figure was 13 per cent.*
>
> *Our statistical analyses indicate that at least 500 deaths could be avoided every year, the number of complications decrease and waiting times reduced if there were an increase to at least 100 of a particular type of procedure at Swedish hospitals. Given that the situation has been more or less static over the past decade, thousands of avoidable deaths have demonstrably occurred. For that reason, the Inquiry suggests that hospitals at least perform 50–100 procedures and that key professionals perform at least 30 procedures every year.*

To remedy this, the inquiry proposes a new knowledge and decision-making structure for highly specialised care at the national level. This would involve conscious sharing of responsibility among various hospitals and clinics for the various contributions to the care process.

[12] Socialstyrelsen/National Board of Health and Welfare (2016b) Ökad tillgång på hälso- och sjukvårdspersonal.
[13] Socialstyrelsen/National Board of Health and Welfare (2016e) Nationella planeringsstödet 2016: Tillgång och efterfrågan på vissa personalgrupper inom hälso- och sjukvård samt tandvård.
[14] Swedish Institute (2017) Health Care in Sweden.
[15] SOU (Official Government Reports Series) 2015:98 Träning ger färdighet. Koncentrera vården för patientens bästa.

Increase in number of pharmacists since the deregulation

The pharmacy market was deregulated in 2009 and the government controlled pharmacy monopoly ceased to exist in June 2009 (see section 2.4.3). Since then, the number of pharmacies has continuously increased and between 2009 and 2016, the total increase is approximately 50 per cent, (see section 2.4.3.1).

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 2014, there were 51 dispensers per 100 000 inhabitants and there were 25 pharmacists per 100 000 inhabitants, an increase of 44 per cent compared to five years earlier.[16]

1.3 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 done by the regional and local authorities (county councils and municipalities). It is the county councils 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 source of funding.

Taxes covers costs for pharmaceuticals used in hospitals

The county councils 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 county councils also generate income through state subsidies and user fees.

Government grant covers costs for out-patient medicines

Costs for out-patient pharmaceuticals are formally financed by the county councils. The county councils receive a grant from the government to cover these costs (Pharmaceutical Benefits Scheme). The government and the Swedish Association of Local Authorities and Regions, SALAR, negotiates agreements concerning the amount and other the conditions of the subsidy. Lately, this negotiation has been a yearly activity.

In 2015 the county councils received SEK 21.8 billion[17] from the government, in 2016 SEK 23.9 billion[18] and in 2017 SEK 24.0 billion[19] (2017 to be confirmed). These agreements

[16] Socialstyrelsen/ National Board of Health and Welfare (2014) Tillgång på legitimerad hälso- och sjukvårdspersonal för utvalda yrken.

[17] SKL/SALAR (2015) Överenskommelse mellan staten och Sveriges Kommuner och Landsting för 2015.

[18] Regeringen (2016a) Överenskommelse mellan staten och Sveriges Kommuner och Landsting 2016, June 9, 2016, protokoll vid regeringssammanträde.

include a risk-sharing component where the county councils and the state equally share the cost of the difference between the actual costs and the fixed subsidy exceeding +/- 3 per cent.

Patient payments and costs for non-reimbursed medicines, OTC and traded pharmacy goods

The patient fee for a hospital stay is maximum SEK 100 (€~11) per day. Patient fees for primary care vary between SEK 100 and 250 (€~11-26) depending on the county. For specialist visits, there is a maximum fee of SEK 350 (€~37). After a patient has paid a total of between SEK 900 and 1 100 (depending on the county council) in the course of a year, medical consultations within 12 months of the first consultation are free of charge. There is a similar ceiling for prescription medication, where no one pays more than SEK 2.200 (€~232) in a 12-month period.[20] (See section 3.3.5 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 cost for these pharmaceuticals is excluded from the patient's high-cost threshold.

The county council's cover the costs for infectious disease medicines, prescribed under the Swedish Communicable Diseases Act. The full cost for those medicines are covered by the government, and there is no co-payment for the patient.

Non-prescription pharmaceuticals sold in pharmacies and other retail settings is financed by the patient.

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. 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.[21]

Health insurance

Health insurance is an insurance against loss of income in the event of illness. The first day is a qualifying day for which no compensation is paid. The employer pays sick pay for up to the following 13-day period. 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

[19] Regeringen/the Government (2016b) Förslag till statens budget för 2017, Hälsovård, sjukvård och social omsorg, prop. 2016/17:1, utgiftsområde 9, p. 69.
[20] Swedish Institute (2017) Health care in Sweden.
[21] Regeringen/ the Government (2016e) Social Insurance in Sweden.

Social Insurance Agency may require a doctor's certificate from an employee from the first day of sickness absence. [22]

If you are insured in Sweden and study or stay in another EU or 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.[23] The European health insurance card does not pay for private health care or for an ambulance flight or other special transport back to Sweden.

1.4 Health expenditure

Sweden is a highly industrialised country. The economy is export-orientated and well diversified. The gross domestic product has increased by 76 per cent between 2000 and 2015, from SEK 2 380 billion to 4 181 billion. In the same time period, total health expenditure has increased by 137 per cent, from approximately SEK 20 000 to 47 000 (€~2 112 - 4 963) per capita.

Table 1.2: Health expenditure 2000, 2005, 2010–2015

Health expenditure in NCU = SEK[1]	**2000**	**2005**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
GDP (in MSEK)	2 380 358	2 907 352	3 519 994	3 656 577	3 684 800	3 769 909	3 936 840	4 181 103
THE (per capita)	19 887	26 636	31 830	40 843	42 340	43 594	45 186	47 192
- thereof public HE, %	86%	82%	82%	84%	84%	83%	83%	84%
- thereof private HE, %	14%	18%	18%	16%	16%	17%	17%	16%
HE in the out-patient sector (per capita)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
HE in the in-patient sector (per capita)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exchange rate (NCU per €)	8.45	9.28	9.54	9.03	8.71	8.65	9.10	9.36

GDP = gross domestic product, HE = health expenditure, NCU = national currency unit, THE = total health expenditure
Source: Statistics Sweden (GDP), OECD (THE), Riksbanken (exchange rate)

According to the OECD, Sweden's healthcare spending amounted to 11.1 per cent of GDP in 2015. The public share amounted to 9.3 per cent and the private 1.8 per cent of the total health expenditure.

[22] Regeringen/the Government (2016e) Social Insurance in Sweden.
[23] Försäkringskassan (2017) About social Insurance.

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

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.[24] The Ministry is responsible for submitting legislative proposals regarding changes to the healthcare and social systems, and later 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.

Sweden joined the European Union in 1995 and has since harmonised its legislation regarding authorisation of pharmaceuticals etc. with the European Union.

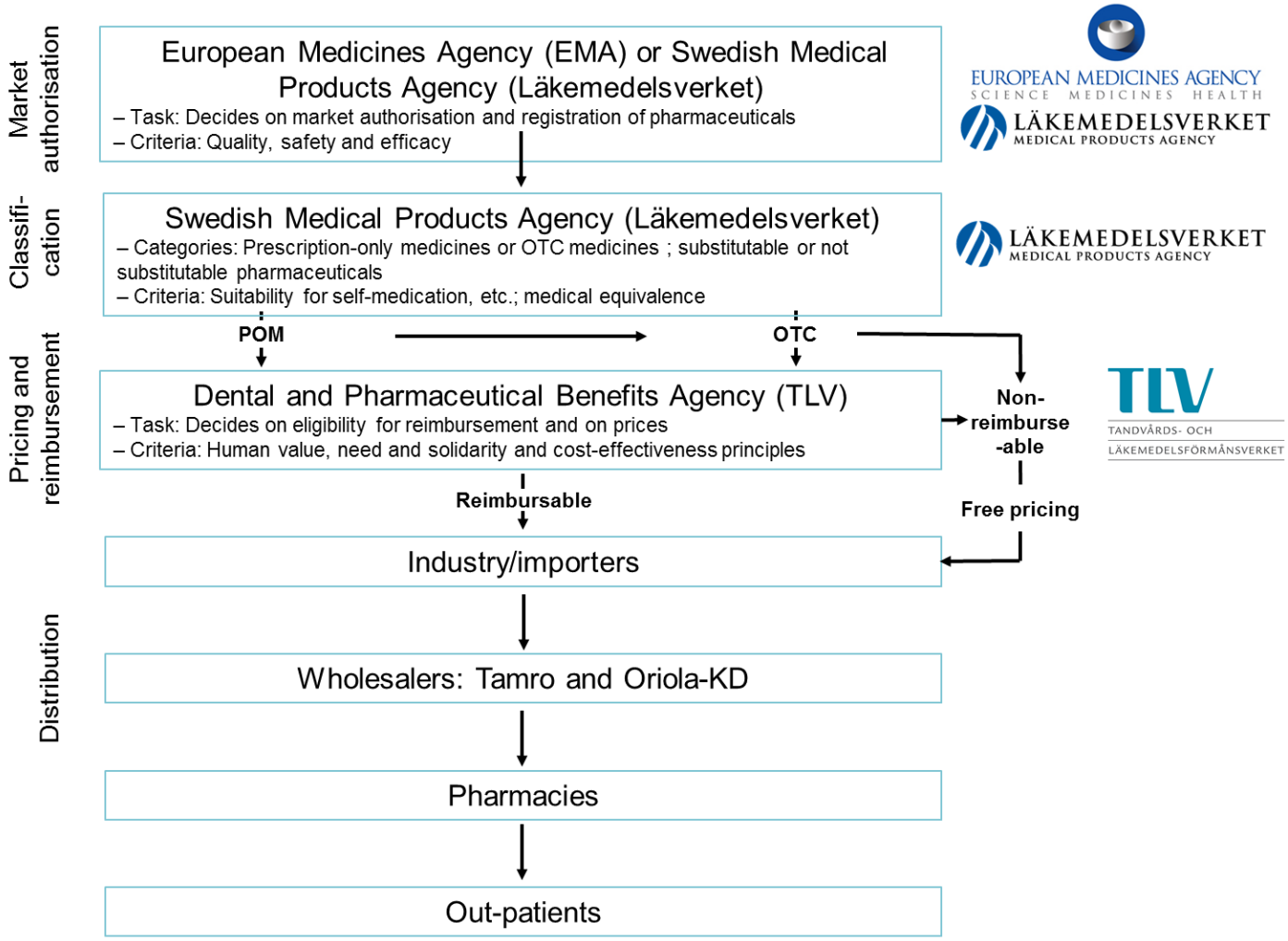
The legislative framework for the production, registration and distribution of pharmaceuticals is the Medicinal Products Act (Läkemedelslagen 2015:315). This is complemented by the Medicinal Products Ordinance (SFS 2015:458) and by numerous other provisions.

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 adopted an ordinance on Pharmaceutical Benefits etc. (2002:687) and TLV has issued provisions which provide rules on the application of the legal framework and published general guidelines for economic evaluations[25] submitted with applications for the inclusion of a medicine in the Pharmaceutical Benefits Scheme and for price increases of pharmaceuticals.

[24] Regeringen/ the Government (2017) Socialdepartementet.

[25] TLV (2017a) Tandvårds- och läkemedelsförmånsverkets allmänna råd om ekonomiska utvärderingar (TLVAR 2017:1), January 2017.

Figure 2.1: Flowchart of the pharmaceutical system



Source: TLV.

2.1.2 Authorities

MPA assures the safety of pharmaceutical treatments

Medical Products Agency, MPA, 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. The Ministry of Health and Social Affairs is responsible for MPA and the agency is primarily financed by fees.

According to the MPA's annual report for 2016, the agency is responsible for supervising a market involving 121 national manufactures of pharmaceuticals (and a large number of international manufacturers), 276 companies with a license to distribute pharmaceuticals,

121 marketing authorisation holders in Sweden with pharmacovigilance system, 1 426 community pharmacies, 5 553 registered retailers for selling OTC in non-pharmacies and 1 344 medical device companies.[26]

TLV decides on reimbursement and prices of pharmaceutical and medical devices

TLV is a governmental agency 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 county councils, universities/health economic expert centres and user groups/patient organisations. TLV is an agency under The Ministry of Health and Social Affairs.

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

The agency is mandated to investigate how the agency 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.

Table 2.1: Authorities in the regulatory framework in the pharmaceutical system

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Socialdepartementet	The Ministry of Health and Social Affairs	Responsible government department.	The Ministry of Health and Social Affairs is responsible for issues concerning health and welfare.
Läkemedelsverket (LV)	The Medical Products Agency (MPA)	Governmental agency under the Ministry of Health and Social Affairs.	In charge of market authorisation, classification, vigilance and monitoring of clinical trials.

[26] Läkemedelsverket (2017a) Läkemedelsverkets årsredovisning 2016, p. 36.

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 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	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 wholesalers.
Socialstyrelsen (SoS)	The National Board of Health and Welfare	Governmental agency under the Ministry of Health and Social Affairs.	Has supervisory function over the county councils, is in charge of guidelines for care and treatment of serious chronic illness and follows up and evaluates the services provided.
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	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.

Landsting	The county councils	21 regional self-governing local authorities. The county councils have together with the 290 municipalities formed an interest organisation - The Swedish Association of Local Authorities and Regions (SKL/SALAR).	Providers of healthcare. Procures medicines used in hospitals. County councils' 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 County Councils, with representatives both from the counties and the SKL/SALAR, deliberates with TLV in pricing and reimbursement cases.

Source: TLV.

The county councils provide healthcare to the public

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

In each county council, 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 county councils have a right to deliberate with TLV before the Pharmaceutical Benefits Board makes its decisions. This is due to the fact that decisions made by the board directly affect the financial situation of the county councils. The county councils have appointed a group of experts called The Council for New Therapies (NT-rådet), that make recommendation on various treatment options. See sections 4.3.1 and 4.5.2.1.

Table 2.2: Legal basis and actors (authorities and market players) of the pharmaceutical system

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	Läkemedelslag (2015:315) Lag (2009:366) om handel med läkemedel	In- and out-patient sector	The Medical Products Agency (MPA), 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	Lag om offentlig upphandling (2016:1145) Hälso- och sjukvårdslag (2017:30)	In-patient sector	The county councils (landstingen).	Providing health care and procurement of medicines.	Patients and patient organisations.
Pricing and reimbursement	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	Läkemedelslag (2015:315)	In- and out-patient sector	The Medical Products Agency (MPA), Läkemedelsverket (LV).	Marketing and advertising is regulated in the Medicines Act and in the MPA's regulation on the advertising on medicinal products.	
Distribution	Lag (2009:366) om handel med läkemedel	In- and out-patient sector	Tamro and Oriola KD, both privately owned wholesalers	Distributing medicines to pharmacies and hospitals.	Pharmaceutical companies and pharmacy associations.

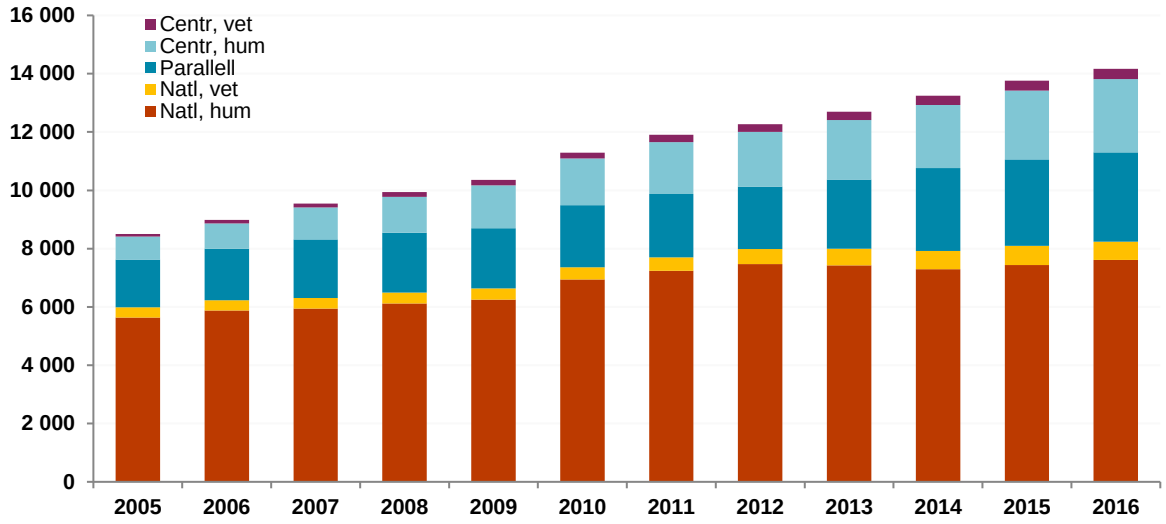
Source: TLV, Socialstyrelsen, Läkemedelsverket (MPA)

2.2 Availability and access to medicines

Figure 2.2: Authorised medicines, 2005–2016 illustrates the year-end number of authorized medicines and medicinal products from 2005 to 2016. This figure also illustrates by what procedure, national (NP/MRP/DCP) or centralized, the medicine was approved.

Each year, more products are authorized than withdrawn or delisted. During 2015, 513 new products was approved and the total number of authorised medicine amounted to 13 760. In 2016, an additional 410 products were approved and the total number of approved products amounted to 14 170, according to the MPA.[27]

Figure 2.2: Authorised medicines, 2005–2016



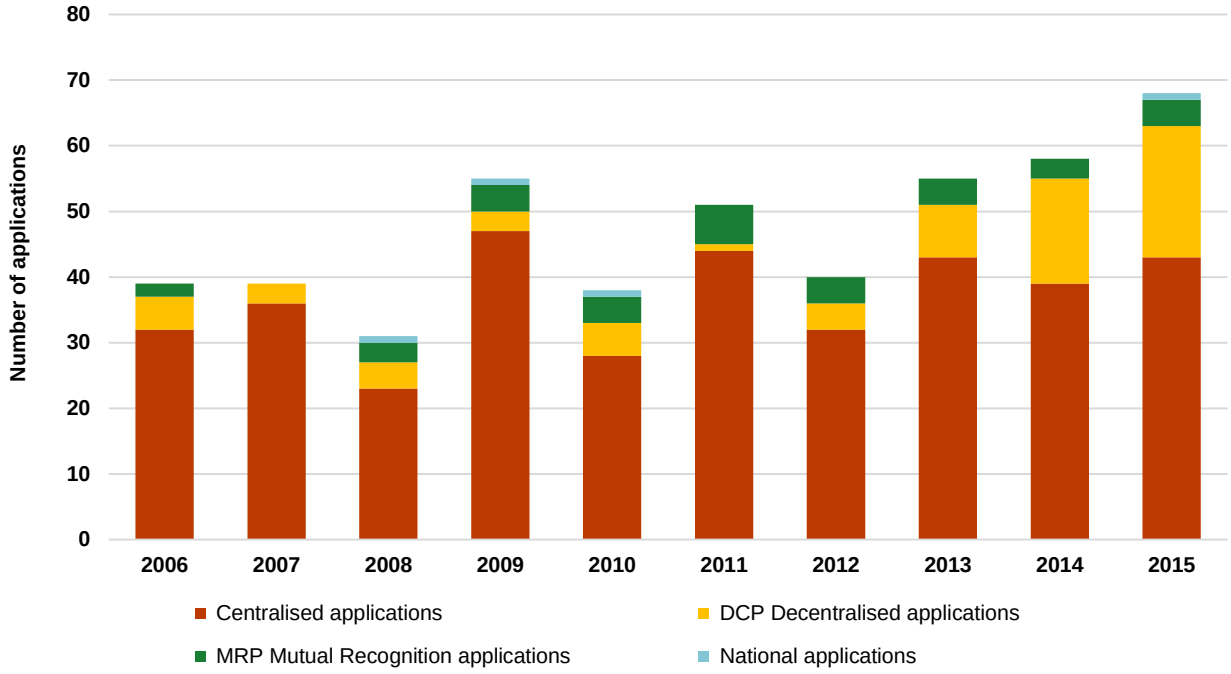
Source: Läkemedelsverket/The Medical Products Agency.

2.2.1 New chemical entities

Figure 2.3 illustrates the number of new chemical entities from 2006 to 2015. During 2015, 68 new entities were approved.

[27] Läkemedelsverket/ The Medical Products Agency (2017a) Läkemedelsverkets årsredovisning 2016, p. 24.

Figure 2.3: New chemical entities (excl. duplicate applications), human medicines, 2006–2015



Source: Läkemedelsverket/The Medical Products Agency and LIF

2.2.2 National strategy for access and equal use of pharmaceuticals[28]

Medicines provide great opportunities to cure and alleviate disease, but also pose a number of challenges that must be addressed in both the short and long terms. One challenge is to secure equal access to medicines for the whole population, based on the needs of the individual patient. Another is to ensure environmentally sustainable use of medicines.[29]

Another challenge is the financial issue in providing access to new, effective, but also expensive medicines. Equal access to medicines is also fostered by a pharmacy market with high availability and good service throughout the country.

The Swedish Government and the Swedish Association of Local Authorities and Regions (SKL/SALAR), together with a broad set of pharmaceutical actors, have agreed to continue

[28] SOU (Official Government Reports Series) 2012:75, Pris, tillgång och service – fortsatt utveckling av läkemedels- och apoteksmarknaden, p. 346.
[29] Läkemedelsverket/The Medical Products Agency (2015b) The National Pharmaceutical Strategy 2016–2018, 2015-12-17 (2017-02-14).

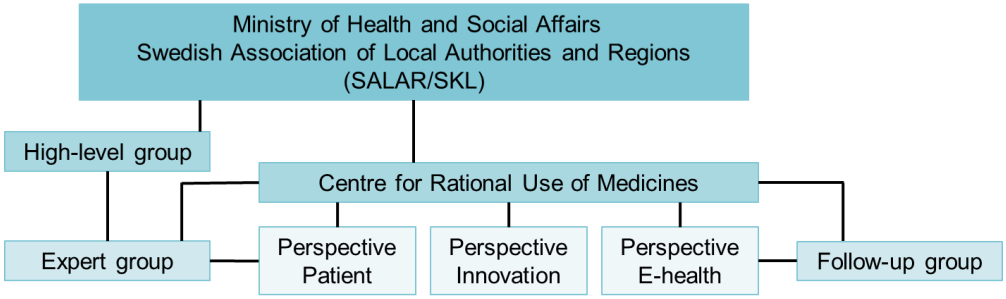
to build on the work that has been in progress for several years under the National Pharmaceutical Strategy (NPS). [30]

Objectives for accessible medicines and equal use in the NPS:

- National collaboration for the development of adaptive licensing of new medicines.
- Monitor and evaluate the benefit of work aimed at managed national introduction of new medicines.
- Greater quality and safety at pharmacies.
- Follow-up of medicines in collaboration between government agencies and healthcare.

The goal is ultimately to use medicines in the most cost-effective way in order to achieve the greatest possible health gains for the resources allocated to medicines.

Figure 2.4:Organisation of the national pharmaceutical strategy



Source: Läkemedelsverket/The Medical Products Agency (2015b), p. 16.

2.2.3 Processing times

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

[30] The work on the National Pharmaceutical Strategy is directed by a high-level group chaired by the Ministry of Health and Social Affairs and with representatives from the Swedish Association of Local Authorities and Regions, the Medical Products Agency, the Swedish Association of Health Professionals, the Swedish E-health Agency, the Public Health Agency of Sweden, the Health and Social Care Inspectorate, county councils and regions, the Swedish Association of the Pharmaceutical Industry, the National Board of Health and Welfare, the Swedish Agency for Health Technology Assessment and Assessment of Social Services, the Swedish Pharmacy Association, the Swedish Medical Association, the Dental and Pharmaceutical Benefits Agency and the Swedish Pharmacists Association.
The high-level group decides annually on an updated action plan. There is an expert group linked to the high-level group with a member from each authority/ organisation. The expert group prepares proposals for changes to the pharmaceutical strategy and associated action plan.

The processing of pricing and reimbursement applications for new medicines should not exceed 180 days, according to the Regulation on Pharmaceutical Benefits. In 2016, no case exceeded the time limit.[31]

In recent years, the average processing time for new original pharmaceuticals has been reduced. TLV is actively working to reduce processing times. In 2016 TLV announced decisions, on average, within 113 days for new original pharmaceuticals (this may be compared to 115 days in 2015 and 123 days in 2014).[32]

The processing time for new chemical entities is longer than other types of cases since they require a more extensive investigation than for example new pharmaceutical form or new package size where the ingredient already is included in the pharmaceutical benefits scheme.

Two recent examples where fast processing has enabled early access is Zepatier and Eplcusa used against hepatitis C. In these cases, TLV decided within 63 days after Zepatier had received marketing approval and 79 days after Epclusa had received marketing approval from EMA.

2.3 Pharmaceutical expenditure and consumption

2.3.1 Overview by segment

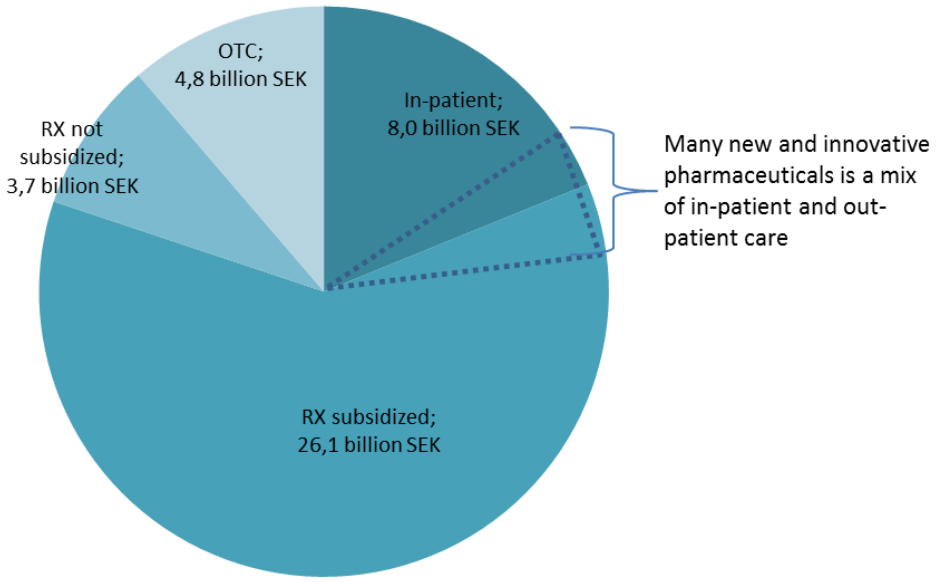
The Swedish pharmaceutical market can be divided into different segments as illustrated by the following figure:

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

In 2016, the cost of medicines in the benefit scheme amounted to approximately SEK 26.1 billion including patient own payments. In addition, pharmaceuticals not included in the benefits scheme amounted to SEK 3.7 billion.

[31] TLV (2017c) Årsredovisning 2016/Annual report 2016.
[32] TLV (2017c) Årsredovisning 2016/Annual report 2016.

Figure 2.5:The pharmaceuticals market in 2016, by segment



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

2.3.2 Prescriptions in the out-patient sector

Prescription of a pharmaceutical product is the most common treatment method in the Swedish healthcare system. Two-thirds (66 %) of the population used at least one prescribed pharmaceutical in 2015. This level has remained almost unchanged for several years. Nevertheless changes have occurred in the use of individual groups of pharmaceuticals such as antibiotics and antiviral medications (hepatitis C).[33]

Table 2.3 shows annual prescriptions in the out-patient sector. The number of prescription medicines in the out-patient sector have increased by 5 per cent between 2010 and 2015. The increase in prescriptions is corresponding closely to the increase in population on an aggregated level.

[33] Socialstyrelsen/National Board of Health and Welfare (2016b) Statistics on Pharmaceuticals.

Table 2.3: Annual prescriptions in the out-patient sector 2000, 2005, 2010–2015

Prescriptions	2005	2010	2011	2012	2013	2014	2015
No. of prescriptions (in volume)	n/a	100 326 904	101 357 623	102 539 924	102 056 186	102 913 130	105 750 022
Prescriptions in value (in NCU = MSEK)	22 591	25 534	25 867	25 272	25 324	26 422	28 320

Prescription in volume = number of items prescribed. Prescription in value = public expenditure of prescribed medicines.
Source: Socialstyrelsen/ National Board of Health and Welfare, statistikdatabas för läkemedel, 2016-12-27, Detaljhandel med läkemedel 2015, e-Hälsomyndigheten/The Swedish eHealth Agency, dokumentnummer: 2016/01930-2, maj 2016.

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+. The proportion of children, from 0 to 4 years, for whom prescribed antibiotics have been purchased at least once, has decreased by 40 per cent since 2006, while the corresponding figure for the age group 75 years and older is almost 20 per cent.[34]

2.3.3 Pharmaceutical expenditure

The following table show the total pharmaceutical expenditure in the out-patient and in-patient sectors separately.

Table 2.4: Pharmaceutical expenditure 2000, 2005, 2010–2016

Pharmaceutical expenditure	2000	2005	2010	2011	2012	2013	2014	2015	2016
TPE in NCU = TSEK	19 442	26 827	32 448	33 053	32 306	32 349	33 659	36 209	37 663
thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
PE out-patient sector	17 144	22 584	25 572	25 907	25 313	25 368	26 465	28 366	29 674
thereof public	16 951	21 928	23 904	24 091	23 269	23 221	23 549	24 681	26 027
thereof private	193	656	1 668	1 816	2 045	2 147	2 916	3 685	3 647
PE in-patient sector	2 298	4 243	6 875	7 146	6 992	6 981	7 194	7 843	7 989
thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

NCU = national currency unit, PE = pharmaceutical expenditure, TPE = total pharmaceutical expenditure.
Note: depending on definition of total market and market segmentation, the shares of respective segment differ.
Source: E-hälsomyndigheten/The Swedish eHealth Agency.

Pharmaceuticals in the out-patient sector amounts to approximately 79 per cent of total pharmaceutical expenditure and pharmaceuticals in the in-patient sector to 21 per cent.

[34] Socialstyrelsen/National Board of Health and Welfare (2016b) Statistics on Pharmaceuticals.

Pharmaceutical expenditure has increased in recent years. The increase is partly due to new products for the treatment of hepatitis C, to the introduction of various types of cancer medicines and to the increased use of certain older products, e.g. anti-TNF and new oral anticoagulants (NOAC).

2.3.3.1 Pharmaceutical consumption in DDD and in packages

The following table shows annual pharmaceutical consumption, in DDD and in packages sold.

Table 2.5: Pharmaceutical consumption 2000, 2005, 2010–2016

Consumption (mio.)	2000	2005	2010	2011	2012	2013	2014	2015	2016
Total pharmaceutical consumption									
In packages	81	95	104	105	106	107	109	111	113
In DDD	3 511	4 507	5 273	5 341	5 355	5 394	5 458	5 576	5 735
Pharmaceutical consumption in the in-patient sector									
In packages	12	14	15	15	15	15	15	15	14
In DDD	3 370	4 350	5 119	5 187	5 200	5 242	5 306	5 422	5 583
Pharmaceutical consumption in the out-patient sector									
In packages	68	82	89	90	91	93	95	96	99
In DDD	141	157	154	155	154	152	151	154	152

DDD = defined daily doses.
Source: E-hälsomyndigheten/The Swedish eHealth Agency.

Annual pharmaceutical consumption has increased between 2000 and 2016 by almost 40 per cent, from 81 million to 113 million packages. In DDD's, the increase is 63 per cent to 5 735 million daily doses. The increase in packages is primarily due to increases in the out-patient sector. The change in the in-patient sector regarding the number of packages sold is minor. However, in DDD's the increase is 66 per cent (in the in-patient sector).

2.3.3.2 Generics

Pharmaceuticals in the benefits scheme that are used in the out-patient sector may be divided in two segments:

- pharmaceuticals without competition, mainly patented protected products
- pharmaceuticals with competition (within the PV-system for substitution at the pharmacy, see 3.2.2.4)

In 2016, sales in the in the PV system (out-patient reimbursement market) was approximately 21 per cent of the subsidised market in value. In volume, calculated as the number of packages sold, however, the generic segment corresponds to an approximate market share of 52 per cent.

The extent of the PV system constantly increases due in part to a volume increase (more and more patients get pharmaceuticals prescribed), and that large therapy groups get exposed to competition when patents expire. It is the MPA that decides which pharmaceuticals are interchangeable and that may be subject to substitution at the pharmacy.

Table 2.6: Development of the generic shares in volume and value 2012, 2016

Generic share	Volume[1]		Value[2]	
	2012	2016	2012	2016
Shares in % of total market (in-patient/ out-patient)	32%	34%	16%	16%
Shares in % of total out-patient market	46%	49%	19%	19%
Shares in % of out-patient reimbursement market[3]	49%	52%	20%	21%
Shares in % of out-patient off-patent market	51%	57%	18%	22%
Shares in % of the in-patient market	33%	34%	9%	6%

Note: [1] Expressed in number of packages. [2] Expressed in expenditure (Pharmacy retail price, excl. VAT). [3] Excl. original and parallel imported products with competition.

Source: E-hälsomyndigheten/The Swedish eHealth Agency, and TLV.

2.3.4 Top 10 medicines

Table 2.7: Top 10 active ingredients in volume and value in the out-patient sector 2016

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption (packages)		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure	
1	N02BE01	Paracetamol	1	L04AB04	Adalimumab
2	C07AB02	Metoprolol	2	L04AB01	Etanercept
3	A02BC01	Omeprazol	3	J05AX65	Sofosbuvir and ledipasvir
4	B01AC06	Acetylsalicylsyra	4	B02BD02	Factor VIII
5	N05CF01	Zopiklon	5	R03AK07	Formoterol and budesonid
6	H03AA01	Levotyroxinnatrium	6	N06BA04	Metylfenidat
7	C09AA02	Enalapril	7	B01AF02	Apixaban
8	A10BA02	Metformin	8	J05AX15	Sofosbuvir
9	C10AA01	Simvastatin	9	N02BE01	Paracetamol
10	C08CA01	Amlodipin	10	L02BB04	Enzalutamid

Source: E-hälsomyndigheten/The Swedish eHealth Agency, and TLV.

Table 2.8: Top 10 active ingredients in volume and value in the in-patient sector 2016

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption (packages)		Position	Top active ingredients used in the in-patient sector, ranked with regard to expenditure	
1	D08AC02	Klorhexidin	1	L01XC02	Rituximab
2	N02BE01	Paracetamol	2	L04AB02	Infliximab
3	B05BB01	Elektrolyter	3	L01XC03	Trastuzumab
4	N01BB02	Lidokain	4	S01LA05	Aflibercept
5	H02AB01	Betametason	5	J06BA02	Humant immunglobulin
6	B05DBÖÖ	Hypertona lösningar	6	L04AA23	Natalizumab
7	N02AA05	Oxikodon	7	L01XC07	Bevacizumab
8	B05AA01	Albumin	8	L01XX32	Bortezomib
9	N01AX10	Propofol	9	L01XC17	Nivolumab
10	N02AA01	Morfin	10	S01LA04	Ranibizumab

Source: E-hälsomyndigheten/The Swedish eHealth Agency, and TLV.

2.4 Market players

2.4.1 Pharmaceutical industry

In 2016, the 25 largest pharmaceutical companies in Sweden, based on sales were Novartis, Pfizer, Orifarm, MSD, Glaxosmithkline, Roche, Gilead Sciences, Abbvie AB, Johnson & Johnson, Astrazeneca, Meda, Bayer, B-MyersSquibb, Novo Nordisk, Medartuum, Boehringer Ingelheim, Orion Pharma, Biophausia, CSL Group, Astellas Pharma, Actavis, Eli Lilly, Sanofi-Aventis, Takeda, and Teva.[35]

The main industry organisations are:

- The Swedish Association of the Pharmaceutical Industry (LIF, Läkemedelsindustriföreningen) is the trade association for the research-based pharmaceutical industry in Sweden with about 85 members and associate companies who represent approximately 80 per cent of the total sales of pharmaceuticals.
- Association for Generic Medicines and Biosimilars (FGL, Föreningen för generiska läkemedel och biosimilarer) is an industry organisation with 20 member companies that actively pursues issues to protect and develop the system of generic drugs.
- Läkemedelshandlarna is a trade association consisting of eight member companies that together account for about 98 per cent of all parallel imports into Sweden.

[35] LIF (2017) Topplistor.

- SwedenBIO is the national trade association for life science in Sweden and has more than 200 member companies.

2.4.2 Wholesalers

There are two wholesalers on the market that dominate the distribution: Tamro and Oriola-KD. Tamro and Oriola-KD are logistics service providers rather than traditional wholesale dealers. Both wholesalers have contracts with manufactures and manages the delivery of their goods to all pharmacies in Sweden.

The wholesalers are allowed to deliver to pharmacies, primary care centres and hospitals, but not directly to patients.

There is no statutory wholesale margin. Instead the wholesalers negotiate the margin directly with the manufacturers.

2.4.3 Retailers

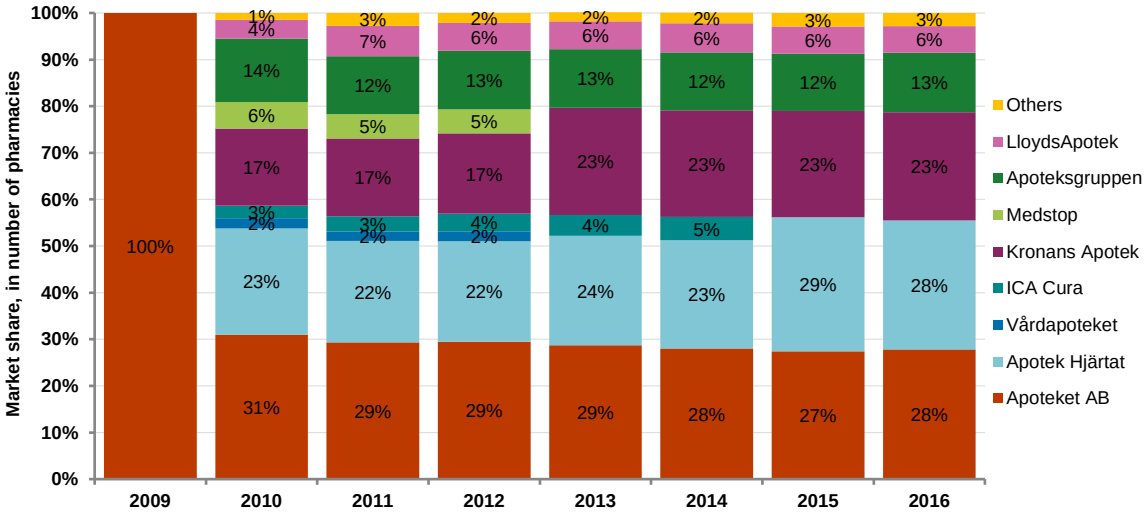
In general, only community pharmacies and hospital pharmacies are allowed to dispense medicines along with small outlets; pharmacy agents (apoteksombud). Other dispensaries (supermarkets, petrol stations etc. are allowed to distribute a small selection of OTC products.

2.4.3.1 Community pharmacies

The pharmacy market was reregulated in 2009 and state-owned Apoteket AB's pharmacy monopoly ceased to exist in June 2009. Approximately half of Apoteket AB's 900 pharmacies were sold grouped into eight clusters, each consisting of ten to 199 pharmacy's and sold to other investors. In addition to this, 150 pharmacies were reserved for small businesses, which today constitute Apoteksgruppen, a pharmacy chain with a centralized service organisation and voluntary affiliated pharmacies. During the first year after the regulation, eight pharmacy chains were operational. In September 2011, the number of pharmacies had increased by over 30 per cent. Some of the restrictive conditions in the cluster purchase agreements were ceased in March 2013. Shortly thereafter, several mergers and acquisitions begun. In 2016, there are five larger pharmacy chains; Apoteket AB, Apotek Hjärtat, Kronans Apotek, Apoteksgruppen and LLoydsApotek, and several independent pharmacies.

Market shares, based on number of pharmacy outlets, is illustrated in the following figure.

Figure 2.6: Pharmacy market shares 2009–2016



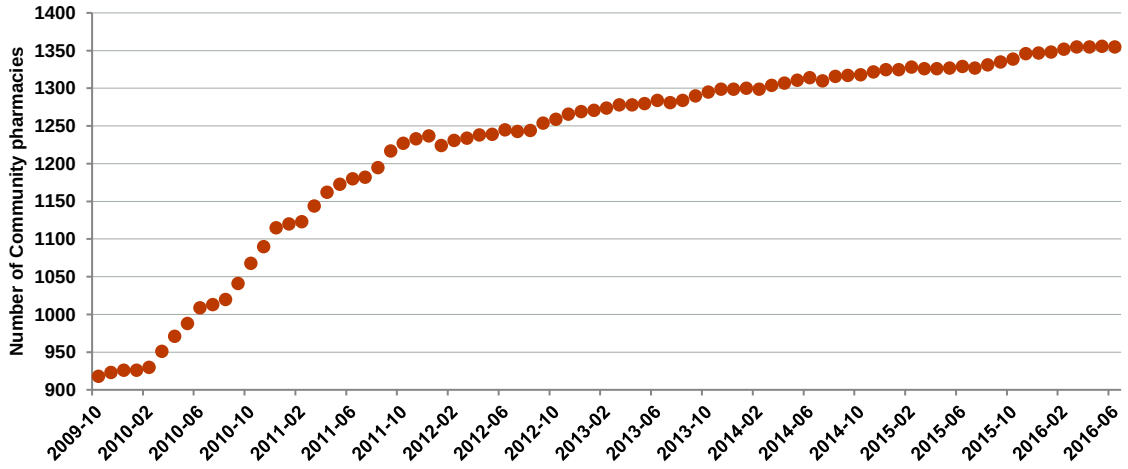
[1] Pharmacy market share based on the number of pharmacies open to the public.

[2] Apotea is the only pharmacy retailer that is only selling pharmaceuticals and other goods the e-commerce, without any physical outlet.

Source: Pharmacy retailers, Sveriges Apoteksförening and TLV.

In June 2016, there were 1 355 dispensing community pharmacies. This is an increase by 48 per cent since October 2009. The growth was highest in 2010 and 2011. After 2011, it has been a continuous net increase in the number of dispensing pharmacies, but at a slower pace.

Figure 2.7: Number of dispensing community pharmacies 2009–June 2016



Note: The figure illustrates the net effect of pharmacies established during the period and also closed down.
Source: TLV.

Since 2016, all major pharmacy chains have e-commerce in the operation, which will help drive the development of sales through the distribution channel. Distribution of pharmaceuticals and other related products through e-commerce is increasing in terms of volume, but from a relatively modest level.

The clearest trends in the pharmacy market, according to a recent government commission inquiry (SOU 2017:15), are a rapid growth in e-commerce, a focus on traded goods and recently started cooperation between pharmacies and companies that provide health care services. Pharmacies' e-commerce with medicines and other goods increased by almost 70 per cent in 2016, to SEK 1.7 billion. This is equivalent to approximately 4 per cent of total revenue. The inquiry estimates that in 2020, e-commerce will account for roughly 8 to 15 per cent of combined pharmacy revenue.[36]

2.4.3.2 Dispensing doctors

In Sweden, there are no dispensing doctors in out-patient care.

[36] SOU (Official Government Reports Series) 2017:15 Nya apoteksutredningen (2017), Kvalitet och säkerhet på apoteksmarknaden, p. 29 (p. 3 English summary).

2.4.3.3 Hospital pharmacies

In principle, each full-service hospital has its own hospital pharmacy, which primarily serve internal needs. Hospital doctors are allowed to use any of the pharmaceuticals granted marketing authorisation.

County councils procure medicines for hospital use

Public procurement of medicines used in hospitals is carried out by the county councils. These pharmaceuticals are put on a list of preferred medicines and 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 it.

Normally, all purchases of pharmaceuticals are done on the county council level. Only in very few situations are the hospitals free to purchase by themselves. There are no national price decisions on pharmaceuticals used in hospitals. If the same product is used for out-patients, there is a price set for the prescribed pharmaceutical, which acts as a "reference" price for hospital use.

2.4.3.4 Other POM dispensaries

Pharmacy agents (apoteksombud) is a distribution point for pharmaceuticals and other medicinal products. Pharmacy agents are usually located in smaller communities.

In 2015, there were approximately 650 pharmacy dispensaries located mainly in rural areas.

2.4.3.5 Other retailers

Both community pharmacies and internet pharmacies[37] are allowed to dispense all POM and OTC products.[38] The patient pays the entire cost for non-prescription (OTC) pharmaceuticals and pricing is unregulated.

Since 1 November 2009, it is allowed for other retailers than pharmacies to sell certain non-prescription medicines. Other dispensaries (supermarkets, kiosks, petrol stations, health care and beauty stores, etc.) are allowed to distribute a small selection of OTC. This is regulated in Act (2009:730) regarding trading with certain prescription free medicines, Ordinance (2009:929) and MPA's regulation (LVFS 2009:20).

[37] Läkemedelsverket/The Medical Products Agency (2017b) Distanshandel.
[38] Läkemedelsverket/The Medical Products Agency (2017c) Tillstånd för apotek.

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 also describes the organisation of the reimbursement system, pharmaceutical expenses and the volume control mechanisms in the out-patient sector.

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[39] 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 widening the analysis from a health care perspective to also include effects outside the health care sector. 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 Flowchart of the pharmaceutical system (Figure 2.1) and Legal basis and actors (authorities and market players) of the pharmaceutical system (Table 2.1).

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:

- pharmaceuticals without competition, mainly patented protected products

[39] Health and Medical Services Act of 2017 / Hälso- och sjukvårdslag (2017:30)

- pharmaceuticals with competition, within the system for substitution at the pharmacy, product of the month (PV)

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 a Pharmaceutical Benefits Board (Nämnden för läkemedelsförmåner). The board makes joint reimbursement and pricing decisions for new: original brand products, dosage forms of medicines already granted reimbursement status, licensed medicinal products, and generic medicinal products. The board consists of seven members often recruited from the county councils, universities and patient organisations.

The eligibility criteria for reimbursement are laid out in the Act on Pharmaceutical Benefits and can be summarised 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 weighed together 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.[40] (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

[40] TLV (2017c) Årsredovisning 2016/Annual report 2016.

amount of the cost for the product is included in the patients' high-cost threshold (see section 3.3.5 for patient´s co-payment). There is currently no negative list in place.

Table 3.1: Ways of pricing medicines at different levels

Pricing policies	Manufacturer level	Wholesale level	Pharmacy level
Statutory pricing		Statutory pricing for reimbursed pharmaceuticals. Decision is taken by TLV after reviewing application from manufacturer. Manufacturers and wholesalers negotiate their share of the price.	Wholesale price plus mark-up, that is regulated by TLV.
Free pricing	Free pricing for pharmaceuticals not included in the benefits scheme i.e. non-reimbursed prescription-only medicines and most OTC medicines.	Not applicable.	See Manufacturer level.
Price negotiations	Manufacturers and wholesalers negotiate the wholesale margin.		Pharmacies may negotiate to prices below the pharmacy purchasing price for branded and parallel imported products without generic competition.
Discounts / rebates	See section 4.2.	No.	No.
Public procurement	➢ Relevant for pharmaceuticals used in hospitals (performed by the county councils). See section 4.3.		
Institution in charge of pricing	➢ TLV (decides price of reimbursed pharmaceuticals and the pharmacy margin).		
Legal Basis	➢ Act on Pharmaceutical Benefits etc. (Lagen om läkemedelsförmåner m.m.). ➢ TLV's decision on revised Pharmacy Mark-ups for POM in the benefits scheme from 1 April 2016.		

POM = prescription-only medicine, OTC = over-the-counter medicines.
Source: TLV.

3.2.2 Pricing procedures

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

The pharmaceutical company submits an application 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

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 county councils and the pharmaceutical company.

The board will reject the application for reimbursement if the price is too high and 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 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 decides on price changes.

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 more or less simultaneously, 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.

Another tool at TLV's disposal is the possibility to initiate a review of a pharmaceutical's pricing and reimbursement status. A review can be initiated to ensure that a group or a single pharmaceutical within the reimbursement scheme still is cost-effective. The outcome of a review may be lowering the price of a pharmaceutical or a change in reimbursement status.

Prices are set at the wholesale level and correspond to the pharmacy purchase price. Wholesalers are free to negotiate their margin directly with the manufacturer. The pharmacy retail price corresponds to the wholesale price and 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 3.4.1).

International Reference Pricing ("IRP") – also known as external price referencing - is not applied in Sweden.

Table 3.2: Pricing procedures

Pricing procedure	In use	Price type[1]	Scope[2]
External price referencing	No		
Internal price referencing	No*	* However, products subject to generic substitution in the PV-system. See section 3.4.1.	
Cost-plus pricing	No		
Indirect profit control	No		
Price/volume agreements	No		
Other managed-entry agreements, pls. specify:	Yes	MEA may exist between the county councils and pharma-ceutical companies. MEAs do however not affect the list price, but may affect the cost of treatment for the county councils.	
Others, specify: Value based pricing	Yes	Pharmacy purchasing price (AIP) and pharmacy retail price (AUP). Reimbursement is 100 % of AUP.	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 procedure does not always refer to all medicines: e.g. a pricing procedure could only refer to reimbursable medicines, whereas for Over-The-Counter medicines there is free pricing.
Source: TLV.

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

A managed entry agreement[41] between the county councils and a pharmaceutical company may be one of several factors considered when TLV decide on price and reimbursement status. New pharmaceuticals may be introduced at an earlier stage, and some of these pharmaceuticals are 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. Such agreements may ensure cost effectiveness and may also dampen the increasing costs for new pharmaceuticals. Discussions between

[41] 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.

county councils, 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.[42]

Managed entry agreements between county councils 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. 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 November 2016, there are managed entry agreements in six therapeutic groups that totally encompasses 16 products.[43] This primarily applies to new pharmaceuticals in the benefits scheme where different types of risk following their introduction are handled by managed entry agreements.

The first case where a managed entry agreement was applied as part of the grounds for TLV deciding on price and reimbursement was for a pharmaceutical against hepatitis C in Q4 2014. This was followed by pharmaceuticals for prostate cancer during the summer of 2015 (Xtandi and Zytiga). Several pharmaceuticals have subsequently been added. Zykadia (against lung cancer) was added at the end of 2015 and Entresto (to treat heart failure) were included in the benefits scheme in April 2016. In these cases, managed entry agreements have concerned refunds at high patient volumes.

In June 2016, an additional MEA was entered in to for the anti-cancer pharmaceutical Mekinist (against malignant melanoma) where the risk of long duration of treatment is handled through the agreement. In the same month, Repatha (for high LDL cholesterol) was added to the list of products that had a MEA between the pharmaceutical company and the county councils. Here, the managed entry agreement dealt with the risk for a high number of patients and the uncertainty surrounding the effect. The case concerning the orphan pharmaceutical Raxone (against eye disease) from October 2016, has a managed entry agreement that deals with risk for the number of patients who will be treated and the uncertainty about the effect. Raxone is the first case where an orphan pharmaceutical product was covered by a managed entry agreement. The reason why Raxone already had sales in September, even though the benefits scheme decision was not taken until October, is due to

[42] TLV (2016h) Uppdrag att redovisa arbetet med att utveckla den värdebaserade prissättningen för läkemedel inom förmånerna.
[43] TLV (2016b) Uppföljning av läkemedelskostnader.

sales having taken place previously via a special license permission.[44] Pharmaceuticals granted a special license permission are automatically covered by the benefits, even before a reimbursement decision has been taken.

In October 2016, managed entry agreements for Enbrel and Benepali were renewed while agreements for Cimzia and Humira were added.

3.2.2.4 An auction based system for products with competition

For off-patent products, generic substitution is mandatory between medically equivalent pharmaceuticals subject to competition from more than one manufacturer. 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. The physician and the pharmacist may prohibit substitution on medical grounds only.

The preferred product is appointed through a monthly auction, were the product that the pharmacies should offer their customers is decided. 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. TLV also appoints two back-up products that pharmacies can switch to if it is not possible to obtain the cheapest alternative.

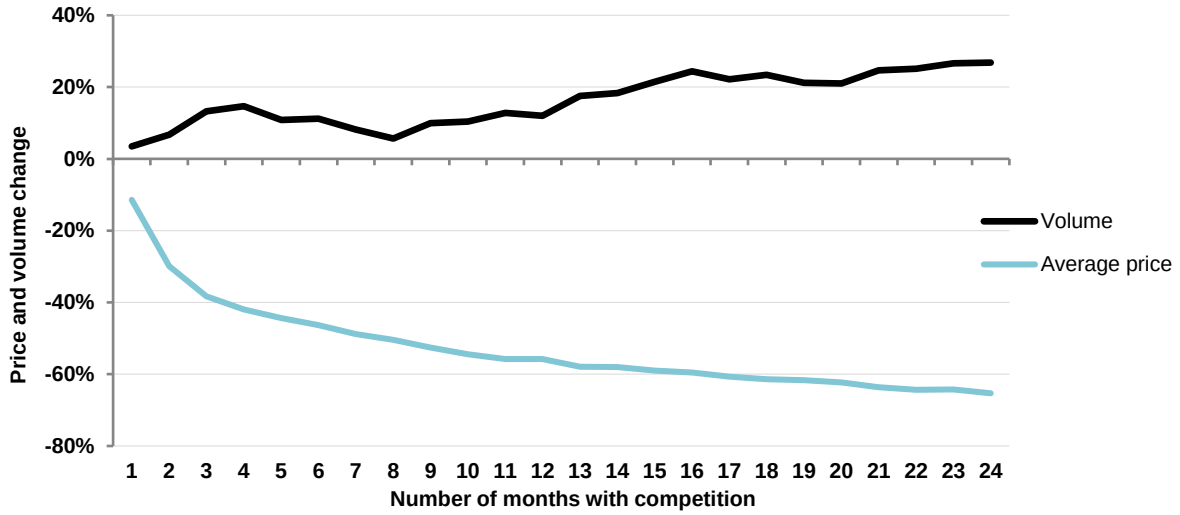
The purpose of the substitution system of pharmaceuticals in pharmacies is to keep the society's cost down for pharmaceuticals whose patent protection has expired.

The dynamics of the system for substituting pharmaceuticals at the pharmacy, including the development of prices for interchangeable products with more than one manufacturer, have been analysed by TLV. The results of the analysis were published in a report in November 2016.[45]

Competition between manufacturers have resulted in significant price reductions on pharmaceuticals. Already after three months, the price has fallen on average by 40 per cent and after two years the price has fallen further, to 35 per cent 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.

[44] Pharmaceuticals granted market authorisation in a different country, that are not authorised to be marketed in Sweden, may receive a special permission license to be dispensed to specific patients. The cost will be covered by the benefits scheme and the patients' co-payment within the high-cost threshold scheme.
[45] TLV (2016c) Det svenska periodens vara-systemet.

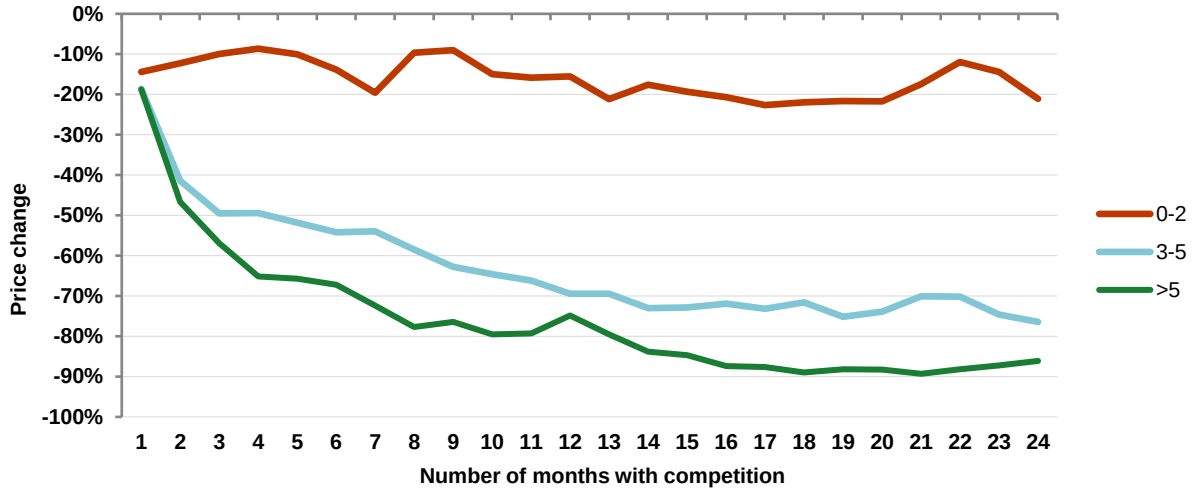
Figure 3.1: Price- and volume change for pharmaceuticals with competition after 2003



Source: TLV.

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 3.2: 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,

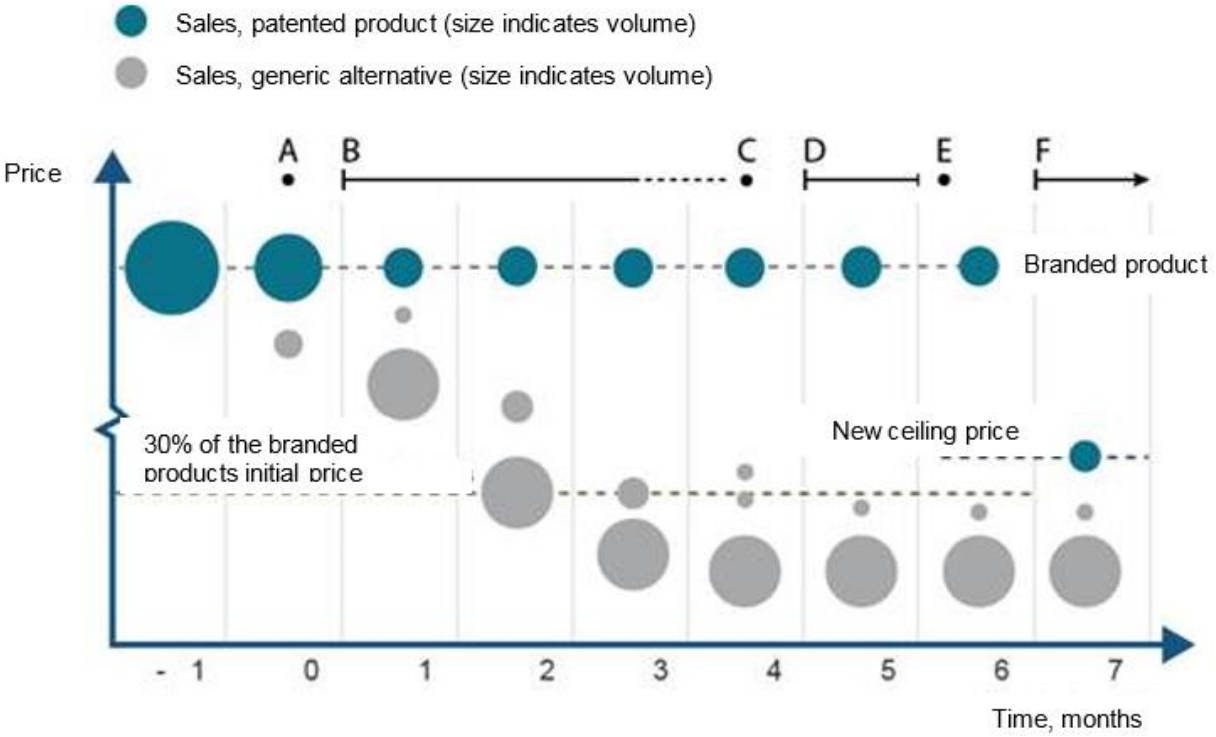
there does seem to be a clear linkage between price trend and the number of competitors in an exchange group.

Generic substitution leads to lower prices, and afterwards significant price differences between generic substitutes can arise. (See section 2.3.3.2 and 3.4.1.) 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 65 per cent of the price that the pharmaceuticals had before generic competition arose.[46] 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.

[46] TLV (2016f) Takpriser.

Figure 3.3: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 ceiling price is meet.
Point/period D: TLV establish an official final ceiling 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 ceiling price is established.

Source: TLV.

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 January 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 per cent of the price that applied in October 2012.[47] The 7.5 per cent reduction was optional during 2014. However, as of 2015 it is enacted in law.

For example, in 2016, the price cuts under this 15-year rule was carried out on two occasions, in June and December, and involved a total of 305 pharmaceuticals packages (substance, package size, dosage form and strength-level). The pharmaceutical companies that markets a product may however request a product to be exempted from the price cut, if the price of a product becomes too low. In 2016, there were 40 requests for exemption from the price reduction and 23 exemptions were granted exemption.[48]

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.

Managed entry agreements may exist between the county councils 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 county councils.

[47] TLV (2016g) Prissänkning enligt 15-årsregeln.

[48] TLV (2017c) Årsredovisning 2016/Annual report 2016.

3.2.5 Remuneration of wholesalers and pharmacists

The pharmacy retail margin is a regulated remuneration that the pharmacies receive when dispensing a prescription medicine included in the benefits scheme. The retail margin is the difference between pharmacy purchasing price and pharmacy retail price. The pharmacy margin is regulated by TLV.[49]

The pharmacy retail margin increases with higher purchasing price. This means that pharmacies receive a higher compensation, for higher-priced products, up to a ceiling.[50]

Table 3.3: Regulation of wholesale and pharmacy mark-ups

	Wholesale mark-up			Pharmacy mark-up		
	Regulation	**Content**	**Scope***	**Regulation**	**Content**	**Scope***
Sweden	*No regulation of the wholesale mark-up.*	*Manufactures and wholesalers negotiate the wholesale margin.*	*All products*	*Yes, regulation of the pharmacy mark-up*	*Regressive mark-up up to a ceiling*	*All prescription medicines that are included the benefits scheme.* *For medicines not included in the benefits scheme, trade pharmacy 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.*

* Regulations concerning mark-ups do not always apply to all medicines, it may also target only POM or reimbursable medicines.
Source: TLV.

In 2014 and 2015, TLV conducted a major review of several issues related to the pharmacy retail margin. Among other topics, TLV assessed the profitability of the pharmacies, need for availability and access to medicines (from a national / government perspective), pharmacy services and efforts by the pharmacy's in relation to the goals set up by the government. TLV published four interim reports (TLV 2014a, 2014b, 2014c, 2015a), and the final report of the 2014/2015 review of pharmacy retail margin in June 2015 (TLV 2015b). In the final report, TLV proposed changes in the formula for calculating the retail margin. The reason being the increased sales of pharmaceutical packages with very high pharmacy retail prices.

[49] TLV (2015d) Tandvårds- och läkemedelsförmånsverkets föreskrifter (TLVFS 2009:3) om handelsmarginal för läkemedel och andra varor som ingår i läkemedelsförmånerna.
[50] TLV (2017b), Apotekens marginaler.

Table 3.4: Formula for calculating pharmacy sales price, including the retail margin for pharmaceuticals without competition in the benefits scheme, before and after the change April 1st 2016

Previous formula, *before* April 1st 2016			**Current formula, *after* April 1st 2016**		
Pharmacy purchasing price, (PPP) SEK	**Pharmacy retail price (PRP), SEK**	**Max retail margin, SEK**	**Pharmacy purchasing price, (PPP) SEK**	**Pharmacy retail price (PRP), SEK**	**Max retail margin, SEK**
≤ 75	PPP x 1.20 + 31.25	46.25	≤ 75	PPP x 1.20 + 30.50	45.50
> 75–300	PPP x 1.03 + 44	53	> 75–300	PPP x 1.03 + 43.25	52.25
> 300–6 000	PPP x 1.02 + 47	167	> 300–50 000	PPP x 1.02 + 46.25	1 046.25
> 6 000	PPP + 167	167	> 50 000	PPP + 1 046.25	1 046.25

Note: For pharmaceuticals in the product of the month system, with competition, SEK 11.50 is added per package.
Source: TLV.

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.[51]

Table 3.5: 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 x 1.20 + 30.50
> 75–300	PPP x 1.03 + 43.25
> 300–50 000	PPP x 1.02 + 46.25
> 50 000	PPP + 1 046.25

Source: TLV.

[51] TLV (2017b), Retail margins for products included in the benefits scheme.

Table 3.6: 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 x 1.20 + 30.50 + 11.50
> 75–300	PPP x 1.03 + 43.25 + 11.50
> 300–50 000	PPP x 1.02 + 46.25 + 11.50
> 50 000	PPP + 1 046.25 + 11.50

Source: TLV.

Table 3.7: 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 x 1.362 + 4
> 47.35–4 500	PPP x 1.108 + 16
> 4 500	PPP + 502 +0.01 x (PPP - 4 500)

Source: TLV.

Table 3.8: 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 x 1.402 + 3.36
> 47.35–4 500	PPP x 1.106 + 17.36
> 4 500	PPP + 494.36 + 0.01 x (PPP - 4 500)

Source: TLV.

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 per cent, and is applied to both OTC-pharmaceuticals and medical devices. There is no VAT on prescribed pharmaceuticals.[52]

[52] The Swedish Tax Agency (Skatteverket) VAT of goods and services.

3.3 Reimbursement of medicines

3.3.1 General reimbursement scheme

The reimbursement system is a national scheme and covers the whole country. In other words, all reimbursed pharmaceuticals are reimbursed in every county and the price is the same across the country. However, in every county 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 pharmacy's.

3.3.2 Specific reimbursement schemes

Pharmaceuticals prescribed to children under 18 years are since from January 2016 without co-payment for the patient, as long and the pharmaceutical is included in the benefits scheme.

The government has adopted a new 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 (i.e. hepatitis C and HIV), are subsidised at 100 per cent and is without co-payment for the patient.[53] Also visiting clinics and testing for communicable diseases and is free of charge for the patient.

[53] 1177.se (2017a) Vad kostar läkemedel på recept?

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.[54]

3.3.2.1 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 county council area 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 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. LMA is short for 'Lagen om mottagande av asylsökande' (Swedish Reception of Asylum Seekers' Act), and 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. Dental treatment provided by the Swedish Public Dental Service (Folktandvården) costs a maximum of SEK 50 (€~5). A repeat appointment with a dentist costs a maximum of SEK 50 (€~5).[55]

3.3.3 Reimbursement procedure

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

3.3.4 Reference price system

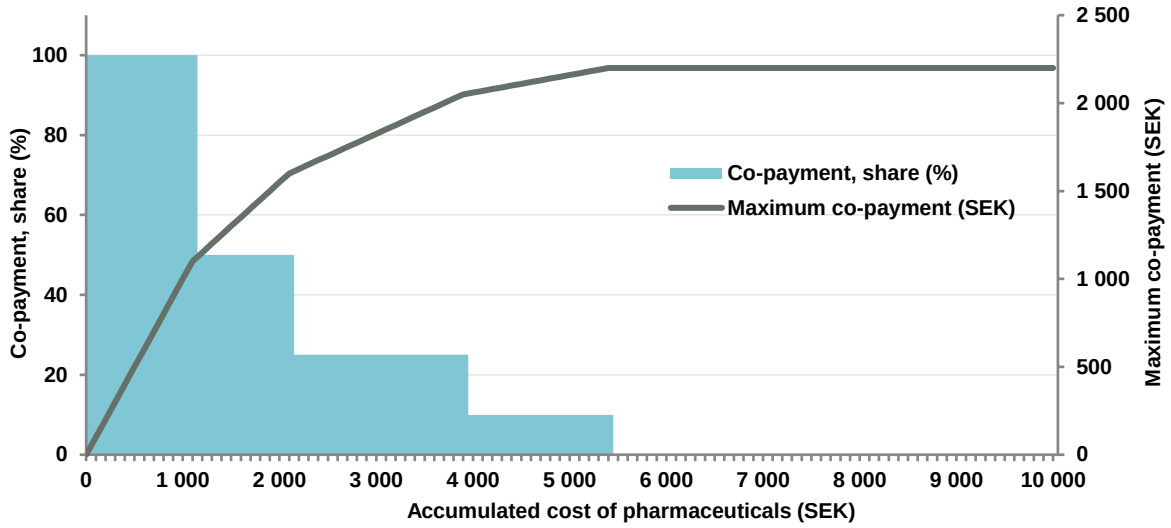
There is no reference price system, see section 3.2.2.4 for information about the product-of the-month system for substitutable pharmaceuticals with generic competition.

[54] 1177.se (2017a) Vad kostar läkemedel på recept?
[55] 1177.se (2017b) Healthcare in Sweden for asylum-seekers, people with no papers and people in hiding.

3.3.5 Private pharmaceutical expenses

For pharmaceuticals included in the benefit scheme, the patient and the state share the costs of the pharmaceuticals. During a 12-month period, a patient pays the full amount of the pharmaceutical up to SEK 1 100 (€~116). After paying SEK 2 200 (€~232), the patient is fully subsidized. Between SEK 1 100 and 2 200, the patient is subsidized 50, 75 or 90 per cent, depending on the accumulated costs.[56]

Figure 3.4: Co-payment for pharmaceuticals



Source: TLV.

See section 3.3.2 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 3.3.2.1).

[56] Swedish Institute (2017) Health care in Sweden.

Table 3.9: Out-of-pocket payments for medicines

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	N.a.	-
Percentage payments for pharmaceuticals included in the benefits scheme	The patient pays the full amount of pharmaceuticals up to SEK 1 100 (€~116). Between SEK 1 100 and 2 200, the patient is subsidized 50 %, 75 % or 90 %. After paying SEK 2 200 (€~232), 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 subsidized at 100 %.
Deductibles	SEK 2 200 / €~232	-
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.

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.

3.4.1 Generic substitution

Generic substitution of pharmaceuticals in pharmacies is mandatory since October 2002. This system is referred to as the product-of-the-month. For products with competition, pharmacies are obliged to offer the equivalent medicine with the lowest price (per unit).

The purpose of substitution is to limit society's as well as patients' 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 which have 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 it the cheapest product no longer is available.

Table 3.10: Substitution at the pharmacy, how it is managed at the pharmacy and the patients' cost

How it is managed at the pharmacy	Patients' 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 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.

The government have on several occasions commissioned the MPA to analyse pros and cons of a potential introduction of a system with generic prescription. The MPA submitted a report in May 2015 recommending that INN prescribing should not be implemented in Sweden.[57] In a consultation response, TLV rejected MPA's recommendation not to introduce

[57] Läkemedelsverket/ The Medical Products Agency (2015a) Insatser för att förbättra patientsäkerheten vid generiskt utbyte, 2015-05-28.

generic prescribing.[58] TLV is of the opinion that generic prescribing is a simplification that could generate positive effects on patient safety and price dynamics within competition within the Product-of-the-month system.

Prescription targets

Pharmaceutical and Therapeutic Committees have set up targets for the prescription rate of off-patent pharmaceuticals within some classes of medicines. The committee in the County of Västerbotten has, for example, set a prescription target more than 90 per cent of all patients using lipid inhibitors should use either atorvastatin, simvastatin or pravastatin.[59]

3.4.3 Other generic promotion

Pharmacies receive an extra SEK 11.50 (€~1.2) in retail margin when dispensing a product with competition from generics, i.e. within the Product-of-the-month system.

TLV and MPA 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, county councils, and other pharmacy associations. The information is based on current regulations and guidelines, research findings and other studies and reports as well as interviews.

[58] TLV (2015c) Yttrande över Insatser för att förbättra patientsäkerheten vid generisk utbyte.

[59] Västerbottens läns landsting (2016) Läkemedelsmål i Västerbotten 2016.

Table 3.11: Examples of information material regarding generic substitution

	Link
Information to patients in eight languages 	Swedish: www.tlv.se/Upload/Apotek/Utbytesmaterial/Folder_patienter_A4.pdf www.tlv.se/Upload/Apotek/Utbytesmaterial/Folder_patienter_A5.pdf Arabic: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_arabiska.pdf Bosnian / Croatian / Serbian: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_bosniska_kroatiska_serbiska.pdf English: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_engelska.pdf French: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_franska.pdf Persian: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_persiska.pdf Sorani: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_sorani.pdf Spanish: www.tlv.se/Upload/Apotek/Utbytesmaterial/Patientfolder_2014_spanska.pdf
Information to pharmacists 	www.tlv.se/apotek/informationsmaterial-om-det-generiska-utbytet/informationsmaterial-apotekspersonal/ www.tlv.se/Upload/Apotek/Utbytesmaterial/Kunskapsunderlag_farmaceuter.pdf www.tlv.se/Upload/Apotek/Utbytesmaterial/Faktablad_farmaceut.pdf
Information to prescribers 	www.tlv.se/apotek/informationsmaterial-om-det-generiska-utbytet/informationsmaterial-forskrivare/ www.tlv.se/Upload/Apotek/Utbytesmaterial/Kunskapsunderlag_forskrivare.pdf www.tlv.se/Upload/Apotek/Utbytesmaterial/Faktablad_forskrivare.pdf www.tlv.se/Upload/Apotek/Utbytesmaterial/Affisch_A4.pdf

Source: TLV.

3.4.4 Claw-backs

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

3.4.5 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 county councils are also continuously evaluating aspects of the market regarding financial, medical and other aspects.

TLV, for example, regularly monitors the outcome of the agreement between the government and LIF regarding the 7.5 per cent price cut on products older than 15 years. The agreement is based on 2012 prices and volumes and covers four years, 2014 to 2017. The outcome for the first three years are well in line with expected savings. The 7.5 per cent reduction was optional during 2014. However, as of 2015 it is enacted in law, and will continue even after the initial agreement has ended.

TLV also monitors the impact of TLV's reassessments of price and reimbursement status for products included in the reimbursement scheme as well as the development of value-based pricing. Total savings are estimated at SEK 1.2 billion between 2014 and 2017.[60]

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, MPA 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.[61]

Despite national guidelines, variations remain in the care and treatment of patients with for example chronic illnesses. The guidelines have also been criticized for having a weak link to clinical practice. As a result of the gap between guidelines and actual clinical practice, recent policy work in the area has come to focus on strategies for the implementation of guidelines and recommendations.[62]

[60] TLV (2016b) Uppföljning av läkemedelskostnader.
[61] Anell A., Glenngård A.H., Merkur S. (2012), p. 36.
[62] Anell A., Glenngård A.H., Merkur S. (2012), p. 36.

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. 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.[63]

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.

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 (county 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 and county authorities by 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.

3.5.3 Decision making tools

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

See section 5.1.1 for information about horizon scanning activities.

[63] Socialstyrelsen/National Board of Health and Welfare (2017) Läkemedelsregistret.

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 regional level, the county councils or regions, are responsible for providing specialised care within the county. The legal framework for hospital pricing, reimbursement of practitioners and monitoring applies to both public and private hospitals.[64]

It is the responsibility of the county councils 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 one or two county councils provide the medical care for the whole country, not just for the population of their county. The National Board of Health and Welfare (Socialstyrelsen) defines what type of care should be considered national care and grants time restricted permissions for county councils to provide it (normally five years.).[65, 66]

Hospitals are generally classified according to size and degree of specialisation into regional hospitals, central county hospitals and district county hospitals. These subtypes have, however, become less relevant over the past years, as the trend has been specialisation at all levels. This means that two central county hospitals do not necessarily offer the exact same type of care, but may instead have different specialities and cooperate with each other.[67]

4.1 Organisation of the in-patient sector

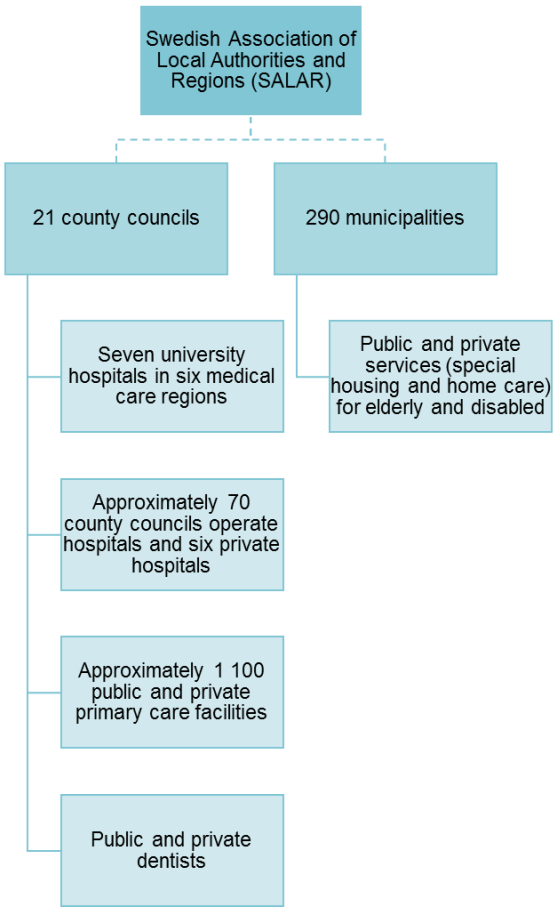
The county councils and regions are responsible for purchasing pharmaceuticals for the hospitals in their respective area. Purchasing procedures are regulated in the Public Procurement Act (2007:1091), which was revised in 2017 to be compliant with updated EU-directives (Directive 2014/24/EU on public procurement, and Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors).[68] The legal framework for hospital pricing, reimbursement and monitoring stipulated on a national level applies both to public and private hospitals.

[64] PHIS (2009) Hospital Pharma Report 2009 – Sweden, December 2009.
[65] PHIS (2009) Hospital Pharma Report 2009 – Sweden, December 2009.
[66] Specialized treatments are listed on The National Board of Health and Welfares web, www.socialstyrelsen.se/rikssjukvard
[67] PHIS (2009) Hospital Pharma Report 2009 – Sweden, December 2009.
[68] Lag (2016:1145) om offentlig upphandling.

The market for providing hospital pharmacy services in is subject to competition, even if there in practice only exist two service providers, Apoteket AB, and Apoex AB. An increasing number of smaller country councils 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.

Figure 4.1:The organisation of health care services



Source: Anell A., Glenngård A.H., Merkur S. (2012).

4.2 Pricing and purchasing policies

Public procurement of pharmaceuticals used in hospitals is carried out by the county councils. Lately, county councils are generally aiming at purchasing agreements without discounts or claw-backs beyond the negotiated price. There has been a successive movement towards

achieving purchasing agreements with a given net price in later years, even if discounts may still occur to a limited degree.[69]

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 on 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, there is a price set for the prescribed medicine. That price acts as an informal "reference price for hospital use".[70]

The hospital pays the net pharmacy retail prices for pharmaceuticals purchased from the hospital pharmacy. However, it is the county council that procures pharmaceuticals (exceeding a certain threshold value) from the pharmaceutical company.

Pharmaceuticals used in smaller volumes are bought from a community pharmacy. The purchaser at the hospital is responsible for the order[71] and the hospital price for these pharmaceuticals is equivalent to the pharmacy retail price.[72] The price includes a wholesale and a pharmacy mark-up.

Pharmaceuticals are exempt from VAT, although for OTC-products the standard rate of 25 per cent applies.

4.3 Procurement

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

[69] Interview with M. Svensson and J. Eriksson at SALAR, 2017-01-31.
[70] Anell A., Glenngård A.H., Merkur S. (2012).
[71] SLL (2016) Upphandlade läkemedel.
[72] PHIS (2009) Hospital Pharma Report 2009 – Sweden.

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 county council (or a group of county councils) that decide(s) which pharmaceuticals to procure, and on the local level each hospital decides the structure for requiring medicines. At county council level, there is a procurement body managing the legal and administrative aspects of the process and, in most counties, deciding which tenders to accept. The pharmaceutical committees play an important advisory role in the procurement process.[73]

The Public Procurement Act details the procedure of procurement and applies to the 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 county councils can also specify technical requirements or define required characteristics, for example medicine information about the product or information on fulfilling of environmental standards.[74]

The decision to accept a tender is based on a set of criteria that the county councils have laid down. Since most county councils group together with other counties 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.[75]

The frequency of procuring medicines varies between the county councils, but it is usually performed once a year.

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

[73] PHIS (2009) Hospital Pharma Report 2009 – Sweden, p. 12.
[74] PHIS (2009) Hospital Pharma Report 2009 – Sweden, p. 12.
[75] PHIS (2009) Hospital Pharma Report 2009 – Sweden, p. 13.

4.3.1 Health economic assessments of pharmaceuticals used in in-patient care

See section 5.1.2 for more information.

4.4 Reimbursement

The provision of health care services is decentralised to county level, and it is financed mainly through county council taxes. Both public hospitals and private hospitals on a contract with the county council are reimbursed by the county councils 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 due to the fact that county councils decide on which treatments to use and finance them accordingly at the regional level.

Maximum fee for medical care amounts to €~116 per year

It is largely up to the counties 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 counties are quite similar.[76]

Patients pay a fixed fee for an appointment, but no more than SEK 1 100 (€~116) during a period of 12 months. If the amount is exceeded, health care is fully covered by the county council and the patient will receive treatment without additional payment up to twelve months after the first appointment. No co-payment is required for pharmaceuticals used during a hospital stay.[77]

Visits to maternity clinics and welfare centres are free of charge throughout the country. As is mammography screening for women between 40 and 74 years old. Children 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-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.[78]

[76] 1177.se (2017c) Patient fees.
[77] 1177.se (2017c) Patient fees.
[78] 1177.se (2017c) Patient fees.

Foreign citizens are entitled to emergency care[79]

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.

4.4.1 Hospital pharmaceutical formularies

4.4.2 Pharmaceutical and Therapeutic Committees

All county councils and regions are obliged by law to have a Pharmaceutical and Therapeutics Committee.[80] 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 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 county councils.

Clinical recommendations are issued by pharmaceutical committees, the MPA and the National Board of Health and Welfare. The formulary committees provide lists of recommended pharmaceutical treatments for out-patient care in each county council, 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.

[79] 1177.se (2017b) Healthcare in Sweden for asylum-seekers, people with no papers and people in hiding.
[80] Lag (1996:1157) om läkemedelskommittéer.

4.5 Volume Control in the in-patient sector

4.5.1 Monitoring

Registers provide key information for research and follow-up

The Board of Health and Welfare manages the National Patient Register (NPR), 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.[81]

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 county council 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.[82]

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

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; within all healthcare production. It is annually monitored and approved for financial support by an Executive Committee with representatives from the state, the county councils and the municipalities.[83] Some examples are registries for diabetes, cancer (in 15 different registers) and approximately 80 other conditions.[84] 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.[85]

[81] Socialstyrelsen/National Board of Health and Welfare (2017) In English – the National Patient Register.
[82] PHIS (2009) Hospital Pharma Report 2009 – Sweden.
[83] SKL/SALAR (2017a) About the National Quality Registries.
[84] SKL/SALAR (2017b) All Swedish Quality Registries.
[85] SKL/SALAR (2017c) Certification levels.

The eHealth Agency provides the necessary infrastructure by collecting statistics on pharmaceuticals, 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 the eHealth Agency. The data is used by county councils for their internal purposes and for research. Data in also available for different agencies and organisations.

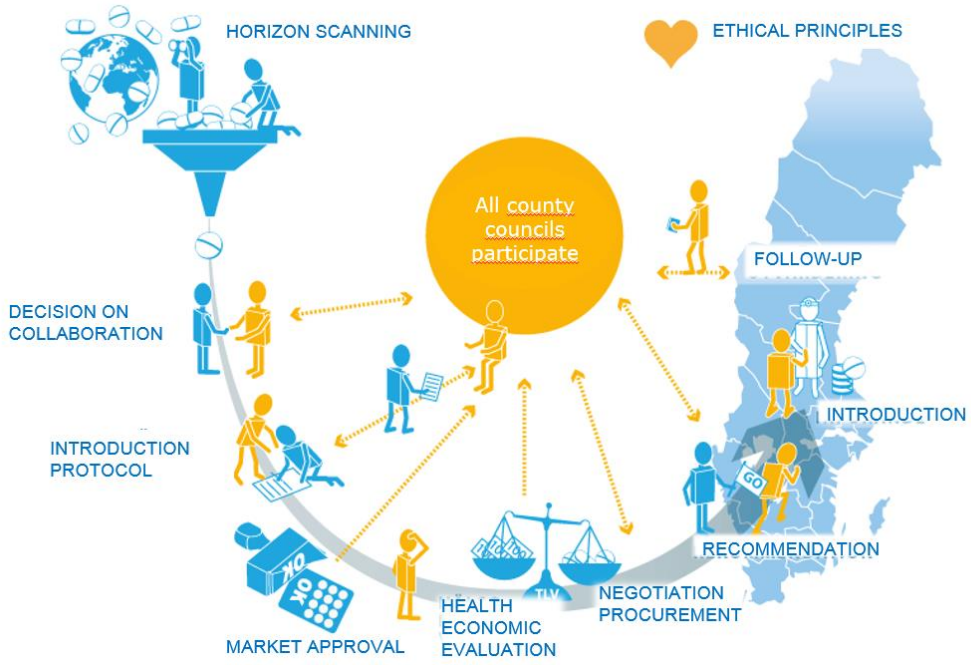
4.5.2 Decision-making tools

4.5.2.1 Managed introduction of new pharmaceuticals

All county councils and regions have agreed to collaborate on pricing, introduction and monitoring of new pharmaceuticals used in the in- and/or out-patient sector.

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 county councils 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.

Figure 4.2: Process for managed introduction of new pharmaceuticals



Source: SKL/SALAR.

An advantage of collaborating is that the county councils 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 county would act on their own.

A representative from each healthcare region is assigned to participate in the process, appointed by the county councils. Medical experts as well as experts in the field of health economics, ethics, oncology, horizon scanning et cetera are involved in the process.

More information on managed introduction of new drug therapies is available on janusinfo.se.[86]

4.5.3 Evaluation of measures

See sections 4.5.2 and 5.1.2.

4.5.4 Reports and results

See section 5.1.2.

[86] SLL (2017) Janusinfo.

5 Interface management and developments

This concluding chapter covers information about the interface management and the most important pharmaceutical developments for the health care system.

5.1 Interface management

5.1.1 Horizon scanning

Key players, organisational set-up and aim

Horizon scanning is performed as a joint effort of four county councils on behalf of all the Swedish county councils, 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 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 its 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 similar to the NIHR-HSC model. 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 the health care system. For the most prioritised substances, in-depth reports are written with the support of medical expertise. The reports are finalized around six months prior to market authorisation. They are not publicly available as they are based on preliminary data.

Output and on-going developments

The county councils make medicinal and budgetary forecasts based on for example current trends, at what stage in its life-cycle the pharmaceutical is in, expected launches of new

products, patient experiences and treatment guidelines. The forecasts are publicly available in Swedish.[87] [88]

The county councils are deepening their collaboration regarding horizon scanning, structural introduction and follow-up activities.[89]

5.1.2 Health economic assessments of pharmaceuticals used in in-patient care

The government have commissioned TLV to conduct economic assessments of pharmaceuticals used in the specialized 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 county councils. See section 4.5.2.1.

The purpose of the health economic assessments of hospital pharmaceuticals is to provide the NT Council with a better basis for their recommendations.

The assessments that TLV provides are made in collaboration with other organisations beside the NT-council, i.e. the Ministry of Health, pharmaceutical companies, LIF, medical and health economical experts, the National Board of Health and Welfare, Medical Products Agency 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 all the counties
- a more knowledge-driven and equitable use of medicines in the country
- long-term cultural change regarding the perception of health economic information as well as open comparisons of therapy

TLVs 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 about preferred treatment of choice. The recommendations and information provided will support the county councils when deciding on choice of treatment. In 2016, TLV made nine

[87] SLL (2014) Prognos över användning och kostnader för läkemedel.
[88] Socialstyrelsen/ National Board of Health and Welfare (2016) Läkemedelsförsäljningen i Sverige – analys och prognos.
[89] SLL (2017) Janusinfo.

health economic assessments – all for products used in the treatment of cancer. Several assessments have focused on PD1-inhibitors used in the treatment of skin cancer and various forms of lung cancer. They are expected to be approved for additional indications. Several new PD1 inhibitors are expected to be approved within the next few years and the area is expected to be a major driver for pharmaceutical costs for the county councils in the future.

Fast and equitable access remains a key issue for both the in- and out-patient sector. In evaluating Opdivo indicated for treatment of lung cancer, TLV published a report only 56 days after the indication received market approval. The NT-council published its recommendation 31 days later. In evaluating Opdivo indicated for treatment of renal cell cancer, TLV delivered a report in 86 days after the indication approval, and NT-council published a recommendation the day after.

5.2 Developments

5.2.1 A commission of inquiry is to review the quality and safety in the pharmacy market

The government has commissioned an inquiry in late 2015 to investigate the possibility to increase the focus on quality and safety in the pharmacy market (directive 2015:118). The review of the pharmacy market and propose changes were published in a report in March 2017 (SOU 2017:15).[90]

In December 2016, the government decided to include additional assignments and to extend the inquiry. An interim report focusing on the regulation of pharmacy trade margin for the pharmaceuticals not included in the pharmaceutical benefits is to be reported in October 2017. The final report is due in May 2018.

5.2.2 A commission of inquiry is to review financing of pharmaceuticals

The government has commissioned an inquiry of the current system of financing, reimbursement and pricing of pharmaceuticals in Sweden. The review's overall goal is to achieve a sustainable system that enables a socio-economic effective use of pharmaceuticals that is

[90] SOU (Official Government Reports Series) 2017:15 Nya apoteksutredningen (2017), Kvalitet och säkerhet på apoteksmarknaden.

in line with the ethical platform for healthcare and, at the same time, allows the costs for treatment to be kept at a reasonable level. [91]

A clear division of responsibilities between the state and county, equitable and patient-centred care, predictable processes for the actors concerned, as well as good conditions for research and innovation for the benefit of the patient should be sought.

The first matter to be investigated is the division of responsibility between the state and county regarding the funding of pharmaceuticals. Followed by an analysis of the subsidies and pricing of the pharmaceuticals including and proposals for improvements.

An interim report, containing a comprehensive description of the situation and the challenges, is to be submitted in the beginning of November 2017. The final report is to be delivered in December 2018.

[91] Regeringen/the Government (2016d) Kommittédirektiv - Finansiering, subvention och prissättning av läkemedel.

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Tandvårds- och läkemedelsförmånsverkets föreskrifter (TLVFS 2009:3) om handelsmarginal för läkemedel och andra varor som ingår i läkemedelsförmånerna tlv.se/Upload/Lagar_och_foreskrifter/HSLF-FS_2015_32.pdf

Tandvårds- och läkemedelsförmånsverkets allmänna råd om ekonomiska utvärderingar (TLVAR 2017:1), January 2017, www.tlv.se/Upload/Lagar_och_foreskrifter/TLVAR_2017_1.pdf

6.3 Web links

Ministry of Health and Social Affairs (Socialdepartementet): www.government.se/government-of-sweden/ministry-of-health-and-social-affairs/

National Board of Health and Welfare (Socialstyrelsen): www.socialstyrelsen.se/

Swedish Association of Local Authorities and Regions (SALAR/ SKL): www.skl.se

Swedish council on technology assessment in healthcare (Statens beredning för medicinsk och social utvärdering, SBU): sbu.se/sv/

The Dental and Pharmaceutical Benefits Agency (TLV): www.tlv.se/

The Health and Social Care Inspectorate (IVO) www.ivo.se/

The Public Health Agency of Sweden (Folkhälsomyndigheten) https://www.folkhalsomyndigheten.se/

The Swedish Agency for Health and Care Services Analysis (Vårdanalys) www.vardanalys.se/

The Swedish eHealth Agency (eHälsomyndigheten) https://www.ehalsomyndigheten.se/

The Swedish Medical Products Agency (MPA/ Läkemedelsverket), www.lakemedelsverket.se