



Pharmaceutical Health Information System

PHIS Hospital Pharma Report 2009

Sweden

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PHIS

Pharmaceutical Health Information System

Sweden

PHIS Hospital Pharma Report

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Executive Summary

Background

Sweden has a National health care system. Health care is regulated at a national level in Sweden, but actual provision is decentralised to regional and local levels. Health care services are funded through taxation. The regional level – represented by the county councils – is responsible for providing specialised care within the county. The legal framework for hospital pricing, reimbursement and monitoring occur at the national level and encompasses public and private hospitals equally.

There is no explicit definition of the term hospital or classification of hospital subtypes in Sweden. Instead the hospital is defined by its functions. This does not interfere with the objective of this report since the pricing and reimbursement of pharmaceuticals differ based on whether they are *prescribed* in the out-patient/primary care sector or *required* in the hospital care.

Hospital pharmacies

Each hospital has a hospital pharmacy that provides its wards with medicines. A hospital pharmacy is defined as a function rather than a place, and does not serve out-patients. There has been a monopoly on the Swedish pharmaceutical retail market for several decades. In 2008, a process was initiated to re-regulate the market and open it up for competition. At the time of compiling this report, no hospital pharmacy operators apart from the former monopolist have entered the market. All hospital pharmacies are therefore operated by the same state-owned company, Apoteket Farmaci. It's to be expected though that new operators will take up competition when existing contracts expire,

Pricing

Costs for medicines for in-patient care are not covered by the Pharmaceutical Benefits Scheme. Instead, the county councils are solely responsible for costs for medicines used for in hospitals. There are no national prices for medicines used in hospitals. If the same product is reimbursed for out-patients, there is a price set for the prescribed medicine. That price acts as a "reference" price for hospital use.

There is free pricing on medicines used in hospitals in Sweden. The county council is the responsible body for the health care produced in the county and procures pharmaceuticals for the hospitals in the area. County councils (primarily the smaller ones) come together to carry out the procurement. This way they can procure large enough volumes to get discounts. The price level is usually lower for medicines in hospitals than pharmaceuticals in the retail trade because of these discounts. How much lower is unknown since the sale statistics does not include the discounts.

Reimbursement

Hospitals are reimbursed by the county councils for the in-patient care they produce. The purchasing organisations in the county council negotiate with hospital health care providers and establish financial and activity contracts. These contracts are often based on fixed prospective per-case payments (based on diagnosis-related groups, DRG) and complemented with price or volume ceilings and quality components. Prices are determined by historical costs and negotiations between purchasers and providers. The use of diagnosis-related groups and other classification systems, however, varies among regions and county councils. In the DRG-system the cost of all medicines is included in the price.

Specialist out-patient care is also provided by the hospital and financed by the county councils. As most of the hospitals are operated by the county councils, the cost, apart from the patient's fee decided by the individual county council, is covered by that body. Medicines used during the consultation are usually included. Prescriptions are covered by the reimbursement scheme.

There are no national reimbursement lists for in-patient medicines in place since county councils purchase them. The individual patient's need is a determining factor but the hospitals use the preferred, i.e. the purchased medicine if possible. Each county council has at least one pharmaceutical committee. In relation to the in-patient care the role of the pharmaceutical committee is to advise 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.

Patients pay a fee of SEK 80 /€ 8 for every day as an in-patient which also covers costs for medicines as well as all other treatments.

Evaluation

In Sweden there are registers such as the National Patient Register and the National Medical Register containing information on the utilisation of health care and pharmaceuticals. The Apotekens Service AB gathers sales statistics from pharmacies. Approximately 70 diseases are closely monitored in the National Quality Register to enable a follow up on different treatments.

On a national level, the Swedish Council on Technology Assessment in Health Care (SBU) evaluates health care methods. County councils, who are responsible for financing the in-patient care and medicines used therein, use different methods to contain the costs. Hospital medicines guidelines, clinic-specific medicines exchange lists and rationalising the supplies are a few examples.

Interface management

On a hospital pharmacy level, the border between in-patient and out-patient care medicine needs is sometimes indistinct. The hospital pharmacy is organised to provide an efficient overall solution, rather than strictly divide its organisation by type of care.

Developments and outlook

The Swedish pharmacy retail market is being re-regulated. The monopoly on pharmacy retail has been taken away during 2008 and 2009 to open up for competition. The first licenses for private operators were granted in November 2009. This is expected to affect the market structure, the price of hospital pharmacy services and, to some extent, prices on pharmaceuticals used in hospitals.

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List of abbreviations

AIFA	Agenzia Italiana del Farmaco / Italian Medicines Agency
ATC	Anatomic Therapeutic Chemical classification
BMG	Bundesministerium für Gesundheit / Federal Ministry of Health (Austria)
CIVAS	Centralized Intravenous Admixtures Service
DDD	Defined Daily Doses
DG SANCO	Health and Consumer Protection Directorate General of the European Commission
DRG	Diagnosis-related group
EAHC	Executive Agency for Health and Consumers
EU	European Union
GDP	Gross Domestic Product
GÖG/ÖBIG	Gesundheit Österreich GmbH, Geschäftsbereich ÖBIG / Austrian Health Institute
HE	Health Expenditure
HOSHE	Health expenditure in hospitals
HOSPE	Pharmaceutical expenditure in hospitals
HPF	Hospital Pharmaceutical Formulary
HSAN	Hälsa- och Sjukvårdens Ansvarsnämnd/Medical Responsibility Board of Sweden
HTA	Health Technology Assessment
IHHII	International Healthcare and Health Insurance Institute (Bulgaria)
NCU	National Currency Unit
NHS	National Health Service
Mio.	Million
MPA	Medical Products Agency of Sweden
OAB	Apotekets Omstrukturering AB (Apoteket's parent company, responsible for restructuring the market and selling pharmacies)
ÖBIG	Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute
OECD	Organisation for Economic Co-operation and Development

OPP	Out-of pocket payments
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
PHIS	Pharmaceutical Health Information System
POM	Prescription-Only Medicines
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parities
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
SALAR	Swedish Association of Local Authorities and Regions/ Sveriges kommuner och landsting
SBU	Statens Beredning för Medicinsk Utvärdering/The Swedish Council on Technology Assessment in Health Care
SUKL	Statny Ustav pre Kontrlu Lieciv / State Institute for Drug Control (Slovakia)
THE	Total Health Expenditure
TLV	Tandvårds- och Läkemedelförmånsverket/ Dental and Pharmaceutical Benefits Agency of Sweden
TPE	Total Pharmaceutical Expenditure
VAT	Value Added Tax
WP	Work Package

Introduction

PHIS research project

PHIS (Pharmaceutical Health Information System) is a research project commissioned under the call for proposals 2007 in the priority area “health information” of the European Commission, DG SANCO. It has been commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project aims at increasing knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union (EU) Member States, covering both the outpatient and the inpatient sector.

This will be done via different work packages (WP) resulting in the following deliverables:

- the PHIS Glossary with key terms related to pharmaceuticals,
- the PHIS Library offering country specific information on outpatient and inpatient pharmaceutical pricing and reimbursement for the EU Member States,
- the PHIS Indicators and the PHIS Database, containing major data for the developed indicators in the Member States,
- the PHIS Hospital Pharma Report with information on pharmaceutical policies in the inpatient sector in the EU Member States, including a price survey.

The PHIS project management is a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG), which is a research institute situated in Vienna, Austria, and four associated partners:

- the Italian Medicines Agency (AIFA),
- the International Healthcare and Health Insurance Institute (IHHII), Bulgaria,
- SOGETI Luxembourg SA., which is a services provider, and
- the State Institute for Drug Control (SUKL), Slovakia

SUKL is the WP leader of Hospital Pharma.

Further key stakeholders are the PHIS Advisory Board covering EU Commission services and agencies and other international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project runs from September 2008 to April 2011 (32 months). Further information and all deliverables are made available at the PHIS project website <http://phis.goeg.at>.

PHIS Hospital Pharma

The aim of the work package “Hospital Pharma” is an in-depth investigation of the inpatient sector, as systematic knowledge of pharmaceutical policies in this sector has been rather poor.

The survey is divided in two phases:

- Phase 1: General survey

Country reports on pharmaceuticals in hospitals (“PHIS Hospital Pharma Reports”), designed to describe specific pharmaceutical policies in the inpatient sector in the EU Member States (spring 2009).

- Phase 2: Case studies

A specific survey, including a price survey, provided by means of case studies, in a limited number of hospitals in a few countries (autumn 2009).

The final PHIS Hospital Report, covering information from the general survey (phase 1) and the case studies (phase 2), is scheduled for February 2010.

Methodology of the general survey

The production of the country-specific PHIS Hospital Pharma Reports is based on three steps:

1. Development of a uniform PHIS Hospital Pharma Report Template

The PHIS Hospital Pharma Report Template offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the inpatient sector of a country. The Template was developed by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader) and further members of the PHIS project management. It is based on literature and internet reviews as well as interviews with experts in the hospital sector in the EU Member States. Members of the PHIS network received the draft Template for feed-back, and had an opportunity to discuss and provide personal feed-back during a meeting.

2. Collecting information and data and drafting the PHIS Hospital Pharma Report

The country-specific PHIS Hospital Pharma Reports were written by members of the PHIS network. In order to get the needed information and data, hospital experts were contacted and involved in several countries. They provided information and data in written form and during telephone conversations and personal talks. In some countries the reports (or parts of it) were written by hospital experts. In several countries, the preparatory work for drafting the PHIS Hospital Pharma Reports also included study visits of the authors to hospitals and hospital pharmacies. Information on persons and institutions involved can be found in the “Acknowledgements” at the beginning of this PHIS Hospital Pharma Report and in section 8

“References and data sources”, listing “Literature and documents” (section 8.1) and “Contacts” (section 8.2).

3. Editorial process

The draft PHIS Hospital Pharma Reports were submitted to the project management for review, which was undertaken by SUKL, Slovakia (Work Package leader of Hospital Pharma) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template and terminology (PHIS Glossary). In the course of the editorial process, the reviewers contacted the authors for providing feed-back on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Background

1.1 Definition and scope

Sweden has a National health care system. Health care is regulated at a national level in Sweden, but actual provision is decentralised to regional and local levels. The regional level – the county councils – is responsible for providing specialised care within the county. The legal framework for hospital pricing, reimbursement and monitoring is laid down on a national level and applies to both public and private hospitals.

There is no explicit definition of the term hospital in Sweden. Art. 5 of the 1982 Health and Medical Services Act stipulates that hospitals should be provided for in-patient care. It is the responsibility of the county councils to plan and provide for health care based on the needs of the population. Thus the emphasis lies on how well the hospital functions in terms of providing in-patient care. Since the 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 nation, not just for the population of their county. The Socialstyrelsen (National Board of Health and Welfare, SoS) defines what type of care should be considered national care (rikssjukvård) and grants time restricted permissions for county councils to provide it.

Two major health care reforms have affected the in-patient care sector in recent years and reduced the scope of it. Since the 1992 ÅDEL reform, long time care for the elderly is no longer provided at the county level but by the municipality. Hence nursing homes are not included in the definition of a hospital. The 1995 mental health reform meant a shift in the health care from in-patient treatment to out-patient care. Ambulatory care has also helped to shift some of the workload from in-patient to out-patient care. Today, a lot of the planned surgery for minor interventions is carried out in the out-patient sector.

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 on all levels. This means that two central county hospitals do not necessarily offer the exact same type of care, but may instead have different specialisations and cooperate with each other (Hjortsberg and Nordling, 2008 p 23).

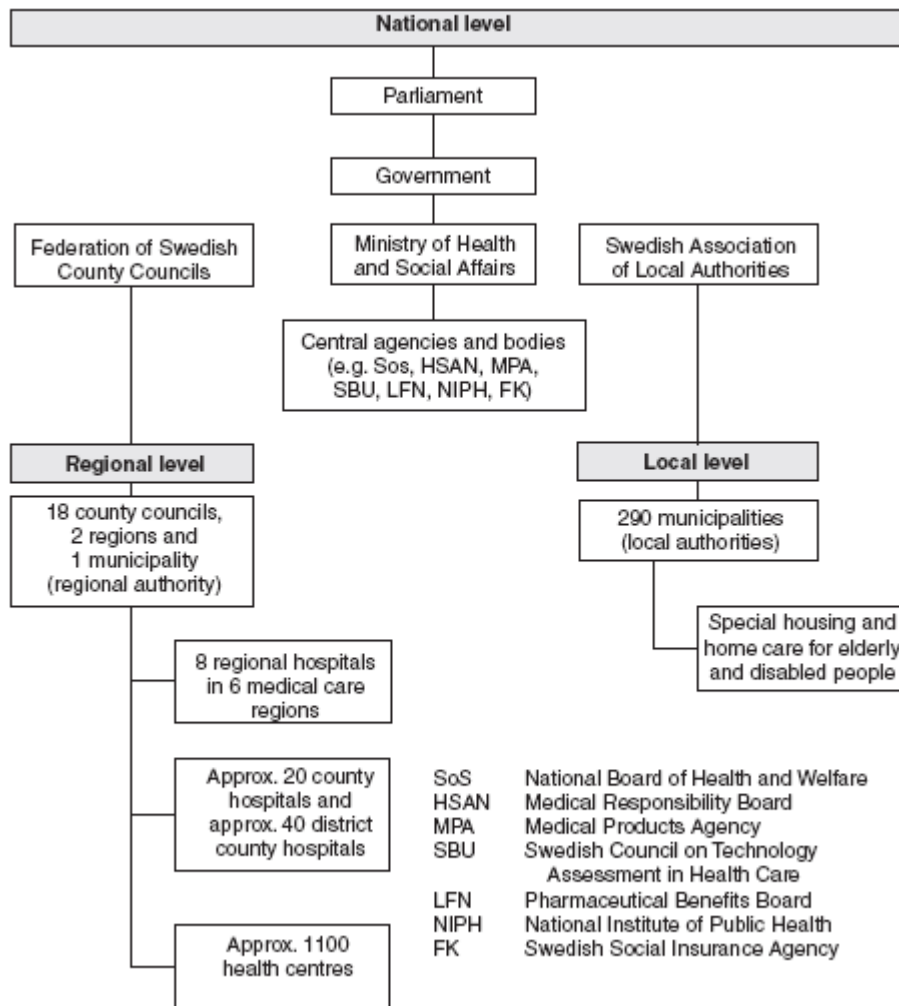
The term hospital will be used for the facilities established to provide in-patient care. As such, the definition of the term hospital in the Swedish context is relevant to this study.

1.2 Organisation

The most important law regulating the provision of healthcare is the Health and Medical Services Act of 1982. The law not only incorporates equal access to services on the basis of need, it also emphasises a vision of equal health for all. The healthcare system provides coverage for all residents of Sweden, regardless of nationality.

There are three independent governmental levels – the national government, the county councils and the municipalities – and they are all involved in health care. The overall goals and policies are decided at the national level, while the actual provision of services is done by the local authorities.

Figure 1.1: Sweden – Organisational chart of the statutory health system, 2009



Source: Glengård et al 2005, p 19

The national level

Overall responsibility for the health care sector rests, at the national level, with the Ministry of Health and Social Affairs (Socialdepartementet). The National Board of Health and Welfare (Socialstyrelsen), a semi-independent 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 Board supervises implementation of public policy matters and legislation in health care and social welfare services. Its most important duty is to follow up and evaluate the services provided in order to see if they correspond to the goals laid down by the Government. Furthermore, it keeps official statistics on health and health care. The Board includes the Centre for Epidemiology (Epidemiologiskt Centrum), whose objective is to describe, analyse and report on the distribution and development of health and diseases. All health care personnel come under the supervision of the National Board of Health and Welfare.

The Board is also the licensing authority for physicians, dentists and other health-service staff. In addition, the Board is the designated authority under European Community directives for the mutual recognition of diplomas and certificates relating to the health professions. The Ministry of Health and the National Board of Health and Welfare collaborate with other central government bodies. The most important are the Medical Responsibility Board (Hälsö- och Sjukvårdens Ansvarsnämnd, HSAN), the Medical Products Agency (MPA) (Läkemedelsverket), the Swedish Council on Technology Assessment in Health Care (Statens Beredning för Medicinsk Utvärdering, known internationally by its Swedish acronym, SBU), the Dental and Pharmaceutical Benefits Agency (Tandvårds- och Läkemedelsförmånsverket, TLV formerly LFN) and the National Institute of Public Health (Folkhälsoinstitutet). (Glenngård et al. 2005)

The regional level

The 21 county councils (including two regions and one municipality not belonging to a county council) own and run most of the health care facilities, such as hospital and primary care centres. Counties are grouped into six medical care regions to facilitate cooperation regarding tertiary medical care. The 290 municipalities are responsible for meeting the nursing-home care, social services and housing needs of the elderly. There are few private hospitals, and the number of private physicians and health centres varies widely between counties. (PPRI 2007)

In most cases these private providers have contracts with the county councils to provide certain services. Contracting-out of certain health care services has increased in some regions. It is mainly in the larger urban health care regions that contracting-out has become increasingly common. (Glenngård et al. 2005)

The county councils are grouped into six medical care regions (the Stockholm Region, the South-Eastern Region, the Southern Region, the Western Region, the Uppsala–Örebro Region and the Northern Region). These regions were established to facilitate cooperation in tertiary care among the county councils. Each region serves a population averaging more than 1 million people. (Glenngård et al. 2005)

Hospitals

Hospitals in Sweden are divided into regional hospitals, central county hospitals and district county hospitals, depending on their size and degree of specialisation. In the approximately 40 district county hospitals, there are at least four specialties: internal medicine, surgery, radiology and anaesthesiology. At the county hospitals, the levels of medical competence and equipment enable treatment of patients suffering from almost all kinds of conditions, including psychiatric problems. Both in-patient and out-patient care are provided. Currently, there are approximately 20 central county hospitals in Sweden, i.e. one hospital for each county council area. In these hospitals, there are about 15-20 specialties. Patients with complex and/or rare diseases and injuries that need highly specialised care are attended to at one of the eight regional hospitals.

For highly specialised care, and for research and medical training of doctors, the county councils cooperate in six medical care regions. The population of these regions varies from 1 to 1.9 million and in each medical region there is at least one university hospital. This collaboration is based on agreements between the county councils in the region – for example, on the prices charged for highly specialised care. The regional medical care system is responsible for patients whose medical problems require the collaboration of a large number of specialists and sophisticated diagnostic or treatment facilities. (Glenngård et al. 2005)

The regional, central county and district county hospitals vary in size. In 2001, the average number of hospital beds was 151 per district hospital. The central county hospitals serve as referral hospitals for their geographical area. In 2001 the average number of beds per hospital was 458. The regional hospitals each had, on average, 1,025 beds, which is a relatively large number in comparison with the same type of hospital in other countries. (Glenngård et al. 2005)

Private hospitals

Public hospitals are larger than private hospitals and have more highly specialised sectors and equipment. They also have a different patient distribution. For the most part, private hospitals (both for-profit and not-for-profit) tend to concentrate on care that requires smaller investment. Private-hospital in-patient care is provided in few small, traditional hospitals in the larger cities. At these hospitals, both out-patient care and advanced hospital care, such as elective surgery, are offered (Glenngård et al. 2005). Private hospitals can operate for profit, but this is an issue that has caused a lot of debate in Sweden. In 2001 an Act, the “Stop Law”, preventing county councils from selling their in-patient care to companies operating for profit was passed. This Act was cancelled in 2007.

The county councils also regulate the payment of private health care providers. A private health care provider must have an agreement with the county council in order to be reimbursed from social insurance. County councils regulate the establishment of new private practices and the number of patients that private practitioners can see during a year. If the private provider does not have any agreement or if the private provider does not use the regulated fee schedule, the provider is not reimbursed and the patient will have to pay the full charge to the provider (Glenngård et al. 2005). County councils regulate the private practitio-

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ners' market in the sense that, by approving an establishment, a county council also approves public reimbursement for the respective practitioner. A county council cannot prevent a practitioner from establishing a private practice; the regulatory power is restricted to controlling the public financing of private practitioners.

Regulation

The key laws regulating the health care and pharmaceutical market are:

- The Health and Medical Services Act (1982:736)
- The Medical Products Act (1992:859)
- The Act on Pharmaceutical Retail (2009:366)
- Medical Products Committees Act (1996:1157)
- The Act on Pharmaceutical Benefits etc. (2002:160)
- The Dental Care Act (1985:125)

Table 1.1: Sweden – Key data on inpatient care, 2000 and 2004–2008

Inpatient care	2000	2004	2005	2006	2007	2008
No. of hospitals¹	80	81	n.a.	80	81	80
<i>Classified according to ownership</i>						
- thereof public hospitals	74	74	n.a.	71	72	n.a.
- thereof private hospitals	n.a.	7	n.a.	9	9	n.a.
- thereof other hospitals (please specify)	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.
<i>Public hospitals classified according to subtypes</i>						
- thereof regional hospitals	n.a.	9	n.a.	9	9	n.a.
- thereof central county hospitals	n.a.	22	n.a.	22	22	n.a.
- thereof district county hospitals	n.a.	43	n.a.	40	41	n.a.
No. of acute care beds	31,765	26,961	26,426	26,244	26,051	25,758
- thereof in the public sector	n.a.	25,943	25,492	25,337	25,172	24,851
- thereof in the private sector	n.a.	1,018	934	907	897	907
Average length of stay in hospitals	6.2	5.9	5.8	5.8	5.5	n.a.
No. of hospital pharmacies	89	77	77	76	76	74
thereof no. of hospital pharmacies that serve outpatients	84	77	0	0	0	0

n.a. = not available, n.appl. = not applicable

Note: Data are indicated as of 31 December

¹ The number of hospitals varies over the years mainly due to organisational changes.

Source: SALAR, Apoteket AB annual reports, Apoteket AB 2000, PPRI 2007, tab 1.1, 2.7

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Table 1.2: Sweden – Pharmaceuticals, 2000 and 2005–2009

Number of pharmaceuticals	2000	2005	2006	2007	2008	2009
Authorised pharmaceuticals in total	4,843	8,047	8,504	n.a.	n.a.	n.a.
- thereof hospital-only pharmaceuticals	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.

n.a. = not available, n.appl. = not applicable

Note: In contrast to other tables, in Table 1.2 data are asked for as of 1 January, as this refers to administrative data.

The data include different pharmaceutical form but exclude different dosages and pack sizes.

Source: PPRI table 2.2, p 9

Hospital pharmacies

Each full-service hospital has its own hospital pharmacy, which only serves for internal use. Care providers running hospitals are required by law (2009: 366) to have a hospital pharmacy staffed with pharmacists. The aim, also laid down in law, is to organise the provision of medicines to the hospital rationally so that the need of safe and effective medicines is met. A hospital pharmacy is defined as a function rather than a place, and does not serve out-patients. Usually there are out-patient pharmacies in the hospital building, and in some cases they share facilities with the hospital pharmacy. Since 2005, all hospital pharmacies and out-patient pharmacies located on hospital grounds have a separate budget and organisation (OAB).

Apoteket Farmaci, at the moment the only hospital pharmacy company, offers different services to the customer (i.e. the county council). The main part is the medicines' supply. The hospital pharmacy ensures that the agreed range of medicines is available in the hospital and in nursery wards supplies. Pharmacists working for the hospital pharmacy also produce extemporaneous medicines (e.g. cytostatica) as a part of the supply service. Other services include pharmaceutical consumption reviews for individual patients, medicine training courses for health care personnel and performance reviews. There are four production facilities in Sweden where medicines not supplied by the pharmaceutical industry are prepared. These can be medicines for different patients or patient groups with special needs (Apoteket AB 2008).

In Sweden there is a national classification system of prescription-only medicines and over-the-counter medicines, but there is no classification system regarding hospital-only medicines in place (PPRI 2007).

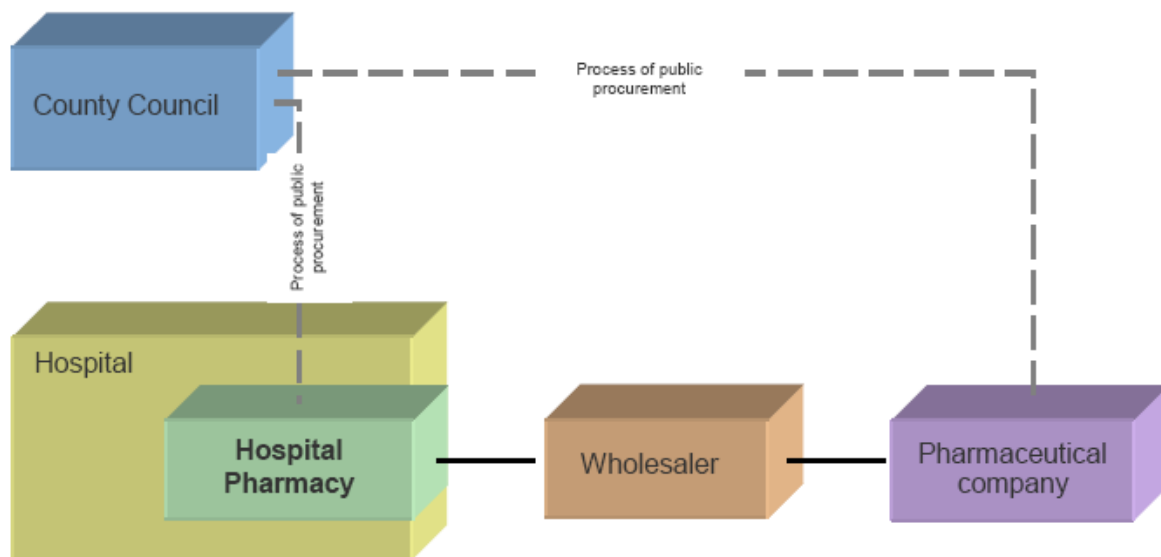
Until 2009 The National Corporation of Swedish Pharmacies (Apoteket AB) was a state monopoly that owned all of the pharmacies and thereby maintained a countrywide distribution system. It operated hospital pharmacies under one-year contracts with the county councils as well as community pharmacies. The state monopoly on pharmaceutical retail has not, however concerned the purchasing of hospital pharmaceuticals. The county councils procure medicines through Apoteket and negotiate discounts directly with the pharmaceutical

companies. The medicines are procured on behalf of both public hospitals and private hospitals operating on a contract with the county council.

The county council procures the services regarding provision of medicines to and within the hospital, i.e. the operator of the hospital pharmacy. Until 2008 the monopoly on pharmaceutical retail applied to hospital pharmacies too. At the moment no new actors have entered the hospital pharmacy market. Apoteket Farmaci, part of the Apoteket AB currently operates all hospital pharmacies.

There are two wholesalers, Tamro AB and Kronans Droghandel. Together they manage most of the distribution of medicines to the hospitals through the Apoteket hospital pharmacies. The Swedish wholesale market is organised as a single-channel distribution system, under which pharmaceutical companies have exclusive distribution agreements for different products with either of the two wholesalers.

Figure 1.2: Sweden – Distribution of pharmaceuticals to hospital pharmacies, 2009



Source: Authors of the report

The hospital pharmacy buys medicines through the distribution and delivery system that the Apoteket AB has established with the two wholesalers, as shown in figure 1.2. As the pharmacy retail market is being re-regulated and opened up to competition, this could be subject to change over the coming years.

1.3 Funding

The in-patient sector

All levels of government play important roles in the welfare system and are represented by directly elected political bodies that have the right to levy proportional taxes on the population in order to finance their activities. It is the 21 county councils that are responsible for providing health services and for striving to achieve a good standard of public health. The population of these 21 areas varies between 60,000 and 1.8 million people (Glenngård et al. 2005). The county councils also generate income through state subsidies and user charges.

Hospitals are reimbursed by the county councils for the in-patient care they produce. The purchasing organisations in the county council negotiate with hospital health care providers and establish financial and activity contracts. These contracts are often based on fixed prospective per-case payments (based on diagnosis-related groups) and complemented with price or volume ceilings and quality components. The amount of the payments for the different activities are determined by historical costs and negotiations between purchasers and providers. The use of diagnosis-related groups and other classification systems, however, varies among regions and county councils. Per-case reimbursements for outliers, such as complicated cases that grossly exceed the average cost per case, may be complemented by per-diem payments (Glenngård et al. 2005).

Private medical insurance is very limited in Sweden. However, the market for voluntary health insurance is growing. One of the reasons behind the growing market for voluntary health insurance is the long waiting lists for elective treatment in the county councils. The main benefit of having supplementary insurance is that it allows quick access to a specialist in ambulatory care when necessary. Another benefit might be the possibility of jumping waiting lists for elective treatment. However, voluntary health insurance is a small sector in Sweden in comparison with other EU countries. It should be noted that the number of surgical operations that are privately financed is quite low. Even in the few private hospitals, an overwhelming proportion of the activities are financed by public money, i.e. they are purchased and contracted by county councils. (Glenngård et al. 2005)

In-patient care fees for adults are uniform across the country and include medicines consumed during the stay (see below). Reductions in fees for in-patient care are possible for pensioners and those in low-income groups. In almost all county councils, children and young people (under 20 years of age) are exempted from patient fees. Only a few county councils have small user fees for people under the age of 20 (Glenngård et al. 2005).

Medicines in hospitals

Costs for medicines for in-patient care are not covered by the Pharmaceutical Benefits Scheme. Instead, the county councils are solely responsible for costs for medicines used in hospitals. This is a part of their overall responsibility for providing health care. Patients pay a fee of SEK 80.- / € 8.62 for every day in hospital care which covers costs for medicines as well as all other treatments (PPRI 2007).

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Table 1.3: Sweden – Health and pharmaceutical expenditure, 2000 and 2004–2008, in million SEK

Expenditure (in million SEK)	2000	2004	2005	2006	2007	2008
Total health expenditure (THE)	185,305	241,378	250,479	263,000	277,949	n.a.
- thereof THE public	157,306	197,461	204,504	215,555	227,143	n.a.
thereof THE private	27,999	43,917	45,975	48,445	50,806	n.a.
THE in hospitals (HOSHE)	n.a.	106,545	110,727	117,609	124,422	n.a.
thereof HOSHE public	n.a.	103,922	107,756	114,570	121,316	n.a.
thereof HOSHE private	n.a.	2,623	2,971	3,039	3,106	n.a.
Total pharmaceutical expenditure (TPE)	25,603	33,523	34,356	35,951	37,286	n.a.
- thereof TPE public	17,915	20,404	20,742	21,345	21,672	n.a.
- thereof TPE private	7,688	13,119	13,614	14,606	15,614	n.a.
Pharmaceutical expenditure in hospitals (HOSPE)	2,106	3,461	4,081	4,757	5,404	5,985
- thereof HOSPE public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof HOSPE private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

HOSHE = health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, n.a. = not available, NCU = national currency unit, PE = pharmaceutical expenditure, THE = total health expenditure, TPE = total pharmaceutical expenditure

Note: Data are indicated as of 31 December.

Source: OECD Health Data 2009, Apoteket AB 2008, Apoteket AB 2000

2 Pricing

2.1 Organisation

2.1.1 Framework

The hospital pays the net pharmacy retail prices for the medicines required from the hospital pharmacy. It is the county council however that procures medicines (exceeding a certain threshold value) from the pharmaceutical company. Discounts are usually paid back to the hospital or county council directly, without passing the hospital pharmacy.

Regulations

The Act on Pharmaceutical Retail (2009) gives a set of criteria for pharmaceutical retailers and wholesalers. Pharmaceutical retailers approved by the Medical Products Agency of Sweden (MPA), with regards to the criteria, may also run hospital pharmacies. Wholesalers approved by the MPA, with regards to the law, may sell medicines to hospital pharmacies and out-patient pharmacies. The MPA is also authorised by the government to issue guidelines and codes of statutes regarding certain aspects of the pharmaceutical market such as production, clinical trials and marketing. The county councils procure medicines from the pharmaceutical companies. The procurement procedure is regulated in the Public Procurement Act (2007).

Pharmaceutical committees

Each county council has a pharmaceutical committee whose responsibility is to make recommendations concerning the use of medicines. The pharmaceutical committees have an advisory role in the procurement process (Glenngård et al. 2005). By law every county council should have at least one committee (Medical Products Committees Act 1996). Hospital-based physicians are allowed to use any medicine that has been granted marketing authorisation (by the MPA). A pharmaceutical committee compiles a list of preferred medicines that are supposed to be first choice use when possible. Hospital pharmacies are expected to dispense and stock other pharmaceuticals as well, if there is a demand for it.

Free pricing on pharmaceuticals used in hospitals

Normally, all purchases of medicines are done by the county council, only in very few situations are the hospitals free to purchase by themselves. There are no national prices for medicines used in hospitals. If the same product is reimbursed for out-patients, there is a price set for the prescribed medicine. That price acts as a "reference" price for hospital use. Often, the hospitals receive lower prices than patients shopping at community pharmacies, mainly due to larger sales volume (PPRI 2007).

No discount or claw back system applies for products sold by community pharmacies in Sweden. However, public procurement of medicines used in hospitals is carried out by the county councils. As a result of these procurements the county councils are often given discounts for medicines used in hospitals. Discounts are generally paid to the county council directly from the manufacturer based on the volume of products purchased during a certain period (PPRI 2007). In many counties, this discount is returned directly to the requiring clinic to encourage the use of procured medicines.

The main responsibility for purchasing medicines for hospital use rests with the County Councils. They have the right, since 1997, to procure medicines directly from manufacturers (Glenngård, 2005). The process is regulated by the Public Procurement Act. Smaller county councils often come together to purchase medicines through a tendering system. Although medicines used in hospitals are normally purchased at the county council level, under certain circumstances hospitals can obtain discounts directly from manufacturers when purchasing medicines for their own use (Glenngård et al. 2005). Although hospitals have the option of running their own pharmacies, they have not chosen to do so. As a consequence, all medicines are delivered to hospitals through Apoteket.

Hospital prices

Not all medicines for hospital use are procured. Medicines used in smaller volumes are bought through the Apoteket. The hospital price of medicines when these are bought from Apoteket corresponds to the pharmacy retail price. The price includes a pharmacy mark-up and a wholesale mark-up. The market for in-patient medicines is characterised by free pricing.

The wholesale margin is not regulated by the state but is instead based on free agreements between manufacturers and wholesalers. These agreements are not public. The pharmacy mark-up is regulated for medicines included in the National Benefit Scheme. During the monopoly years, Apoteket chose to use the same mark-up for medicines sold to hospitals. On the re-regulated market pharmacies decide on the pharmacy mark-up of goods sold to hospitals (OAB).

Pharmaceuticals are exempt from VAT in Sweden, although for OTC-products the standard rate of 25% applies.

Because of the discounts that county councils get when procuring large volumes of medicines, the price level is generally lower in the in-patient sector. The discount is often not included in the price, but is paid back as a lump sum at the end of a period. Thus the discount is not connected to the price of the medicines in the statistics, and the lower price level is "invisible" in the sales statistics.

The procedure of procurement is regulated in law and can be deemed as transparent (Jansson and Anell, 2005 p 46). The price level is not fully known since the discounts are not reflected in the statistics. The sales statistics are available through Apotekens Service Aktiebolag (<http://www.apotekensservice.se/Statistik/>).

To sum up, there is free pricing for medicines used in hospitals in Sweden. The county council is the responsible authority for the health care produced in the county and procures medicines for the hospitals in the area. County councils (primarily the smaller ones) come together to carry out the procurement. This way they can procure volumes large enough to receive discounts. Because of the discounts, the price level is lower for medicines in hospitals compared to medicines in the retail trade. How much lower is unknown since the sale statistics does not include discounts.

2.2 Pricing policies

2.2.1 Procurement

The decision concerning which medicines should be primarily used in the in-patient sector is made on two levels. On the regional level it is the county council (or a group of county councils) that decide(s) which medicines to procure, and on the local level each hospital decides the structure for requiring medicines. On county council level there is a procurement body handling 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; in the Skåne region (the southernmost region in Sweden) the pharmaceutical committee has the formal decision-making role.

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 publically procured in line with the Act. 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 the 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 (Jansson and Anell 2005).

There is usually a timeframe of a minimum of 52 days to submit tenders from the day the notice of procurement was published. All tenders are opened at the same time. The tenders that meet the legal requirements are sent to expert groups for review. The procurement body/pharmaceutical committee makes the formal decision, based on recommendations from the expert groups on which tenders to accept.

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 in order 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 (Jansson and Anell 2005).

The frequency of procuring medicines varies between the county councils, but it is usually performed once a year. The contracts typically run for a year with a possibility to prolong them for another year.

There are no other pricing policies besides procurement.

3 Reimbursement

3.1 National hospital reimbursement procedure

The provision of health care services is decentralised to county level, and it is financed mainly through county council taxes. Medicines used in in-patient care are not covered by the national benefit scheme. Only prescription medicines are covered by the national benefit scheme, dental care and social insurance are financed by the government. The hospitals are therefore reimbursed by the county councils; this also applies to private hospitals on a contract with the county council.

The reimbursement system varies between the county councils. In a study from 2005 where four counties are examined with regards to procurement and reimbursement of in-patient medicines, Jansson and Anell find that three out of the four uses a diagnosis-related group (DRG) based system for reimbursement of the in-patient sector. Two of those combine the DRG-system with a ceiling on expenditures. The fourth county council has a system of fixed sums based on the expenditure of previous years. In this county the medicines have a separate budget. In the counties that use a DRG-system, the cost of medicines is included in the DRG cost (Jansson and Anell 2005, p 27).

There are no nation-wide reimbursement lists for in-patient medicines since county councils finance them according to decision on that level.

3.2 Hospital pharmaceutical formularies

In each county council there is at least one pharmaceutical committee. The committees support doctors 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 of the common diagnoses. There are no

sanctions against doctors in place 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 advise 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 (cf. section 2.2).

For the county councils it is important that the procured medicines are used by the doctors. Clinical recommendations are issued by pharmaceutical committees, the MPA and the National Board of Health and Welfare, etc. 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.

4 Consumption of pharmaceuticals

Table 4.1 Sweden – Pharmaceutical consumption, 2000 and 2004–2008

Pharmaceutical consumption	2000	2004	2005	2006	2007	2008
Annual pharmaceutical consumption in total						
in million packs	n.a.	n.a.	n.a.	296	310	328
in million DDD			6,188	6,396	6,619	6,867
Annual pharmaceutical consumption in hospitals						
in million packs	n.a.	n.a.	n.a.	15	15	16
in million DDD		224.4	231.2	200	210	214

DDD = Defined Daily Doses, n.a. = not available

Source: Apoteket AB 2007 and 2008; National Board of Health and Welfare 2005

Table 4.2 Sweden – Top 10 pharmaceuticals by pharmaceutical expenditure and consumption 2007

Position	Top pharmaceuticals used in hospitals, indicated by active ingredient, ranked with regard to consumption ¹	Position	Top pharmaceuticals used in hospitals, indicated by active ingredient ranked with regard to expenditure ²
1	A11CB Vitamin a+d	1	L04AB02 Infliximab
2	B03BB01 Folic Acid	2	L01XC03 Trastuzumab
3	N02BE01 Paracetamol	3	J06BA02 Normal, human immunoglobulins
4	C03CA01 Furosemide	4	L01XC02 Rituximab
5	D02AE01 Carbamide	5	L01CD02 Docetaxel
6	H02AB01 Betamethasone	6	B05BA10 Carbohydrates, combinations
7	D02AX Other emollients and protectives	7	L04AA23 Natalizumab
8	A02BC01 Omeprazole	8	S01LA04 Ranibizumab
9	B01AB04 Dalteparin	9	B03XA01 Erythropoietin
10	B01AC06 Acetylsalicylic Acid	10	B05BB01 Electrolytes

Source: National Board of Health and Welfare 2009

¹ Consumption in DDD

² Possible discounts not included, therefore the expenditure that the table is based on could be overestimated.

5 Evaluation

5.1 Monitoring

The Board of Health and Welfare manages the National Patient Register, containing information on in-patient and out-patient care. Both the out-patient and in-patient care sectors have a responsibility to register patients' visits/contacts. This gives the register a high degree of validity. The National Patient Register contains patient data, geographical data, administrative data and medical data. 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 personal identification number for each registered person. Various laws apply to the registers, to ensure the protection of the rights of those listed. The drop-out rates are very low (usually less than 4–5%). Patient databases located in every county council are important sources of information. These databases are based on individual identification numbers and include complete information about inpatient treatment and clinical investigations (Xrays, laboratory tests) and partial information about outpatient care.

Until July 2009 Apoteket AB (the former monopolist) collected statistics on pharmaceuticals, both from the in-patient sector and prescribed medicines. This task is now performed by Apotekens Service, an independent body formed to collect statistics and provide it-infrastructure to the pharmacies on the market. At the hospital level, the hospital pharmacies collect and report statistics to Apotekens Service. The data is used by county councils for their internal purposes and for research. Apotekens Service, the National Board of Health and Welfare and the MPA use the data in reports available to the public.

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. Examples of this include diabetes, cancer and approximately 70 other conditions. The aim is to monitor effects of different treatments and to give hospitals a tool to compare the outcome of their care to the rest of the country.

5.2 Assessment

On a national level, the Swedish Council on Technology Assessment in Health Care (SBU) evaluates health care methods (<http://www.sbu.se/en/Published/>). Under Swedish law, health-service staff must work in accordance with scientific knowledge and accepted standards of practice. Research results and comprehensive clinical experience should guide the delivery of health care. SBU has the mandate of the Swedish Government to review and

evaluate health care technology from medical, economic, ethical and social points of view. SBU reviews the benefits, risks and costs of methods used in health care delivery, with the aim to identify which method is the most appropriate for treating a specific disease, but also to determine which methods are ineffective or not cost-effective, so that they can be avoided. It also identifies important knowledge gaps – areas in which further research is urgently needed. SBU organises its work on a project basis. For each project, a multidisciplinary team, consisting of leading experts from Sweden and abroad, is recruited. The team conducts comprehensive assessments by systematically searching, selecting, reviewing and evaluating research findings from around the world. Typically, the projects include systematic literature reviews. SBU bases its work on available research findings and does not conduct original research on its own. When assessments deal with very broad subject areas (e.g. back pain, substance abuse, obesity), the process can take several years; projects that address single interventions are completed much faster. Information on results is disseminated to central and local government officials and medical staff to provide basic data for decision-making purposes. SBU has been pursuing different strategies for producing and disseminating its reports. One such strategy is to develop a network of “local ambassadors” for technology assessment, who inform various target groups (e.g. doctors) at the municipal and county levels (Glenngård et al. 2005).

The decentralisation of the financing and provision of both health care and medicines to the regional level gives the county councils an incentive to assess the cost of medicines in the in-patient care. The budgetary responsibility for required medicines is often decentralised to hospital department level. Different methods are used to contain the costs of hospital medicines. Hospital medicines guidelines, clinic-specific pharmaceutical exchange lists and rationalising the supplies are a few examples of methods used in hospitals (Jansson and Anell 2005).

Comprehensive data concerning the financing of health care services in Sweden are rather poor, partly because of the division of responsibility between different levels of government, i.e. between the county councils and the municipalities. The municipalities and the county councils collect information about management and the financing and provision of health care services, both for their own purposes and for reporting purposes. Information regarding the financing and provision of health care services is reported to the Swedish Association of Local Authorities and Regions and Statistics Sweden (Glenngård et al. 2005).

6 Interface management

In recent years the cost of hospital medicines has increased at a significantly higher rate than the cost of prescription medicines. A reason for this is that many county councils have chosen to provide certain medicines outside the reimbursement scheme. For use in the out-patient sector (for example ambulatory care) instead of prescribing them. That way, the clinic can get a discount through the public procurement. This trend has been visible especially in cytostatics and other costly medicines (Jansson and Anell, 2005).

Before 1997 the state had the budgetary responsibility for medicines prescribed in the out-patient care. The cost of medicines required for in-patient sector use were charged to the county council or the hospital itself, which gave an incentive for doctors to prescribe medicines for in-patient use. Since there is a cost ceiling for prescribed medicines the cost would be carried by the state, not by the hospital or the patient. In 1997 the Pharmaceutical Reform meant that the responsibility for costs of all medicines were decentralised to the county councils. The reform also stated that the county councils were required to have formulary committees to list the preferred pharmaceutical treatments (Jansson and Anell, 2005).

As a result of the Pharmaceutical Reform, in some counties the budgetary responsibility for hospital medicines has been decentralised to hospital or clinical level in order to raise cost awareness among the prescribers.

On a hospital pharmacy level, the border between in-patient and out-patient care pharmaceutical needs is sometimes indistinct (Apoteket AB annual report of 2008). The increasing importance of ambulatory care is an example of this. The hospital pharmacy is organised to provide an efficient overall solution, rather than strictly divide its organisation by type of care.

7 Developments and outlook

The Swedish pharmacy market has been re-regulated. The former monopoly on pharmacy retail has been abolished to allow competition. This affects the in-patient pharmaceutical sector since other actors than Apoteket now can offer to operate hospital pharmacies. The government bill (2007/08:142) on pharmaceutical provision in hospitals outlines some of the expected consequences. The re-regulation should enable county councils to get custom-made solutions of the provision of medicines for the hospitals. Competition amongst hospital pharmacy operators should open possibilities to make recent developments in the pharmaceutical logistic sector available to the hospitals. With competition, the price on the services regarding provision of medicines to and within the hospital is expected to decrease. The extra administrative cost of procuring these services is expected to be compensated by the decrease in costs for the actual services.

The re-regulation of the pharmacy retail market does not affect the procurement process or the reimbursement systems. The hospital price of medicines may come to vary between hospital-pharmacy operators both in price level and in elements since there is free pricing on hospital medicines.

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Apoteket Omstrukturering AB: <http://www.omstruktureringsbolaget.se/>

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